BME 361: Term Project Report

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Overview of Proposed Product

The sacroiliac (SI) joint connects the sacrum bone of the spine to the ilium bones of the pelvis; it absorbs shock during the transmission of the forces of the upper body to the hips and legs [1]. Damage to the SI joint via injury, arthritis, pregnancy etc., can cause pain in the lower back and extremities [2]. Patients who suffer from SI joint pain may receive pain medication and physical/occupational therapy to relieve the pain; more severe cases may require spine injection therapy or radiofrequency ablation (RFA) on the nerves sending pain signals from the joint to the brain [2]. SI joint fusion is a surgical procedure provided to patients unable to find relief from other treatment options [3]. Permanent screw implants are used to secure and compress the sacrum and ilium together, promoting bone fusion over time to eliminate motions in the SI joint that cause pain and inflammation [4].

Like many surgical screws, biocompatibility is a key requirement for SI fusion screws; titanium alloys are commonly used due to their mechanical compatibility with bone and long-term biostability [5]. The fusion depends heavily on the mechanical stability provided by the screws inserted across the joint. Breakage or loosening of the screws due to biomechanical forces is one of the main complications that can arise from the surgery. Fully threaded screws offer greater resistance to deformation [6] and higher shear strength [7] than partially threaded screws. Loosening can also be prevented through designs that promote secure bone attachment to bone tissue. Dual-threaded designs improve bone engagement by anchoring to both dense cortical bone (fine threading) and spongy cancellous bone (coarse threading) [8]. Failures due to osseointegration exist but have been greatly reduced in recent implants through features such as porous structures that facilitate bone integration [9] or hydroxyapatite (HAp) coatings that promote bone growth as well as lowering infection risk due to their chemical similarity to bone [10]. Improper placement of the screws during surgery is another commonly reported main complication that can lead to neurologic pain from nerve injury; features such as self-tapping tips and a cannulated design for guide wire placement enhance surgical accuracy and reduce operative time [11].

SI fusion screw products currently on the market each have some or many of the abovementioned properties, but none have all. We propose a screw that integrates all key advancements: a self-tapping, fully threaded, double-pitch, porous titanium alloy design coated with HAp, implantable via a guide wire. It will be available with an 8mm screw diameter and multiple length options.

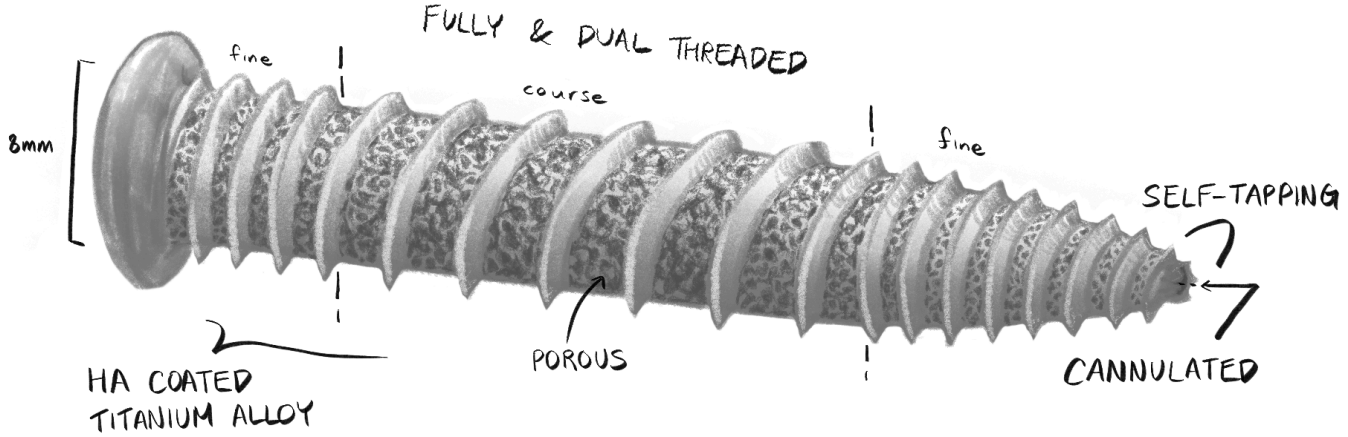

Figure I. The proposed sacroiliac joint fusion screw.

Regulatory Pathway Summary

Our novel design for sacroiliac fusion screw is intended for treating SI joint dysfunction including SI joint disruption and degenerative sacroiliitis, to augment immobilization and stabilization of the SI joint in skeletally mature patients. SI fusion screws are classified under the product code OUR and are a class 2 medical device as defined by the FDA. The primary pathways to FDA market clearance are either through HUD, HDE, De Novo, 510k, and PMA submissions. The device would not qualify for HUD or HDE clearances as it does not meet the criterias for rarity of condition. As SI screws are neither high-risk nor life-sustaining, the PMA process would require unnecessary work and resources. The De Novo process would also be unnecessary as predicates exist for this device. Thus, the 510k process would be the most efficient pathway to utilize to reach market approval.

