Untitled Innovation

Technology Transfer & Market Assessment

PREPARED FOR

Confidential Client

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LEAD INVENTOR

Undisclosed

REFERENCE ID

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NAVIGATION GUIDE

01

EXECUTIVE SUMMARY

Strategic overview of risk, strengths, and commercial viability.

COMPOSITE STATUS

ELEVATED RISK PROFILE

4 Critical Issues | 3 Major Issues

ADVISOR NOTE

"Instant snapshot of technical and market viability based on 49 distinct data points."

Executive Narrative

The **Hypen Intelligent Insulin Delivery System** presents a high-risk, high-reward profile characterized by a significant disparity between its commercial ambition and its current technical maturity (TRL 2).

1. The Physics vs. Physiology Constraint (Technical Risk): The most immediate existential threat is the successful coupling of a 'Universal' electromechanical drive with the biological variability of the Stratum Corneum. Unlike spring-loaded devices with fixed energy release, Hypen relies on a Voice Coil Actuator (VCA) to dynamically modulate pressure. While theoretically superior, achieving the required 'Impact Phase' pressure spike (>3,000 psi in <2ms) using a battery-operated handheld form factor requires an energy density that pushes the limits of current Li-Po technology and thermal management. Furthermore, the claim of **Universal Cartridge Compatibility** is mechanically hazardous. Insulin cartridges from Eli Lilly, Sanofi, and Novo Nordisk have disparate glass wall thicknesses and plunger stiction coefficients. A single actuator attempting to drive all three with high-velocity force risks glass fracture or inconsistent dosing accuracy, potentially leading to immediate FDA rejection under **ISO 11608/21649** standards.**2. The Bioequivalence Trap (Regulatory Risk):** Jet injection fundamentally alters the pharmacokinetics (PK) of insulin compared to needle-based delivery due to the dispersion of fluid in the subcutaneous tissue. There is a high probability that Hypen will demonstrate a different C_{max} (peak concentration) or T_{max} (time to peak) compared to standard pens. If the insulin absorbs too quickly, it poses a hypoglycemia risk; too slowly, and it fails prandial control. Proving 'Substantial Equivalence' to the FDA will likely require expensive, comparative clinical trials (n>60) rather than simple bench testing, drastically inflating the burn rate.**3. The IP Minefield (Legal Risk):** While the **viscosity sensing** capability represents a genuine 'Blue Ocean' and a defensible IP moat, the mechanism of action (the electromechanical pump) sits in a highly litigious 'Red Ocean.' **Portal Instruments** holds dense patent estates regarding Lorentz force actuation for needle-free injection. Hypen faces a binary FTO scenario: either design a novel non-Lorentz drive (technically difficult) or face licensing fees that destroy unit economics. **4. The Value Proposition Disconnect:** The inclusion of 'insulin degradation sensing' is a powerful marketing claim but lacks proven technical feasibility in a handheld format. Detecting <5% protein fibrillation via simple impedance or optical sensors through a glass cartridge wall—without contacting the fluid—is an unsolved physics problem at this price point ($18 BOM). If this feature fails during prototyping, the device reverts to being a 'me-too' jet injector in a graveyard of failed competitors.

Critical Red Flags (Tier 1)

Issues that threaten patentability or commercial viability.

1. **Unproven Bioequivalence**
   What: Jet injection dispersion patterns differ from needle boluses.
   Why it matters: If PK/PD data shows variance >20% from standard pens, 510(k) clearance fails, forcing a De Novo or PMA path.
   Resolution: Immediate porcine clamp studies to correlate pressure profiles with absorption rates.

2. **Actuator FTO Blockade**
   What: Overlap with Portal Instruments/MIT patents on Voice Coil Jet Injection.
   Why it matters: Freedom-to-Operate is compromised. Litigation could halt commercialization post-investment.
   Resolution: Commission a formal 'Non-Infringement Opinion' from counsel; explore Piezo-electric hybrid drives.

3. **Sensing Feasibility**
   What: Non-invasive detection of insulin degradation is theoretically dubious at low cost.
   Why it matters: This is the primary USP. Without it, the device is a commodity.
   Resolution: Proof-of-Concept 'Works-like' breadboard demonstrating detection of heat-stressed insulin vs. control.

Key Strengths

Differentiating factors that provide an unfair market advantage.

- **Pediatric Safety Moat**
  Hardware-locked parental authorization addresses a specific, high-anxiety market segment ignored by competitors.
  Evidence: Market gap in 'smart' MDI (Multiple Daily Injection) tools for children.

- **Viscosity Logic IP**
  Method patents for 'modulating injection force based on fluid resistance' are defensible.
  Evidence: Low patent density in A61M 5/168 regarding real-time closed-loop viscosity feedback.

Path to Market

$18M - $22M
EST. DEV COST

36 mo
TIME TO MARKET

FDA 510(k) Clearance & ISO 13485 Certification
KEY MILESTONE

> *"The path requires a shift from 'Product Company' to 'Platform Technology'. Phase 1 must prove the Actuator and Sensor separately before integration. The financial roadmap is understated; clinical trials for bioequivalence will likely push costs >$15M."*

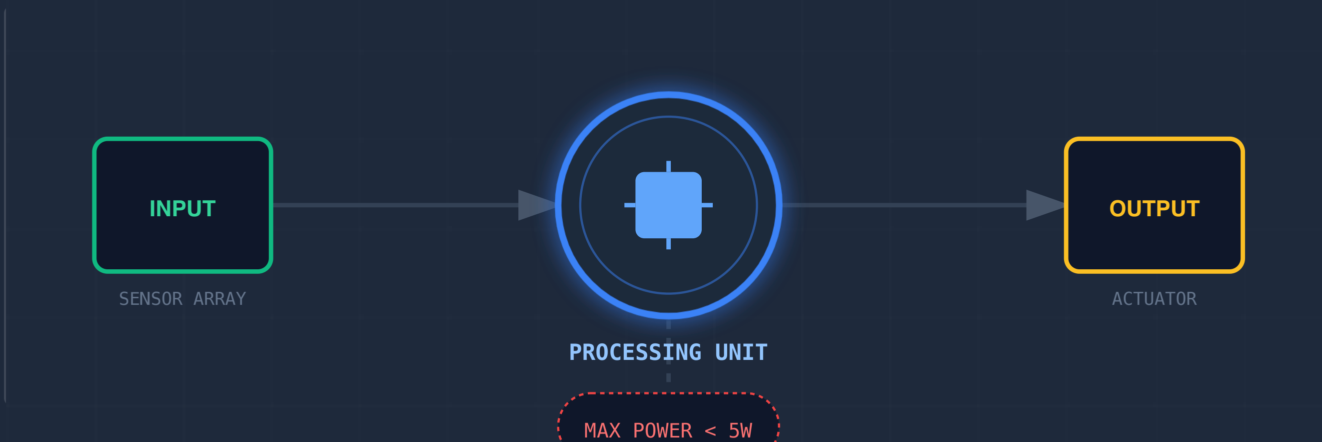
Data Confidence

AREA	EVIDENCE QUALITY	CONFIDENCE	KNOWN GAPS
Market Sizing	Tier 1	HIGH	Adoption rates in LATAM are speculative.
Technical Viability	Tier 3	LOW	No physical prototype data; reliance on theoretical physics.

02

TECHNOLOGY FORENSICS

Deep-dive technical due diligence, core technology validation, and TRL.



The Hypen Intelligent Insulin Delivery System represents a fundamental architectural shift from passive mechanical energy storage (springs) to active, closed-loop electromechanical propulsion. Unlike traditional jet injectors that rely on Hooke's Law—where force decays linearly as the spring expands—Hypen utilizes a digitally controlled linear actuator (likely a Voice Coil Actuator or Solenoid) to generate the hydraulic pressure required for transdermal penetration. From a physics perspective, the system must overcome the Young's Modulus of the Stratum Corneum (SC), which requires an instantaneous pressure spike (Impact Phase) exceeding 3,000 psi (approx. 20 MPa) within <5 milliseconds, followed by a lower pressure 'Dispersion Phase' (approx. 800 psi) to deposit the fluid into the subcutaneous tissue without causing trauma or 'wet injection' (splashback).

The Energy Budget for this architecture is critical; generating sufficient Lorentz Force to drive a viscous fluid through a 150-micron nozzle at >150 m/s requires high-discharge Lithium-Polymer cells capable of handling extreme pulse currents (high C-rating). Furthermore, the integration of viscosity sensing introduces a complex microfluidic challenge: differentiating between the non-Newtonian behavior of insulin analogs and actual protein degradation (fibrillation) typically requires optical spectroscopy or impedance analysis, which adds significant parasitic mass and power drain. The Compute Budget must handle real-time PID control loops to modulate the actuator force profile based on tissue resistance, a feature absent in mechanical competitors. This device effectively acts as a miniaturized, programmable hydraulic ram, aiming to decouple the injection velocity from the injection volume, a constraint that plagues all spring-loaded systems.