Our proposed device has similar qualities to three other SI fusion screws that have received 510k clearance within the past 7 years, the REUNION Sacroiliac Joint Fusion Screw System (K232211) [12], the iFuse TORQ Implant System (K241574) [13], and the SI-LOK Sacroiliac Joint Fusion System (K183119) [14]. Details and comparisons between our solution and the predicates are summarized in Table 1. All devices share the same device description, regulation number, product classification, product code, and have similar intended usage statements that do not raise questions about effectiveness or safety. While there is not a single 510(k) cleared device that exactly matches the technological characteristics of our device, each feature is shared with at least one of our predicate devices listed. The largest difference is the inclusion of a HAp coating with a porous and cannulated screw design and how it may affect the surface adhesion of the screw. Clinical studies have found that HAp coatings will increase the pullout force and improve screw-bone contact [15]. Additionally, the adhesion of the coating to the surface highly depends on manufacturing methodology, with methods such as plasma spraying and vapour deposition being able to apply the coating without issue [16]. Thus, no questions of safety or effectiveness are raised by the novel combination of features. However, the safety and effectiveness of such a device should be verified through benchtop testing and validated through in vivo testing to meet regulatory standards. The primary standards for benchmark testing involve testing torsional strength and breaking angle, defined by ASTM F543-17 [29] and ASTM F3574-22 [31] respectively. In vivo-testing will be primarily used for validating the effects of HAp on osseointegration in bone, and will be defined by ASTM F2721-09 [17]. Other standards may apply for other verification or validation activities.

Table I. Summary of predicate devices

Item	Proposed Novel Device	REUNION Sacroiliac Joint Fusion System	iFuse TORQ Implant System	SI-LOK Sacroiliac Joint Fusion System	Equivalency
Device	Smooth or Threaded Metallic Bone Fixation Fastener	Smooth or Threaded Metallic Bone Fixation Fastener [12]	Smooth or Threaded Metallic Bone Fixation Fastener [13]	Smooth or Threaded Metallic Bone Fixation Fastener [14]	Equivalent
510k Submission	N/A	K232211 [12]	K241574 [13]	K183119 [14]	N/A
Regulation Number	21 CFR 888.3040	21 CFR 888.3040 [12]	21 CFR 888.3040 [13]	21 CFR 888.3040 [14]	Equivalent
Product Class	Class 2	Class 2 [12]	Class 2 [13]	Class 2 [14]	Equivalent
Product Code	OUR	OUR [12]	OUR [13]	OUR [14]	Equivalent
Intended Usage Statement	The proposed device is indicated for sacroiliac joint fusion for sacroiliac joint dysfunction including sacroiliac joint disruption and degenerative sacroiliitis, to augment immobilization and stabilization of the sacroiliac joint in skeletally mature patients.	The REUNION SI Joint System is indicated for skeletally mature patients for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis. [12]	The iFuse TORQ Implant System is indicated for sacroiliac joint fusion for sacroiliac joint dysfunction including sacroiliac joint disruption and degenerative sacroiliitis and augmenting immobilization and stabilization of the sacroiliac joint in skeletally mature patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion. [13]	The Sl-LOK Sacroiliac Joint Fixation System is intended for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis. [14]	Equivalent
Technological Characteristics	Titanium alloy, fully-threaded, dual-threaded, cannulated (for guild wires), porous, self-tapping, coated with HAp	Titanium alloy, cannulated (for graft delivery), fenestrated, micro-textured, dual-threaded, fully threaded, modular screw head, self-tapping [12]	Dual-threaded, fenestrated, cannulated (for guide wires), 3D-printed titanium alloy, optional washers, porous, fully/partially threaded [13]	Fully-threaded, HAp coated, cannulated (for guide wires), titanium alloy, fenestrated, with washer [14]	Equivalent with at least one predicate
Screw Diameter (mm)	8mm	8mm, 10mm, 12mm, 14mm [18]	7.3mm, 10mm, 11.5mm [19]	8mm, 10mm, 12mm [20]	Equivalent

Screw Length (mm)	80mm, 90mm, 100mm	35-80mm, 5mm increments [18]	90mm, 100mm, 110mm [19]	30-60mm [20]	Equivalent

In addition to demonstrating equivalence to predicates for the 510(k) process, a few other regulations can apply to SI screws. Class 2 devices are subject to General Controls for Medical Devices. General Controls outline basic requirements for medical devices including labeling, product quality control, interactions with the FDA, Quality Management Systems, and Good Manufacturing Practices [21]. This includes QMS guidelines like ISO 13485:2016 or 21 CFR 820. No special controls currently apply to SI fusion screws.

Risk Assessment

Nine potential hazards of the product were identified, with potential mitigation activities created for four of them. Overall, all resulting risk priority numbers (RPNs) post-risk control were calculated to be within the yellow or green zone. For the four hazards with potential mitigation activities, RPN was reduced to within the green zone.

The five hazards identified for which potential mitigation activities could not be ideated (RISK-02, RISK-03, RISK-06, RISK-07, RISK-08) are caused by user error or patient response to the procedure, both of which cannot be accommodated for in the implant design. Improper surgical technique and implant placement by the physician are the responsibility of the healthcare team, so risk controls would include proper training and pre-operative planning [22]. In some cases, patient response and anatomy could affect the outcomes as well. Injury to structures like the gluteal artery and/or nerve are considered an unavoidable adverse event due to their proximity to the SI joint space, and have heightened risk in patients with dysmorphism, which also increases the risk of needing the procedure [23][24]. Ultimately, post-operative response to the implant is unpredictable, affected by pre-existing conditions and surgical procedure quality; hazards like halo, loosening, or general failure to properly integrate within the bone, would usually not be caused by the device [25][26]. These surgical outcomes often require additional procedures for revision or explant.