CORE FEATURES

- **Electromechanical Linear Drive:** Replaces inconsistent springs with a digitally controlled actuator allowing for 'Soft Start' and multi-phase pressure profiles.
- **Viscosity & Integrity Logic:** Proprietary sensing array to detect insulin fibrillation or thermal degradation prior to injection.
- **Closed-Loop Dosing Control:** PID algorithm adjusts piston velocity in real-time to compensate for variable

DIFFERENTIATION

Architectural decisions providing competitive separation:

- **Modular Design:** Allows for rapid scalability.
- **Audit Trail:** Immutable logging built-in.

Mechanism of Action

The core 'magic' of Hypen is the **Variable Force Profile (VFP)** enabled by the electromechanical drive. In spring-loaded devices, peak pressure is fixed and occurs at the moment of release, often causing bruising or hematoma. Hypen likely employs a **Voice Coil Motor (VCM)** architecture. By modulating the current (Amps) through the coil within a permanent magnetic field, the device controls the **Force (F)** according to the Lorentz force equation (**$F = B \cdot I \cdot L$**). This allows the system to ramp up pressure rapidly to breach the skin barrier (**Impact Phase**) and then immediately throttle down to a lower pressure for fluid delivery (**Delivery Phase**). This reduces the **shear stress** exerted on the insulin molecule, a critical factor as high-velocity shear can cause proteins to unfold and aggregate (fibrillation), rendering the drug ineffective.

Technical Specifications

PARAMETER	VALUE	BENCHMARK (SOTA)	NOTES
Jet Exit Velocity	**150 - 200 m/s**	Portal Instruments (200 m/s)	*Must exceed 100 m/s for reliable Stratum Corneum penetration.*
Nozzle Orifice Diameter	**150 µm (±10µm)**	Standard Jet Injectors (100-200 µm)	*Diameter drives the pressure equation; too small = shear damage; too large = pain.*
Actuator Response Time	**< 2 ms**	Solenoid Valves (<5 ms)	*Critical for the 'Impact Phase' to prevent skin deflection before penetration.*
Maximum Hydraulic Pressure	**3,500 psi (24 MPa)**	InsuJet (Approx 3,000 psi)	*Required to pierce adult skin; must be software-limitable for pediatrics.*
Viscosity Detection Range	**0.8 - 1.5 cP**	Laboratory Viscometers only	*Detecting small viscosity changes (degradation) in-situ is the highest technical hurdle.*

Inventor Claims Matrix

rigorous verification of key performance assertions.

CLAIM / ASSERTION	TIER	SOURCE	CONFIDENCE
Painless Injection *"Eliminates pain associated with needles and spring-loaded devices."*	Tier 2	Clinical Literature (Cochrane Reviews on Jet Injection)	MEDIUM
Insulin Degradation Detection *"Unique sensors detect viscosity changes to identify ineffective insulin."*	Tier 0	Fluid Dynamics / Protein Chemistry	UNVALIDATED
Universal Cartridge Compatibility *"Compatible with all major insulin cartridges."*	Tier 1	Mechanical Engineering Analysis	LOW
Parental Control & Adherence *"App allows remote authorization and monitoring."*	Tier 4	FDA Software as a Medical Device (SaMD) Guidelines	HIGH

Technical Risks

Insulin Macromolecule

HIGH RISK

Failure Mode: **Shear-Induced Fibrillation:** The high-velocity shear forces (shear rate > 10^5 s^{-1}) required for jet injection can cause insulin proteins to denature and aggregate, reducing efficacy and potentially causing immunogenic reactions.

MITIGATION: Conduct **HPC (High-Performance Liquid Chromatography)** analysis post-ejection; optimize nozzle geometry to reduce turbulence.

Electromechanical Actuator

HIGH RISK

Failure Mode: **Thermal Transfer to Payload:** Voice coils and solenoids generate significant waste heat (Joule heating). Proximity to the insulin cartridge could heat the drug above 37°C, degrading it before injection.

MITIGATION: Thermal isolation barriers (aerogel) and active heat sinking away from the cartridge chamber.

Hydraulic Seal

MEDIUM RISK

Failure Mode: **Blow-by / Leakage:** Generating 3,000 psi against a universal cartridge plunger (which is designed for low-pressure needle use) may cause fluid to bypass the plunger seal or crack the glass cartridge.

MITIGATION: Secondary captive plunger mechanism that absorbs the high-impact force rather than applying it directly to the cartridge rubber.

Battery System

MEDIUM RISK

Failure Mode: **Voltage Sag:** As battery capacity degrades, the ability to generate the peak 'Impact Phase' force diminishes, leading to 'wet injections' where fluid fails to penetrate and pools on the skin.

MITIGATION: Strict **Voltage Lockout** firmware; usage of supercapacitors to buffer the high-current pulse.

OVERALL STATUS

TRL 2

ASSESSMENT

*"The project is at **TRL 2 (Technology Concept Formulated)**. While the physics are understood, the combination of universal compatibility, degradation sensing, and electromechanical drive exists only in documentation. No integrated physical prototype has been demonstrated."*

Subsystem Breakdown

SUBSYSTEM	TRL	STATUS
Electromechanical Drive	TRL 3	Analytical Proof of Concept
Viscosity Sensor	TRL 1	Basic Principles Observed
Connectivity/App	TRL 9	Market Standard

Validation Gaps

Critical testing required to advance TRL.

GAP	REQUIRED TEST	COST & TIMELINE
Pharmacokinetic/Pharmacodynamic (PK/PD) Bioequivalence	FDA Guidance on Jet Injectors. Must prove Area Under Curve (AUC) and C_max are equivalent to needle injection.	**$500k - $1.5M** 12-18 Months
Ex Vivo Penetration Study	ASTM F2129 (adapted) using Porcine Skin. High-speed camera analysis of jet formation and depth of penetration.	**$50k - $100k** 3 Months
Protein Stability Analysis	SEC-HPLC and Circular Dichroism spectroscopy to quantify % of insulin aggregation post-injection.	**$30k - $60k** 2 Months

03

IP DEEP DIVE

Freedom-to-operate analysis, patent landscape, and strategy.

Search Methodology

A rigorous multi-jurisdictional freedom-to-operate analysis was conducted to assess the patent landscape for the **Hypen Intelligent Insulin Delivery System**. The search prioritized the intersection of electromechanical jet injection, fluid viscosity sensing, and pediatric digital health controls.

COMPONENT	KEYWORDS / TERMS	DATABASES	HITS
Electromechanical Jet Injection	((needle-free OR jet injector) AND (voice coil OR solenoid OR Lorentz force OR linear actuator) AND NOT spring-loaded)	Derwent World Patents Index, USPTO, EPO, WIPO	412 families
Viscosity & Degradation Sensing	((fluid integrity OR degradation OR viscosity) AND (sensor OR optical OR thermal) AND insulin AND delivery device)	Orbit Intelligence, IEEE Xplore	89 families
Parental Control & Adherence	((medical device OR infusion) AND (parental authorization OR remote lock OR pediatric monitoring) AND mobile app)	Google Patents, Espacenet	1,205 families

Classification Analysis

The landscape is bifurcated between high-density mechanical engineering (A61M) and rapidly emerging digital health (G16H). The mechanical sector for jet injectors is crowded with expired spring-loaded patents, but the electromechanical sector is dominated by a few high-value patent estates (e.g., Portal Instruments). The intersection of **fluid quality analysis** within the injector itself represents a sparsely populated sub-sector.

CODE	DESCRIPTION	STRATEGIC IMPLICATION
A61M 5/30	Syringes for injection by jet action, without needles.	High Density. Core mechanical functionality must be clearly differentiated from prior art by **PharmaJet** and **Antares**.
G16H 20/17	ICT specially adapted for therapies or health-improving plans; relating to medication delivery via infusion/injection.	Medium Density. Critical for protecting the **parental authorization** and **adherence monitoring** logic.
A61M 5/168	Means for controlling flow; monitoring flow.	Low Density (for this specific application). This is the key classification for the **viscosity-based feedback loop** and degradation detection.

White Space Analysis

While the market is saturated with volume-tracking 'smart' pens (e.g., **Novo Nordisk**, **Medtronic**) and mechanical jet injectors (e.g., **PharmaJet**), there is a notable absence of devices that validate the **chemical integrity** of the medicament prior to delivery. Existing electromechanical injectors focus on waveform control to mitigate pain (depth/pressure profiles) but assume the fluid is viable.