Biocompatibility hazards (RISK-01, RISK-05) risk infection and adverse reactions to certain materials. The materials used for the implant, including HAp and titanium, are generally considered to be biocompatible and safe for implant use, but there is always potential for an allergy to develop [27]. To maximize the implant's safety and efficacy, it is the physicians' responsibility to ensure that the patient does not have existing allergies. In the case that some materials may not be compatible, potential mitigation activities include offering an alternative product, such as one without an HAp coating, which would require some design revision and modification. Reactions can also occur due to unwanted contaminants acquired during manufacturing and transportation. Risk controls and additional potential mitigation activities include conducting regular audits and inspections at partnered facilities and working with them to introduce more precautionary measures for prevention of contamination.

Revision and explant rates of SI joint fusion procedures are low, but a possibility if there is need to address user error or conditions developed post-operatively. Implant removal requires a high amount of force, since the implant is designed to withstand a high axial pullout force. Use of excess force during implant removal might damage removal instruments (RISK-04), risking breakage and foreign objects entering the body [28]. Since the implant's

design is novel, potential mitigation activities include determining a way to remove the implant with minimal risk to the patient. This could include revising and modifying the design to make removal easier, or creating a special removal tool/guide for the implant. This is less feasible, since there is a much lower need due to existing general bone implant removal procedures, and the design-to-market process would likely be lengthier than that of the implant itself.

The final risk associated with the implant is wound infection, which is common to all surgical procedures (RISK-09). It can be especially dangerous if the infection spreads to other parts of the body like the bone and the bloodstream, but has a low risk of occurrence due to sterilization standards and proper wound care required of the healthcare team. The self-tapping feature eliminates the need for pre-drilling and increases efficiency, which reduces surgical time and in turn, risk of infection. Potential mitigation activities include modifying the design to further improve efficiency to contribute to limiting bone exposure time in surgery.

User Needs and Design Inputs

Several user needs and design inputs were identified for this product. For a full list, please refer to Table II in the appendix. The development of these needs and inputs followed the waterfall approach outlined in 21 CFR Part 820, which details the importance of defining user needs early and translating them into effective design inputs. Each input falls into one of four categories: regulatory, customer, technical, or performance. These categories were used to structure both the user needs and design inputs and the traceability matrix.

Regulatory requirements related to non-clinical testing are primarily focused on the implant's mechanical strength, outlining the implant's ability to maintain mechanical stability and resist breakage under stress and mechanical failure over time [17][30][31][32][33]. The design inputs include quantitative requirements for a minimum breaking angle, resistance to a minimum axial pullout strength, a maximum insertion torque, and a maximum self-tapping force at any insertion depth [34][35]. It must also pass certain repetitive fatigue tests. The minimum breaking angle and self-tapping force values listed in Table II in the appendix are internal values taken from devices of similar applications but different intended use, since pre-existing values could not be found in literature or regulatory documents, so they will need reconfirmation. These requirements are essential in ensuring that the product fulfills regulations and can be approved for market. They also align with requirements laid out in ASTM F543-17 and ASTM F3574-22, which provide standard testing procedures for orthopedic screw systems and sacroiliac fusion devices respectively [17][31].

Mechanical integrity is important not just for compliance, but for simulating physiological loading conditions that implants will be exposed to during patient use. For example, the cantilever bending fatigue testing provides insight into how the implant will behave under repetitive lateral stress, which mimics real-world joint loading during movement. By incorporating these specific mechanical thresholds early in the design phase, future verification activities will be streamlined and the results will be directly tied back to the original regulatory needs.

Customer requirements include long-term implant stability and effective osseointegration, which is achieved by including a fully threaded, dual-pitch thread design, a porous surface, and a HAp coating [8][9]. These features improve patient experience and reduce post-operative complications, thus improving the overall quality of the implant. The design also requires improved procedural efficiency and accuracy in implantation for surgeons, which is achieved

by making the screw self-tapping and cannulated to allow for guidewire placement, not only making the procedure easier for the surgeon, but also increasing the safety of the patient by reducing the likelihood of complications associated with the procedure [17][11]. These features are identified as design inputs in response to user needs outlined in literature and ASTM F543.

The cannulated feature in particular is a response to surgeon-reported challenges in placing sacroiliac screws accurately without fluoroscopic guidance or pre-drilling. By adding a guidewire=compatible lumen, this feature significantly enhances control and precision [11]. Similarly the self-tapping function streamlines workflow, allowing for quicker screw insertion and minimizing the number of steps required [11]. These customer-driven features ultimately aim to improve clinical efficiency and reduce surgery time, leading to better outcomes.

Technical requirements of the implant state that it must fit within the anatomy of the patient, meaning that the implant must fit entirely in the bone, and promote bone integration, which is accompanied by design inputs specifying acceptable measurement ranges for porosity, pore size, and roughness parameter S_a [21][36]. These requirements ensure long-term compatibility with the patient.

The technical specifications for porosity and surface roughness are taken from research that highlight their importance for biological fixation. Porosity in the 30-40% range and pores between 250-300 μm are ideal for promoting vascularization and bone ingrowth, which are crucial for long-term implant fixation [21][36]. The roughness parameter is similarly chosen based on surface engineering studies that demonstrate enhanced osteoblast activity in this range. These technical requirements ensure the implant functions biologically in the patient's anatomy [36].