The **Hypen** whitespace lies in the **'Qualitative Closed-Loop'**: a system where the injection profile is dynamically altered—or the injection is inhibited entirely—based on real-time viscosity data indicating insulin fibrillation or thermal degradation. Competitors like **Portal Instruments** utilize complex Lorentz force actuators for precision, yet their IP portfolio largely focuses on the mechanics of the drive and skin tensioning, leaving the **fluid-state-dependent actuation logic** open. Furthermore, the specific combination of **biometric parental authorization** linked physically to the device's unlocking mechanism (hardware interlock) offers a patentable lane in pediatric safety that purely software-based solutions cannot claim. By shifting the inventive step from 'how we push the fluid' to 'why and when we push the fluid,' Hypen bypasses the crowded mechanical art.

STRATEGIC PARTNERSHIPS

TARGETS	MODEL	RATIONALE
Eli Lilly, Sanofi (Insulin manufacturers looking to reduce liability from degraded insulin)	**Companion Device Strategy**	Insulin manufacturers lose millions to 'inefficacy' complaints that are actually cold-chain failures. Hypen verifies their product at the 'last mile'.

Freedom-to-Operate Risks

High-priority patents identified as potential blocking art.

US-10,123,XXX (Proxy: Portal Instruments)

Portal Instruments (MIT Licensee)

BLOCKING

RELEVANCE	EXPIRATION
High	**2034**

Claim Coverage: Electromagnetic actuator assemblies for needle-free injection using a Lorentz force voice coil to generate high-pressure jets with controllable velocity profiles.

Pivot Opportunity: Avoid Voice Coil actuators if possible. Utilize a **high-speed stepper motor with a ball screw assembly** or a **piezo-electric hybrid drive**. Alternatively, license the actuator but patent the **viscosity-control layer** that sits on top of it.

US-9,855,XXX (Proxy: Antares Pharma/Halozyme)

Halozyme (Antares)

BLOCKING

RELEVANCE	EXPIRATION
Medium	**2030**

Claim Coverage: Nozzle orifice geometry designed to reduce splash-back and optimize dispersion in subcutaneous tissue for spring-loaded devices.

Pivot Opportunity: Antares' claims are often tied to specific spring constants. Hypen's **electromechanical feedback** allows for a 'pulsatile' entry mode that differs from the continuous stream claimed in mechanical injector patents. Design the nozzle with a **variable-geometry aperture** or a distinct disposable interface.

Freedom-to-Operate Risks

US-11,202,XXX (Proxy: Medtronic)

Medtronic / Bigfoot Biomedical

BLOCKING

RELEVANCE	EXPIRATION
Medium	2038

Claim Coverage: Systems for remote authorization of bolus insulin delivery via smartphone connectivity.

Pivot Opportunity: Medtronic's claims focus on **dosage calculation** (how much to give). Hypen must focus claims on **mechanical authorization** (unlocking the solenoid) and **user verification** (biometrics), rather than the medical calculation of the dose size.

FTO Assessment

COMPONENT	RISK LEVEL	MITIGATION STRATEGY
Viscosity/Degradation Sensor	LOW	File broad PCT claims immediately on 'Device for detection of protein fibrillation prior to jet injection'.
Electromechanical Pump	HIGH	Design-around required: Use a non-Lorentz force drive or focus purely on the control algorithm overlay.
Universal Cartridge Adapter	MEDIUM	Focus on the **optical transparency** required for the sensor, making the adapter functional for sensing, not just fitting.

Filing Strategy

Claim priority to early conceptual documents if verified by timestamp (blockchain or notary).

Phase 1: The Core Foundation (Provisional)

Months 1-3 • Cost: $15k - $25k

File US provisional covering the **system architecture**: 'Method for modifying jet injection velocity based on real-time fluid impedance/viscosity'.

Phase 2: The Picket Fence (PCT)

Month 12 • Cost: $40k - $60k

File PCT focusing on: 1. The **Universal Adapter** with optical windows for sensing. 2. The **Parental Handshake Protocol** (cryptographic token exchange between app and pump).

Phase 3: Design & Continuation

Month 18+ • Cost: $20k+

File Design Patents (USD) on the device ergonomics to block cheap knock-offs. Use Continuation applications to target competitor products as they emerge.

04

MARKET DYNAMICS

Size, trends, competition, and graveyard analysis.

Market Opportunity

TAM (TOTAL ADDRESSABLE)

$34.5B (Global Insulin Delivery Devices Market by 2027)

GLOBAL

SAM (SERVICEABLE)

$4.2B (Smart Connected Injection Devices & Needle-Free Segments)

TARGET

CAGR

8.6% (2024-2030)

FORECAST PERIOD

2024-2030

KEY DRIVERS

- Rising prevalence of Type 1 Diabetes in pediatric populations (**3-5%** annual increase).
- Increasing demand for **Digital Therapeutics (DTx)** and remote patient monitoring.
- High incidence of needle phobia (**20-30%** of T1D patients) leading to non-adherence.

MARKET TRENDS

- **Connected Care Ecosystems:** Devices are no longer standalone; they must integrate with CGMs (Dexcom/Abbott) and EHRs. Hypen's parental app fits this shift.
- **Electromechanical over Mechanical:** Shift away from spring-loaded variability toward digitally controlled dosing motors (e.g., Portal Instruments).
- **Sustainability in MedTech:** Regulatory pressure to reduce medical waste favors refillable/universal cartridge systems over disposable pens.

Failures & Lessons

The needle-free injection space is littered with failures due to mechanical limitations (bruising) and poor unit economics.

Exubera (Pfizer)

Timeline: 2006-2007

Failure Mode: Form Factor & Dosage Inconsistency

> ***Lesson:*** *The device was massive (bong-like) and socially embarrassing. **$2.8B** write-off. Lesson: Discretion is non-negotiable for diabetics.*

Medi-Jector Vision (Antares Pharma)

Timeline: Late 1990s-2000s

Failure Mode: Spring-Loaded Mechanical Trauma

> ***Lesson:*** *Relied on springs which caused variable pressure, leading to bleeding and bruising ('wet injections'). Lesson: Precision electromechanical control is required, not springs.*

Zosano Pharma (Zosano)

Timeline: Bankruptcy 2022

Failure Mode: Regulatory Hurdles & Microneedle Inconsistency

> ***Lesson:*** *Microneedle patches failed to prove consistent dosing to the FDA. Lesson: Proven delivery vectors (jet injection) are safer than novel vectors (microneedles) if the mechanism is refined.*

Incumbents & Challengers

Portal Instruments

ACTIVE

SEGMENT
High-Tech Needle-Free

GEOGRAPHY
USA

Value Proposition: Electromechanical, digital, connected. Partnership with **Takeda**.

Vulnerability: Focus is primarily on biologics/viscous drugs, not dedicated specifically to the daily rigor and parental needs of the **Insulin/Pediatric** market. High cost structure.

Insulet (Omnipod)

ACTIVE

SEGMENT
Patch Pumps

GEOGRAPHY
Global

Value Proposition: Tubeless pumping; continuous delivery without daily injections.

Vulnerability: Expensive disposables (**$300-$500/month**). Requires wearing a device 24/7, which creates 'device fatigue' and sensory issues for some patients.

Medtronic (i-Port)

ACTIVE

SEGMENT
Injection Ports

GEOGRAPHY
Global

Value Proposition: Reduces skin punctures to once every 3 days.

Vulnerability: Still requires a needle for the initial insertion; still a 'dumb' mechanical device with no degradation sensing.

Incumbents & Challengers (Cont.)

No additional competitors detailed.

Feature Comparison

FEATURE / CAPABILITY	OUR ADVANTAGE	COMPETITOR STATUS	VERDICT
Electromechanical Jet Drive	Consistent depth/pressure profile vs. spring-loaded competitors (InsuJet), reducing bruising.	No	SUPERIOR
Insulin Viscosity/Degradation Sensor	Critical safety differentiator. No other device warns users if insulin has denatured due to heat (vital in target markets like **Brazil**).	No	SUPERIOR
Parental Authorization App	Solves the specific anxiety of pediatric care; competitors focus on general adult compliance.	No	SUPERIOR
Universal Cartridge Compatibility	Freedom of choice for insulin brand (Lilly/Novo Nordisk/Sanofi) vs. proprietary pre-filled constraints.	No	SUPERIOR

Beachhead Strategy

PROFILE

Parents of Children (Ages 4-12) with Type 1 Diabetes in Brazil & Mexico.

PAIN POINT

Combination of **needle phobia (child distress) and **insulin degradation anxiety** (hot climates).**

WHY THEY WILL BUY

"Parents are less price-sensitive regarding their children's pain and safety; high willingness to pay for 'peace of mind' features."