Performance requirements relate closely to technical requirements. Referencing the emphasis on long-term compatibility and efficacy, the implant must not loosen over time, which defines a minimum axial fatigue life for a given load, with the addition of fatigue testing, distinguishing it from the regulatory requirement [37]. To improve the implant's performance and surgical outcomes for the patient, the implant must allow bone ingrowth while preventing fibrous tissue formation to prevent complications requiring revision surgeries, commonly caused by micro-movement of the implant. Thus, a minimum amount of micro-movement is defined to promote growth of healthy bone cells [41]. Finally, the implant must ensure sustained joint stability by preventing early loosening, defined by retaining a minimum percentage of its initial compressive load for an extended period and exhibition of a controlled load relaxation profile [40]. These requirements highlight the implant's longevity, allowing it to perform as advertised to and required by surgeons and their patients.

Traceability Matrix/Design Verification and Validation Plan

The verification and validation plan outlines the process used to ensure the sacroiliac fusion screw meets its regulatory, customer-related, and technical design requirements. For the full list, please refer to Table III in the appendix. The plan involves both mechanical testing and biological assessments to demonstrate that the device performs reliably under physiological conditions and integrates effectively with bone tissue. Verification is used to confirm that the design outputs meet the specified outputs, while validation ensures the device performs as intended in

simulated and living environments. All activities are informed by ASTM standards, peer-reviewed literature, and the FDA.

Each design input was defined based on a combination of regulatory standards, biomechanical performance requirements, and clinical user needs. Mechanical integrity is ensured through breaking angle, axial pullout force, insertion torque, self-tapping performance, and various fatigue criteria. The surface design ensures bone integration through defined porosity, pore size, and surface roughness parameters. Stability is addressed by requiring fatigue resistance in both axial and cantilever loading, minimal micro-movement, and long-term compressive load retention. User-focused inputs include self-tapping and cannulation features for making surgery easier, while biological integration is promoted by implementing hydroxyapatite coating and a porous surface.

The design outputs include detailed mechanical drawings that specify thread design, cannulation, surface roughness, porosity, pore size, and HA coating where applicable. Outputs also include finite element analysis reports for mechanical performance predictions, manufacturing specifications, and custom test fixture designs for fatigue, torque, and pullout testing.

Verification of mechanical integrity will be done using a series of standardized bench-top tests described in ASTM F543-17 and ASTM F3574-22. In order to assess resistance to breakage, a static angular deformation test will be conducted. Screws will be subjected to controlled off-axis loading until failure, and the breaking angle will be recorded [17]. This is compared to an acceptance threshold of 57.3°, selected based on internal benchmarks for clinical safety under extreme joint rotation [17]. Axial pullout resistance is measured by embedding the screws in a rigid polyurethane foam test block, then applying axial tension at a constant rate until failure [17]. The resulting force is compared to an acceptance criterion of 1700 N [29]. Insertion torque is measured by recording the peak torque during insertion into a test block, with the goal of remaining below 5 Nm to ensure usability [29]. Self-tapping performance is measured by obtaining the insertion force per unit depth. This test is conducted under displacement control to ensure that the force slope is at least 0.15 N/mm [29].

Verification of cantilever bending and axial fatigue uses protocols adapted from ASTM F3574-22 and peer-reviewed literature. Cantilever bending fatigue tests evaluate the screw's ability to endure repetitive off-axis loading. Each screw is rigidly fixed at one end and subjected to a cyclic moment of 4 Nm for 2.5 million cycles or less if it fails before that [31]. For axial fatigue testing, the screw is embedded to a depth of 30 mm and subjected to cyclic axial compression using loading parameters derived from Wu et al. [37]. Each sample is tested at a peak load of 1500 N until failure or until 75,000 cycles are completed.

Verification of porous surface design and microstructure will be conducted through mercury intrusion porosimetry. Porosity is evaluated by immersing the sample in mercury under increasing pressure to quantify total void volume, allowing accurate determination of percent porosity within the 30-40% range [44]. Pore size distribution is also extracted from this test to confirm that the mean pore diameters fall in the range of 250-300 0 μm, thus optimizing conditions for osseointegration [44].

Validation using cadaveric or artificial bone models is conducted to assess the clinical usability and intraoperative performance of the sacroiliac fusion screw under realistic surgical conditions. Three orthopedic

surgeons perform guided screw insertions using the intended technique, including guidewire placement and advancement of the self-tapping screw without pre-drilling. The simulated procedures are conducted in synthetic bone blocks that replicate human sacral anatomy, or in cadaveric specimens when available. Throughout the procedure, surgeons will provide qualitative feedback on ease of insertion, tactile feedback, alignment, and screw purchase. Quantitative data such as insertion torque and resistance during tapping will also be recorded. Surgeons will be asked to evaluate the device against predefined usability criteria, including workflow efficiency and fixation confidence. The goal of this type of validation is to confirm that the screw can be implanted smoothly and eliminates unnecessary steps in the surgical process while also addressing user needs related to stability and efficiency.

In order to validate the effectiveness of the hydroxyapatite coating on the reformation of bone post insertion, in vivo testing would need to be performed. As the 510(k) submission avoids the clinical testing route via a PMA submission, in vivo testing should be performed on animal surrogates instead of humans. Bone testing with animals can be classified into two categories, large and small animals. Large animals, such as dogs, pigs, and sheep, share closer skeletal anatomy and metabolic processes to humans, making testing results more accurate at increased costs and resources [38]. However, as the purpose is to verify that the HAp coating improves the bone response compared to a non-coated screw, testing can be performed with small animals [38]. Thus, in-vivo testing will be performed with rabbits. While the lighter bone structure and faster metabolism of rabbits will not accurately reproduce the expected results if implanted in humans, the lower cost of raising rabbits and their faster metabolism allow for initial verification at a lower cost and at a third of the time [38]. Rabbits have also been found to produce good results when assessing implant infection and healing, the latter of which is the focus of the verification tests [38]. If results are insufficient then the screws can be tested on sheep or pigs to yield more accurate results to humans.

For testing in rabbits, testing will follow guidelines of ASTM F2721-09 Standard Guide for Pre-clinical in vivo Evaluation in Critical Size Segmental Bone Defects [17]. While this standard does not list specific test procedures, it highlights various considerations when performing animal in-vivo testing, such as the handling of animals, rabbit specific considerations, and evaluation methods. The screw design would also have to be scaled down to match the size of the rabbit. As literature was unable to be found to support a specific scaling factor for sacroiliac screws, the screw diameter would likely be shrunk to 1-2mm, however these diameters should be verified before starting in-vivo testing. If a screw with the necessary diameter is unable to be manufactured, then again testing should be performed on sheep or pigs. Evaluating the effect of the HAp coating on osseointegration will be performed via radiography or Computed Tomography [47]. The degree of bone growth can be determined visually through the scans, and a failure criterion would constitute seeing no significant improvements from including the HAp coating.

Summary

We propose a sacroiliac (SI) joint fusion screw that combines a self-tapping, fully threaded, double pitch design with a porous alloy body and hydroxyapatite (HAp) coating, cannulated for guidewire placement available in multiple lengths with an 8mm diameter. Our design enhances fixation strength, improves surgical accuracy, and promotes long-term osseointegration.

For bringing this product to market, we chose the 510(k) clearance pathway, as several predicate devices exist with overlapping features. Substantial equivalence was proven with three market devices in intended use, materials and general design. We plan to verify safety and effectiveness through benchtop testing that aligns with ASTM F543 and F3574 standards. Furthermore, validation will be conducted using artificial models and in vivo testing in rabbits to assess the effectiveness of our design. Our risk assessment identified nine potential hazards, ranging from biocompatibility reactions to surgical complications during implant removal. User needs and design inputs were developed, and include mechanical performance metrics, anatomical fit, implant stability, and bone integration. Using a traceability matrix ensured that each design input was related to measurable outputs and specific Verification and Validation (V&V) methods.

Following completion of the planned V&V, the next steps should be checking manufacturability, packaging and sterilization. A shortcoming of our V&V plan is the fact that we rely on internal benchmarks for some mechanical thresholds, such as breaking angle or micro-movement limits. Additionally, using small animal models for osseointegration validation may not translate well to human performance. After the 510(k) submission, collecting early clinical feedback is crucial for additional validation. Long-term, post-market surveillance should be continued throughout the product's life cycle to monitor real-world performance and look for future design updates.

Post-Launch Questions

1. For the design inputs listed, please detail what the biggest unknown or risk present between the verification activities that your group intends to perform and the clinical performance (i.e., patient outcomes) tied to your product?

The biggest unknown or risk present between our planned verification activities and the actual clinical performance of the sacroiliac fusion screw lies in the long-term clinical outcome of the implant with patient bone. While we have precise mechanical verification methods, such as insertion torque and axial pullout testing, these tests are largely conducted in artificial bone that do not fully replicate the biological environment inside the human body. This means it does not account for bone healing rates and variability in bone density across various patients. In particular, osseointegration is highly dependent on an individual patient's bone quality, which is difficult to predict through bench-top tests or animal studies [39]. Especially with testing in small animals like rabbits, while it is cost efficient, the lighter bone structure will integrate differently, and the mechanical properties of the implant may differ in human patients. Actual post market clearance use cases of the screw in patients will also experience different mechanical or chemical stresses which all cannot be accounted for simply with testing. This is especially important as our screw is designed for long-term implant, and thus the efficacy of the screw can be largely impacted despite validation and verification processes taken to ensure safety and efficacy.

2. Marketing has received negative feedback from the field and is requesting the engineering team (your group) to make a small design change to the product. Please write a response on how you would respond to marketing in determining the scope of work as it pertains to the regulatory work that would be required depending on the

requested change. How would you determine if a new 510(k) is required, or is not required, depending on the design change.

We would respond to marketing as follows:

“Hello, thank you for bringing the negative field feedback to our attention. To address the design change request in alignment with regulatory requirements, we will be needing detailed documentation to assess whether the change affects the device’s indications of use, labeling, materials, performance, etc. to help us determine whether a not a new 510(k) submission is required, and the scope of the word required to carry out this modification per your request.”

Whether a new 510(k) submission is required would then depend on the information provided by marketing. If the design change may call into concern the efficacy and safety of the product, significantly changes the device in some way, such as its intended use or how it operates, then a new submission would be required [40]. However, since the change in design is small, there is a possibility that a new submission may not be required. Some examples of changes that would not require a new submission include:

- Cosmetic/aesthetic changes (ie. colour)
- Change to the dimensions available, as long as the new values are not a novel extreme
- Changes to the packaging, as long as corresponding changes in manufacturing process don’t affect the product’s safety
- Small revisions to accessory products that do not affect the product’s safety (eg. redesign of an instruction manual/guide)
- Addition of accessory products, such as a specialized removal tool as per RISK-04 (note that the screw itself would not require a new submission, but the tool would)

Verification information to prove that the final manufactured device meets the plans in design change must be kept in record to be made available to an FDA investigator upon request.

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Appendix

Table I. Risk Analysis

Risk Analysis									Risk Control				
Risk ID	Hazard	Description of Potential Hazard	Potential Effects of Hazard	S	Potential Causes	O	Current Risk Controls	RPN	Potential Mitigation Activities	Actions Taken	Resulting		
											S	O	RPN
RISK-01	Biocom-patibility	Adverse reaction to HAp coating or other materials used [27]	Pain, swelling, inflammation, and other reactions that require implant removal	4	Allergy to HAp or other materials used within the product	2	Preopera-tive testing to ensure that materials are compatible	8	Offer an alternative product without HAp coating or with a different material	Review design to see if modifi-cations are possible	1	2	2
RISK-02	??	Implant fails to properly integrate within the bone [25]	Implant loosens without identifiable cause	3	Incorrect screw size	3	Physician evaluation to determine correct implant and procedure	9	N/A - implant design cannot accommodate for natural causes or incorrect physician judgement	N/A	3	3	9
RISK-03	??	Implant fails to properly integrate within the bone [25]	Implant develops fibrous tissue around the screw, loosening it	3	Pre-existing patient conditions that might affect bone integrity or strength [26]	2	Doctors must evaluate patient to see if this product is right for them	6	N/A - implant design cannot accommodate for pre-existing conditions and patient response	N/A	3	2	6
RISK-04	??	Screw design may complicate implant removal procedures	Use of excess force during removal could damage removal instruments [28]	3	User error or adverse reactions will require screw to be removed. Improper tool use could result in increased risk of tool breakage.	3	N/A	9	Determine a way to remove the implant with minimal risk to the patient, possibly by creating a special removal tool for this purpose	Design revision to make removal easier	2	1	2
RISK-05	Biocom-patibility	Contaminants within the implant acquired during manufactur-ing and transportation	Pain, swelling, inflammation, and other reactions that require implant removal	4	Improper processes and controls in manufactur-ing and transporta-tion	3	Regular visits and inspections at partnered facilities	12	Work with partner facilities to introduce more precautionary measures for prevention	Evaluate current proces-ses and controls of facilities	4	1	4
RISK-06	??	Injury in spine, hip, and lower body joints	Limited mobility in the hip or lower spine [42]	2	Compensa-tion for decreased range of motion in SI joint	1	N/A	2	N/A - implant design cannot accommodate for patient response to treatment	N/A	2	1	2
RISK-07	??	Misplacement of implant in	Failure to stabilize SI	4	Improper placement of	2	Proper, meticulous	8	N/A - implant design cannot	N/A	4	3	8

		position and/or location [22]	joint, increased pain, growth of extra tissue, migration, infection		implant or surgical technique, user error		training and pre-operative planning procedures with a focus on sacral dysmorph-ism		accommodate for user error				
RISK-08	??	Damage to important structures like the superior gluteal artery and/or nerve [23]	Increased pain in the joint might call for removal, haemorrhage in surgery may lead to significant injury and death	5	Improper placement of implant or surgical technique, user error	2	Proper, meticulous training and pre-operative planning procedures with a focus on sacral dysmor-phism [R2]	10	N/A - damage to these structures are an unavoidable adverse event in SI joint fusion [23]	N/A	5	2	10
RISK-09	Injury	Wound infection following surgery [43]	Infection might spread to other parts of the body, including the bone and bloodstream	4	Improper wound care, error from healthcare team, patient error/non-compliance	2	Self-tapping feature eliminates need for a pre-drilled hole, reducing trauma and risk of infection during the surgery. Healthcare providers must help patients practice proper wound care.	8	Modify design to improve efficiency, limiting surgery time and bone exposure time	Design revision	4	1	4

Table II. User Needs & Design Inputs Table

Product Requirement ID	User Need	Design Input	Sources
Section 1: Regulatory - Non-clinical Testing			
PR-01-01	Implant must have sufficient strength to resist breakage under stress	Must have a breaking angle of at least 1 rad, or 57.3° Note that this is an internal value inspired by an ambulatory assistive non-implant device; reconfirmation may be required.	Testing Standard: ASTM F543 [29] Design Input: [30]

PR-01-02	Implant must not be easily loosened	Must be able to withstand an axial pullout force of 1700 N	User Need: ASTM F543, F3574-22 [29][31] Design Input: [32]
PR-01-03	Implant must allow easy insertion	Must have an insertion torque under 5 Nm. Higher threshold allowed due to dual thread	User Need: ASTM F543, F3574-22 [29][31] Design Input: [34]
PR-01-04	Implant's self-tapping must have significant benefit	Must have a self-tapping force of at least 0.15 N/mm at any insertion depth Note that this value is based on HA screw samples with smaller thread diameters and pitches compared to SI screws,which are closer to HC; reconfirmation may be required.	User Need: Testing Standard: ASTM F543 [29] Design Input: [35]
PR-01-05	Implant must resist mechanical failure over time	Must undergo cantilever bending fatigue testing up to 2,500,000 cycles at a 4 N·m bending moment Note that the bending moment is an internal value inspired by a facet screw system; reconfirmation may be required.	User Need: ASTM F3574-22 [31] Design Input: ASTM F3574-22 [31] [33]
Section 2: Customer			
PR-02-01	Improved efficiency and accuracy of implantation for surgeons	Self-tapping feature to eliminate the need for pre-drilling Cannulated design to allow for guidewire placement	User Need: ASTM F543 [29] Design Input: [11]
PR-02-02	Must have long-term implant stability for patients	Fully threaded dual-pitch design to improve bone purchase, control compression, and effectively resist axial loads	User Need: [8] Design Input: [8]
PR-02-03	Must effectively integrate into bone	Porous surface & hydroxyapatite coating to promote osseointegration	User Need: [9] Design Input: [9]
Section 3: Technical			
PR-03-01	Implant must fit within anatomy	All dimensions in mm: ● Shaft diameter: 4.5 ● Head Diameter: 8.0 ● Head height: 1.8 - 2.1 ● Head top radius: 6.35	Testing Standard: ASTM F543 [29]
PR-03-02	Implant must promote bone integration	Porosity of 30-40% with pore size range of 250-300 μm	User Need: [21] Design Input: [21]
PR-03-03		Must have S_a (roughness parameter) value between 0.200 and 0.500 μm	User Need: [36] Design Input: [36]

Section 4: Performance			
PR-04-01	Implant must not loosen over time	Must have a minimum axial fatigue life of n=75,000 cycles for an implant depth of 30 mm at 1500 N peak load	User Need: [37] Design Input: [37]
PR-04-02	Implant must allow bone ingrowth and prevent fibrous tissue formation.	Maximum micro-movement must not exceed 150 µm	User Need: [41] Design Input: [41]
PR-04-03	Implant must ensure sustained joint stability and prevent early loosening	Must retain at least 50% of its initial compressive load for an extended period post-insertion and exhibit a controlled load relaxation profile	User Need: [42] Design Input: [42]

Table III. Traceability Matrix

Product Requirement ID	Design Input	Design Output	Verification	Validation
PR-01-01	Must have a breaking angle of at least 1 rad, or 57.3° Note that this is an internal value inspired by an ambulatory assistive non-implant device; reconfirmation may be required.	Mechanical drawing with specifications for thread design and surface treatment. Include finite element analysis (FEA) report for angular deformation and predicted failure angle.	**Mechanical Testing** *Breaking Angle Testing as per ASTM F543 [29]* **Sample size:** 5 samples as per FDA guidance for orthopaedic non-spinal metallic bone screws **Acceptance Criteria** = 57.3°	**Usability Study:** Cadaveric or artificial bone testing performed by three (3) orthopedic surgeons. Resistance to angular loading is tested under simulated physiological loading, evaluated through pass/fail scoring.
PR-01-02	Must be able to withstand an axial pullout force of 1700 N	Mechanical drawing with specifications for thread design and surface treatment.	**Mechanical Testing** *Axial Pullout Testing as per ASTM F543-17 [29]* **Sample size:** 5 samples as per FDA guidance for orthopaedic non-spinal metallic bone screws **Acceptance Criteria** = 1700 N	**Usability Study:** Cadaveric or artificial bone testing performed by three (3) orthopedic surgeons. Screw fixation stability is tested under simulated physiological loading, evaluated through pass/fail scoring.
PR-01-03	Must have an insertion torque under 5 Nm. Higher threshold allowed due to dual thread	Mechanical drawing with specifications for thread design and surface treatment.	**Mechanical Testing** *Driving Torque Testing as per ASTM F543-17 [29]* **Sample size:** 5 samples as per FDA guidance for	**Usability Study:** Cadaveric or artificial bone testing performed by three (3) orthopedic surgeons to evaluate ease of insertion based on subjective feedback

			orthopaedic non-spinal metallic bone screws **Acceptance Criteria** = <5 Nm	and objective torque measurement.
PR-01-04	Must have a self-tapping force of at least 0.15 N/mm at any insertion depth Note that this value is based on HA screw samples with smaller thread diameters and pitches compared to SI screws,which are closer to HC; reconfirmation may be required.	Mechanical drawing with specifications for thread design and surface treatment.	**Mechanical Testing** *Self-Tapping Performance Testing as per ASTM F543-17 [29]* **Sample size:** 5 samples as per FDA guidance for orthopaedic non-spinal metallic bone screws **Acceptance Criteria** = >0.15 N/mm	**Usability Study:** Cadaveric or artificial bone testing performed by three (3) orthopedic surgeons to evaluate ease of self-tapping during insertion. Surgeons will provide qualitative feedback on the self-tapping effectiveness, while insertion force measurements will be recorded in real time to confirm that self-tapping force meets or exceeds 0.15 N/mm at any insertion depth
PR-01-05	Must undergo cantilever bending fatigue testing up to 2,500,000 cycles at an 4 N·m bending moment Note that the bending moment is an internal value inspired by a facet screw system; reconfirmation may be required.	Mechanical drawing with specifications for thread design and surface treatment.	**Mechanical Testing** *Cantilever Bending Testing as per ASTM F3574-22 [31]* **Sample size:** 5 samples as per FDA guidance for orthopaedic non-spinal metallic bone screws **Acceptance Criteria** = 2,500,000	**Usability Study:** In vivo animal study using rat model. Five (5) test screws are implanted into skeletally mature rats. Animals are allowed normal activity over a period of 4 to 6 weeks to simulate repetitive physiological loading. At the end of the study, implants are examined for degradation, fracture, or loosening.
PR-02-01	Self-tapping feature to eliminate the need for pre-drilling Cannulated design to allow for guidewire placement	Mechanical drawing with specifications for thread design and cannulation.	**Mechanical Testing:** *Self-Tapping performance testing as per ASTM F543-17 [29]* **Sample Size:** 5 samples as per FDA guidance for orthopaedic non-spinal metallic bone screws **Acceptance Criteria:**	**Usability Study:** Cadaveric or artificial bone testing performed by three (3) orthopedic surgeons. Evaluate ease of guidewire-assisted placement and effectiveness of self-tapping without pre-drilling. Surgeons provide feedback on

			Self-tapping force of at least 0.15 N/mm	workflow and insertion performance.
PR-02-02	Fully threaded dual-pitch design to improve bone purchase, control compression, and effectively resist axial loads	Mechanical drawing with specifications for thread design.	**Mechanical Testing:** Axial fatigue testing as described by [44] **Sample Size:** 5 samples as per FDA guidance for orthopaedic non-spinal metallic bone screws **Acceptance Criteria:** Demonstrates increased axial resistance compared to single-pitch control	**Usability Study:** Cadaveric or artificial bone testing performed by three (3) orthopedic surgeons. Subjective assessment of insertion control and compression feel, supported by objective measurements of axial displacement under load.
PR-02-03	Porous surface & hydroxyapatite coating to promote osseointegration	Mechanical drawing with specifications for surface treatment.	**Mechanical Testing:** Mercury intrusion porosimetry measurement as described by [44] performed for each model per sample lot **Sample Size:** 5 samples as per FDA guidance for orthopaedic non-spinal metallic bone screws **Acceptance Criteria:** Minimum of 50% bone-to-implant contact (BIC) ratio.	**Usability Study:** In vivo animal study using rabbit model. Five (5) HA-coated test screws are surgically implanted into skeletally mature rats under sterile conditions. Following a healing period of 4 to 6 weeks, the implant's BIC ratio is measured.
PR-03-01	All dimensions in mm: ● Shaft diameter: 4.5 ± 0.2 ● Head diameter: 8.0 ± 0.5 ● Head height: 1.95 ± 0.1 ● Head top radius: 6.35 ± 0.3	Mechanical drawing with specifications for shaft and head dimensions.	**Dimensional Inspection:** *Inspection performed on the listed dimensions for each model per sample lot* **Sample Size:** Samples per lot determined in accordance to ISO 13845:2016 [46] **Acceptance Criteria:**	**Usability Study:** Physical models will be sent to ten (10) orthopaedic surgeons to evaluate dimension offerings, evaluated through pass/fail scoring.

			Dimensions must fall within tolerances listed	
PR-03-02	Porosity of 30-40% with pore size range of 250-300 μm	Mechanical drawing with specifications for porosity and pore size	**Dimensional Inspection:** Mercury intrusion porosimetry measurement as described by [44] performed for each model per sample lot **Sample Size:** Samples per lot determined in accordance to ISO 13845:2016 [45] **Acceptance Criteria:** Pore measurements must fall within tolerances listed	**Usability Study:** In vivo animal study using rabbit femoral model. Five (5) HA-coated test screws are surgically implanted into the distal femur of skeletally mature rats under sterile conditions. Following a healing period of 4 to 6 weeks, the implant's BIC ratio is measured.
PR-03-03	Must have S_a (roughness parameter) value between 0.200 and 0.500 μm	Mechanical drawing with specifications for roughness	**Dimensional Inspection:** Roughness measurement as described by [46] performed for each model per sample lot **Sample Size:** Samples per lot determined in accordance to ISO 13845:2016 [45] **Acceptance Criteria:** Roughness measurements must fall within tolerances listed	**Usability Study:** In vivo animal study using rabbit femoral model. Five (5) HA-coated test screws are surgically implanted into the distal femur of skeletally mature rats under sterile conditions. Following a healing period of 4 to 6 weeks, the implant's BIC ratio is measured.
PR-04-01	Must have a minimum axial fatigue life of n=75,000 cycles for an implant depth of 30 mm at 1800 N peak load	Mechanical drawing with specifications for thread design and surface treatment.	**Mechanical Testing:** Axial fatigue testing as described by [44] **Sample size:** 5 samples as per FDA guidance for orthopaedic non-spinal metallic bone screws. **Acceptance Criteria:**	**Usability Study:** Cadaveric or artificial bone testing performed by three (3) orthopedic surgeons. Surgeons assess fixation performance during cyclic loading representative of physiological conditions. Fatigue durability is evaluated

			Minimum of 75,000 cycles at specified loading conditions and implant depth without failure.	post-test via inspection and imaging.
PR-04-02	Maximum micro-movement must not exceed 150 µm	Mechanical drawing with specifications for thread design and surface treatment.	**Mechanical Testing:** Micro-motion testing as described by [41] **Sample Size:** 5 samples as per FDA guidance for orthopaedic non-spinal metallic bone screws. **Acceptance Criteria:** Maximum micro-movement of 150 µm under 100 N at 1 Hz for 1000 cycles.	**Usability Study:** Cadaveric or artificial bone testing by three (3) orthopedic surgeons to assess perceived stability. Micro-movement recorded in real time to confirm compliance under loading.
PR-04-03	Must retain at least 50% of its initial compressive load for an extended period post-insertion and exhibit a controlled load relaxation profile	Mechanical drawing with specifications for thread design and surface treatment.	**Mechanical Testing:** Compressive load retention testing as described by [34] **Sample Size:** 5 samples as per FDA guidance for orthopaedic non-spinal metallic bone screws. **Acceptance Criteria:** Minimum 50% of initial compressive load retained after 60 minutes	**Usability Study:** Cadaveric or artificial bone testing by three (3) orthopedic surgeons. Real-time force monitoring used to assess load retention post-insertion. Surgeons provide qualitative feedback on perceived fixation durability.