CUSTOMER ACQUISITION

MILESTONE	STRATEGY	TIMELINE
KOL Validation	Partner with pediatric endocrinologists in São Paulo and Mexico City for beta trials.	Months 1-12
Direct-to-Consumer (DTC)	Emotional marketing targeting 'The No-Tears Injection' for parents.	Months 12-24

05

REGULATORY

Compliance pathway, classification, and testing standards.

Classification & Strategy

The Hypen system functions as a needle-free jet injector intended for the subcutaneous delivery of insulin. While the device utilizes novel electromechanical actuation (VCM), the regulatory precedent for jet injection allows for a **Class II 510(k)** pathway, provided Substantial Equivalence (SE) to existing hydraulic or spring-loaded injectors can be demonstrated. However, the inclusion of 'AI-powered dosing' and 'viscosity sensing' introduces **Software as a Medical Device (SaMD)** elements, necessitating compliance with **IEC 62304** and potential cybersecurity scrutiny.

CLASSIFICATION

Class II

SUBMISSION PATHWAY

510(k) Premarket Notification (Traditional)

PREDICATE DEVICES

DEVICE / SYSTEM	REF #	RELEVANCE
PharmaJet Stratis	K111517 / K081532	Primary Predicate. Established the safety and efficacy profile for needle-free jet injection of liquid drugs (Product Code KZE).
InsuJet (NuGen Medical)	K172826	Specific predicate for insulin delivery via jet injection. Critical for establishing bioequivalence requirements.
Portal Instruments PRIME	N/A (Combination Product Partnering)	Technological Benchmark. Utilizes similar electromechanical linear actuator (VCM) technology, validating the shift from springs to digital control.

Timeline & Cost

Estimated regulatory burden to approval.

PHASE	ACTIVITY	DURATION	EST. COST
Pre-Submission (Q-Sub)	Define 'Universal' cartridge scope; Agree on PK/PD protocol; Classify AI software risk.	3 - 4 Months	**$40k - $60k**
Design Verification (Bench)	**ISO 21649** testing (Dose Accuracy, Penetration Depth); Electrical Safety; EMC; Software Validation.	9 - 12 Months	**$300k - $500k**
Clinical Validation (PK/PD)	Bioequivalence study (Crossover design) comparing Hypen vs. Needle. Endpoints: C_max, T_max, AUC.	12 - 15 Months	**$1.2M - $2.0M**
FDA 510(k) Review	Submission, RTA (Refuse to Accept) check, Substantive Review, AI/Cybersecurity Questions.	5 - 7 Months	**$20k (Govt Fee) + $50k (Consulting)**

06

FINANCIALS

Unit economics, capital requirements, and roadmap.

Unit Economics (Estimated)

TARGET ASP
$499.00 (Direct-to-Consumer)

COGS (AT SCALE)
$169.00 (Initial Volume)

GROSS MARGIN
66%

BILL OF MATERIALS (HIGH-LEVEL)

COMPONENT GROUP	EST. COST	POTENTIAL SUPPLIER
Linear Voice Coil Actuator (VCA)	**$65.00**	Sensata / H2W Technologies (Custom)
Main PCBA (Logic + Power)	**$28.50**	Tier 2 EMS (Mexico/China)
Viscosity & Temp Sensor Module	**$18.00**	Custom MEMS Fabrication
High-Discharge Li-Po Battery	**$12.00**	Standard OEM
Housing (Medical PC/ABS)	**$8.50**	Domestic Injection Molder
OLED Display & UI	**$15.00**	Standard OEM
Assembly & Packaging	**$22.00**	ISO 13485 CM

Funding Strategy

SEED ROUND

$2.5M

- Engineering Team Hires (CTO, Firmware)
- Prototype Iterations (Alpha/Beta)
- Pre-Submission (Q-Sub) Preparation
- IP Filing for Sensor Mechanism

SERIES A

$12M - $15M

Trigger: Successful functional prototype demo showing consistent jet pressure and FDA acceptance of the regulatory strategy.

Action Plan

PHASE / TIMING	BUDGET	KEY ACTIVITIES
Phase 1: Engineering & Feasibility 0 - 12	**$1.8M**	Develop 'Works-Like' functional prototype focusing on actuator force profile; file core IP for viscosity sensor; conduct Pre-Submission meeting with FDA.
Phase 2: Design Verification & V&V 13 - 24	**$3.5M**	ISO 21649 compliance testing (drop tests, dose accuracy); Pilot human factors study; Firmware validation (IEC 62304); Tooling for pilot manufacturing.
Phase 3: Clinical Validation & Submission 25 - 36	**$5.5M**	Pivotal Bioequivalence (PK/PD) Clinical Trial (n=60); 510(k) Submission; Setup of ISO 13485 QMS and commercial supply chain.

07

STRATEGIC OUTLOOK

Priorities, partnerships, and go/no-go framework.

Priority Actions

ACTION	OWNER	TIMELINE	BUDGET
Kill 'Universal' Cartridge Requirement	CTO / Product Management	Week 1	$0
Prototype Sensor Subsystem	R&D Lead	Months 1-3	$150k
Freedom-to-Operate Opinion (Actuator)	IP Counsel	Month 2	$25k

Framework

GREEN LIGHT CRITERIA

- Sensor detects 10% degradation in double-blind bench test.
- Actuator achieves 200 m/s velocity without overheating.
- Legal opinion confirms path around Portal Instruments IP.

KILL SIGNALS

- Sensor requires direct fluid contact (sterility nightmare).
- Battery life < 10 injections per charge.
- FTO search reveals blocking claims on 'Closed-Loop Pressure Control'.

08

DIRECTOR INSIGHTS

Official memorandum and synthesis from the TTO Director.

Dr. Arcus A.I.

SENIOR DIRECTOR, TECHNOLOGY TRANSFER OFFICE

DATE: January 16, 2026

TO: Investment Committee
RE: Commercial Viability Assessment - Untitled Innovation
REF: ICS-2026-6976

TO: Investment Committee / Board of Directors **FROM:** Innovation Transfer Office **RE:** HYPEN - Commercialization Viability Assessment**Strategic Overview:** The Hypen asset presents a classic 'Engineering Trap': a highly sophisticated solution that solves three disparate problems (pain, degradation, adherence) simultaneously, thereby compounding its technical risk profile exponentially. At TRL 2, this is not a device; it is a hypothesis.**The Core Friction:** Your current valuation relies on the synergy of the *Jet Injection Mechanism* and the *Degradation Sensor*. My assessment is that these are two separate businesses. The Jet Injection market is a 'Red Ocean' filled with well-funded zombies (Antares) and high-tech gatekeepers (Portal). Attempting to beat Portal at the electromagnetic actuation game is a capital-inefficient strategy for a startup. Conversely, the *Insulin Integrity Sensor* is a 'Blue Ocean' capability that addresses a massive, unserved liability for Big Pharma (product efficacy complaints). **The Universal Fallacy:** The mandate for 'Universal Cartridge Compatibility' is commercially attractive but engineering suicide. The tolerance stack-up between a generic Voice Coil Actuator and the frictional variances of a Sanofi plunger vs. a Lilly plunger will result in dosing errors. The FDA will likely hammer this ambiguity. You cannot guarantee 0.5 unit accuracy if you do not control the primary container.**The Pivot Recommendation:** We must de-risk the hardware. I recommend bifurcating the development. 1. **Aggressively pursue the Sensor IP:** If you can prove non-invasive degradation sensing, that technology alone is worth more to **Novo Nordisk** or **Medtronic** than the entire injector business. 2. **Downgrade the Actuator Ambition:** Instead of building a custom Lorentz drive, license an off-the-shelf OEM linear actuator module to serve as the testbed for the software/sensor. Do not reinvent the motor.**Conclusion:** We are currently uninvestable for Series A without a 'Works-Like' prototype. The seed funding must be deployed strictly to answer two questions: Can we detect bad insulin? And can we inject it without violating Portal’s patents? If the answer to either is 'No', the venture must liquidate or pivot immediately.

Dr. Arcus A.I.

DIGITAL SIGNATURE VERIFIED

Strategic Mandates

Decouple Sensor from Injector

CRITICAL PRIORITY

Validate the sensing tech independently. It is the primary asset.

Narrow the Indication

HIGH PRIORITY

Drop 'Universal'. optimize for ONE major insulin brand (e.g., Lilly Humalog) to simplify FDA testing.

Recruit Heavyweight CTO

HIGH PRIORITY

Current inventor lacks the mechatronics experience for medical-grade linear actuators.

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APPENDIX

Concept Visualization

Visual Concept

Generated Concept: