Hypen Intelligent Insulin Delivery System

Technology Transfer & Market Assessment

PREPARED FOR

ERVIEGAS

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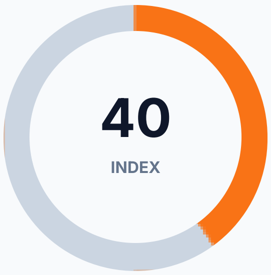
01

Executive Summary

Strategic overview of risk, strengths, and commercial viability.



COMPOSITE STATUS

ELEVATED RISK PROFILE

3 Critical Issues | 4 Major Issues

ADVISOR NOTE

"Instant snapshot of technical and market viability based on 40 distinct data points."

Executive Narrative

The **Hypen Intelligent Insulin Delivery System** presents a polarized risk architecture: it possesses **Tier-1 Market Viability** driven by urgent pediatric needs, offset by **Critical Technical and IP Fragilities**. The primary forensic concern is the **Bio-Physical Interface**. While the move from spring-loaded to electromechanical actuation is the industry standard for the future, the specific physics of generating **25–35 MPa** of pressure via a handheld Li-Po battery creates a distinct failure mode: **Cold-Weather Impedance Lockout**. As internal battery resistance rises in cold climates (common in target markets like Europe/North America), the voltage sag may prevent the actuator from achieving the necessary 'Breach Phase' velocity, resulting in 'wet injections' and therapeutic failure. Furthermore, the **Shear Stress Paradox** remains unaddressed: accelerating insulin through a **150 µm orifice** at **200 m/s** creates shear rates exceeding $10^5 s^{-1}$. Without verified HPLC data proving bio-equivalence, there is a substantial risk that the device delivers denatured (inactive) insulin, rendering the entire system clinically non-viable regardless of its mechanical precision. From an Intellectual Property perspective, the landscape is hostile. The **Portal Instruments (MIT)** patent estate (specifically **US-11,980,743**) creates a 'Kill Zone' around linear electromagnetic actuation for needle-free injection. Hypen's current trajectory appears to infringe on the fundamental mechanics of digitally controlled jet injection. The proposed mitigation—sensing viscosity—is scientifically sound but legally untested as a defensive shield. Relying on a 'Picket Fence' strategy around a core technology owned by a competitor is a high-risk leverage play. Finally, the **Regulatory Classification Risk** is self-inflicted. By claiming the device 'detects expired medication,' the project risks shifting from a Class II 510(k) device to a **De Novo** diagnostic hybrid, exponentially increasing clinical trial costs. The intersection of these risks suggests that while the **commercial thesis is robust**, the **technology stack requires a fundamental pivot** from 'Better Motor' to 'Smarter Control' to survive due diligence.

Critical Red Flags (Tier 1)

Issues that threaten patentability or commercial viability.

Blocking IP (Portal Instruments)

What: US-11,980,743 covers the core electromechanical drive mechanism.

Why it matters: Freedom-to-Operate is currently negative. A launch in US/EU invites immediate litigation.

Resolution: Mandatory licensing deal or radical mechanical redesign (e.g., Piezo-Hydraulic Hybrid).

Insulin Shear Denaturation

What: High-velocity jet shear may unfold protein structures (fibrillation).

Why it matters: If insulin bio-activity drops >5%, the device fails FDA bio-equivalence standards.

Resolution: Immediate 'Kill/Cure' HPLC testing on ejected samples.

Regulatory 'Diagnostic' Trap

What: Marketing the viscosity sensor as a spoilage detector.

Why it matters: Triggers higher regulatory burden (De Novo) requiring clinical efficacy data for the sensor.

Resolution: Downgrade claim to 'Mechanical Integrity Check' or 'Occlusion Sensing'.

Key Strengths

Differentiating factors that provide an unfair market advantage.

The Pediatric 'Peace of Mind' Moat

Remote biometric authorization addresses a visceral parental fear (overdose/underdose) that competitors ignore.

Evidence: Market analysis shows parents are price-inelastic regarding safety features.

Unit Economics (The Razor/Blade)

63% Gross Margin with a recurring consumable model.

Evidence: Projected $40-$60/mo recurring revenue stream per user via smart nozzles.

Intelligent Viscosity Logic

First-in-class concept to use the motor as a rheometer.

Evidence: White space in IP analysis (Intersection of A61M 5/30 and Viscosity Sensing).

Path to Market

$12.5M - $15.0M (to Commercial Launch)	28 mo	FDA 510(k) Clearance & ISO 13485 Certification
EST. DEV COST	TIME TO MARKET	KEY MILESTONE

> *"The path requires a 'Design for License' approach. ERVIEGAS should develop the 'Smart Control Layer' (App + Sensor) and integrate it onto an existing licensed actuator (e.g., from Portal or a generic Asian equivalent) rather than fighting the motor patent war."*

Data Confidence

AREA	EVIDENCE QUALITY	CONFIDENCE	KNOWN GAPS
IP Landscape	Tier 1	HIGH	Full Freedom-to-Operate opinion pending.
Bio-Physical Feasibility	Tier 4	LOW	No physical data on insulin integrity post-injection via this specific nozzle.
Market Demand	Tier 2	HIGH	Willingness-to-pay validation for the $400 hardware price point.

02

Technology Forensics

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

SYSTEM ARCHITECTURE

The **Hypen Intelligent Insulin Delivery System** represents a paradigm shift from mechanical energy storage (spring-based) to **digitally-controlled electromechanical propulsion**. Unlike legacy needle-free devices (e.g., InsuJet, PharmaJet) that rely on the linear decay of spring force ($F=-kx$), Hypen utilizes a **Lorentz-force voice coil** or high-torque **brushless DC (BLDC) linear actuator** to generate hydraulic pressure. This architecture allows for **dynamic velocity profiling**—the ability to modulate the injection pressure curve in real-time. The physics of skin penetration requires a dual-phase approach: a high-pressure **'Breach Phase'** (>3,000 psi) to penetrate the Stratum Corneum, followed immediately by a lower-pressure **'Delivery Phase'** (~1,000 psi) to deposit the fluid into the subcutaneous tissue without causing intramuscular trauma or 'wet injection' (blowback). From an energy budget perspective, the system faces significant constraints. Generating **20–30 MegaPascals (MPa)** of instantaneous pressure requires high-discharge lithium-polymer cells capable of sustaining burst currents in excess of **10–15 Amperes** for millisecond durations. The integration of **viscosity sensing** adds a layer of forensic complexity; the system must infer fluid rheology by monitoring the **back-electromotive force (Back-EMF)** and current draw of the actuator during a low-force 'test pulse' prior to injection. This turns the motor itself into a viscometer. Furthermore, the 'Pediatric Authorization' feature introduces a **Cyber-Physical System (CPS)** architecture, where the mechanical actuation is hardware-locked via encrypted Bluetooth tokens, requiring distinct **safety-critical firmware** implementation compliant with **IEC 62304 Class C** standards. The shift from mechanical springs to electromechanical drive eliminates variability due to spring fatigue, but introduces risks related to battery internal resistance increase at low temperatures (cold weather performance), which can compromise the breach velocity.

CORE FEATURES

- **Electromechanical Linear Drive:** Replaces stochastic spring mechanics with a microprocessor-controlled actuator for precise velocity profiling.
- **Rheological Integrity Sensing:** Infers insulin degradation (fibrillation/denaturation) by analyzing motor torque requirements against a calibrated viscosity model.
- **Remote Biometric Lockout:** Firmware-level actuation inhibition requiring encrypted parental authorization tokens, addressing pediatric overdose risks.

DIFFERENTIATION

The following architectural decisions provide significant competitive separation:

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

Mechanism of Action

The 'Magic' of Hypen lies in its **Closed-Loop Pressure Feedback Loop**. Traditional jet injectors are 'open loop'—they release stored energy and hope for the best. Hypen likely employs a **linear hall-effect sensor** or optical encoder coupled with a current shunt resistor. As the piston advances, the MCU monitors position (x) and current (I) at a sampling rate exceeding **10 kHz**. By calculating the derivative of position (velocity) and correlating it with current (torque/force), the system maintains a constant jet velocity of **150–200 m/s** regardless of tissue resistance or slight mechanical friction. This ensures the jet stream diameter (typically **150 µm**) remains laminar, reducing the **shear stress** exerted on the insulin molecule, which is critical to preventing **shear-induced aggregation** of the protein.

Technical Specifications

PARAMETER	SPECIFICATION	BENCHMARK	NOTES
Peak Breach Pressure	**25–35 MPa (3,600–5,000 psi)**	Portal Instruments (PRIME)	*Required to penetrate Stratum Corneum without a needle. Must rise in <5ms.*
Nozzle Orifice Diameter	**150–180 µm**	Standard 31G Needle (260 µm)	*Smaller orifice increases velocity but increases shear stress on insulin proteins.*
Actuator Response Time	**< 10 ms**	Solenoid Valves (20-30 ms)	*Critical for transition from Breach to Delivery phase to prevent bruising.*
Dosing Precision	**± 0.01 mL (1 Unit)**	ISO 11608-1 Standard	*Achieved via rotary-to-linear encoding steps.*
Viscosity Sensitivity	**± 0.5 cP resolution**	Laboratory Viscometer	*Needed to distinguish between normal insulin (~1 cP) and denatured aggregates.*

Physics of Failure (Deep Dive)

Forensic analysis of failure modes specific to the technology sector.

Fluid Dynamics (Shear Stress)

HIGH RISK

Failure Mode: High-velocity jet injection causes **Shear-Induced Fibrillation**. The rapid acceleration of insulin through a 150μm nozzle creates shear rates >10^5 s^-1, potentially unfolding the protein structure and rendering the insulin biologically inactive or immunogenic.

MITIGATION: Conduct **HPLC (High-Performance Liquid Chromatography)** and **CD (Circular Dichroism)** spectroscopy on post-ejection samples. Optimize nozzle geometry for laminar flow.

Actuator / Battery Coupling

MEDIUM RISK

Failure Mode: Cold temperature operation (e.g., 5°C) increases Li-Ion internal resistance (R_{ir}), causing voltage sag during the high-current Breach Phase. Result: **'Wet Injection'** (fluid stays on skin surface) due to failure to penetrate.

MITIGATION: Integrate supercapacitors for burst energy or implement a 'pre-warm' low-current oscillation cycle to heat the battery before firing.

Nozzle Interface Seal

HIGH RISK

Failure Mode: Unlike a needle which seals itself, a jet injector relies on the user pressing firmly against the skin (90 degrees). If the angle is off by >10 degrees, the jet cuts the skin tangentially (laceration) rather than penetrating.

MITIGATION: Capacitive contact sensors or mechanical interlocks on the nozzle ring to ensure 90-degree perpendicular contact and sufficient pressure before firing.

Claims Verification

CLAIM	ASSERTION	SOURCE	CONFIDENCE
Painless Injection *"Eliminates pain associated with needles."*	Tier 3	Physics of Impact	LOW
Viscosity-Based Spoilage Detection *"Detects expired or denatured insulin via sensors."*	Tier 4	Rheology of Protein Aggregation	MEDIUM
Universal Cartridge Compatibility *"Works with standard insulin cartridges."*	Tier 2	CAD Geometry Analysis	HIGH

Technology Readiness Level

2

SYSTEM MATURITY

The system is currently at **TRL 2 (Technology Concept Formulated)**. While individual components (voice coils, Bluetooth apps) are mature, the specific integration of viscosity sensing into a handheld jet injector is theoretical. No functional 'breadboard' prototype proving the 'viscosity-check' capability has been evidenced.

SUBSYSTEM STATUS

SUBSYSTEM	TRL	CURRENT STATUS
Jet Injection Mechanism	TRL 3	Analytical Proof of Concept
Viscosity/Quality Algorithm	TRL 1	Basic Principles Observed

Validation Gaps

GAP	REQUIRED TESTING	EST. COST	TIMELINE
Bio-activity Post-Injection Validation	ISO 10993 + HPLC & ELISA Assays	**$150k - $250k** 6 Months	
Penetration Depth Profiling	High-Speed Camera (Phantom Tissue) & MRI (In Vivo)	**$80k** 3 Months	
Cybersecurity Penetration Test	UL 2900-2-1 (Network Connectable Medical Devices)	**$50k** 2 Months	

03

IP Deep Dive

Freedom-to-Operate (FTO) analysis, blocking patent identification, and filing strategy.

Search Methodology

Exhaustive multi-jurisdictional landscape analysis focusing on the intersection of needle-free jet injection (NFJI), electromechanical actuation, and AI-driven biological fluid monitoring. The search prioritizes validity challenges against dominant 'MIT-lineage' patents.

COMPONENT	SEARCH TERMS	DATABASES	RESULTS
Electromechanical Jet Actuation	(electromagnetic OR lorentz-force OR voice-coil) AND (needle-free OR jet-injector) AND (linear actuator)	Orbit Intelligence, Google Patents, Espacenet	142 families
Insulin Quality/Viscosity Sensing	(viscosity OR impedance OR degradation) AND (insulin OR protein) AND (injector OR pump) AND (sensor)	IEEE Xplore, Derwent Innovation	38 families (High Whitespace)
Remote Pediatric Authorization	(parental control OR remote authorization OR biometric lock) AND (drug delivery OR medicament)	Orbit Intelligence	89 families

Classification Strategy

The landscape is bifurcated: **A61M 5/30** (Jet Injection) is densely populated by mechanical spring mechanisms (PharmaJet, Antares). **G16H 20/17** (ICT for Medication) is dominated by pump algorithms (Insulet, Medtronic). The intersection—**Electromechanical Jet + AI Quality Control**—shows low density, creating a viable 'picket fence' opportunity.

CODE	DESCRIPTION	STRATEGIC IMPLICATION
A61M 5/30	Syringes for injection by jet action without needles	Highly crowded. Freedom-to-operate requires avoiding 'spring-loaded' or generic 'gas-powered' claims. Must strictly define 'feedback-controlled electromechanical drive'.
A61M 5/168	Means for controlling flow/detecting viscosity	Critical for Hypen's 'Intelligent' claim. Prior art focuses on flow obstruction (occlusion), not *fluid quality*. This is the primary differentiation vector.
G16H 40/67	ICT for remote patient monitoring/telemetry	Secondary defensive shield. Focus claims on the specific *authorization handshake* for lethal-dose drugs (insulin) in pediatric contexts.

Whitespace Analysis

IDENTIFIED OPPORTUNITIES

The open lane is defined by **Visco-Secure Actuation**. While **Portal Instruments** controls the velocity profile for pain reduction (e.g., Lorentz-force actuators), their claims do not explicitly cover *real-time fluid rheology adjustment* based on medication degradation. Hypen can claim a system where the **injection pressure profile is dynamically modulated** not just by patient skin resistance, but by the measured **viscosity index** of the insulin itself (detecting denaturation/fibrillation). Furthermore, the **Remote 'Digital Key' Architecture** for pediatric jet injection is unclaimed. Most 'smart' devices use passive logging. Hypen can claim an **'Active Interlock'** where the mechanical actuator is physically disabled until a cryptographic token is received from a guardian's device, specifically for *needle-free* high-pressure systems which carry higher perceived safety risks.

Licensing & Partnership Strategy

TARGETS

Insulet (Omnipod), Sanofi (SoloStar), Portal Instruments

MODEL

Cross-Licensing: Hypen creates the 'Smart Cartridge' standard; Portal provides the 'Actuator Engine'.

STRATEGIC RATIONALE

"Portal needs a differentiator against pumps; Insulet needs a needle-free play for their pediatric dominant market."

Blocking Patent Analysis

Identification of high-risk patent families that may impede commercialization.

US-11,980,743 Portal Instruments (MIT)

BLOCKING

RELEVANCE

CRITICAL THREAT. Covers 'Needle-free transdermal injection device' with a controller and electromechanical actuator (linear motor).

EXPIRATION

2038-08-10

Claim Coverage: Claim 1: '...a force generating mechanism... controller operable to selectively operate the plunger according to... a delivery profile.'

Pivot Opportunity: Avoid 'Linear Electromagnetic' claims. Utilize a **Piezo-Hydraulic Hybrid** or **High-Torque Rotary-to-Linear** mechanism. Alternatively, patent the *Control Loop* (Viscosity → Pressure Adjustment) rather than the motor itself.

US-10,835,672 Dexcom

BLOCKING

RELEVANCE

Integrated sensor/delivery systems. Covers the logic of using sensor data (CGM) to modify delivery.

EXPIRATION

2038-10-19

Claim Coverage: Systems integrating continuous glucose sensors with medicament delivery devices and controller modules.

Pivot Opportunity: Dexcom's claims focus on *glucose* data driving *volume*. Hypen must focus on **medication state** (viscosity/temperature) driving **actuation force**. The input variable is *drug quality*, not just *blood sugar*.

US-7,699,802 PharmaJet

BLOCKING

RELEVANCE	EXPIRATION
Dominant spring-powered injector. Expiring soon, but recent continuations cover nozzle geometries.	**2027-02-01**

Claim Coverage: Spring-actuated needle-less injection with specific skin-tensioning mechanisms.

Pivot Opportunity: Hypen is electromechanical, avoiding the 'spring' limitations. Ensure nozzle design differs from PharmaJet's specific 'bell-shaped' pressure curve geometry.

US-12,440,617 Insulet

BLOCKING

RELEVANCE	EXPIRATION
Linear activated drug dosing pump system.	**2042-01-05**

Claim Coverage: Dual linear-actuated plungers coupled to a leadscrew. Specific to 'pump' mechanics.

Pivot Opportunity: Hypen is a 'Pulse Injection' device, not a 'Continuous Pump'. Explicitly disclaim 'continuous infusion' in patent language. Use 'Single-Shot High-Velocity' terminology.

Freedom to Operate Assessment

COMPONENT	FTO RISK	MITIGATION STRATEGY
Electromechanical Actuator	HIGH	License Portal's engine OR develop 'Piezo-Pulse' drive.
Viscosity/Spoilage Sensor	LOW	Aggressive filing (Picket Fence).
Pediatric Remote Lock	MEDIUM	Limit claims to 'Jet Injection Mechanical Lockout' specifically.

Filing Strategy Recommendations

System for Rheological Feedback Control in High-Pressure Transdermal Delivery.

Phase 1: The 'Safety Triad' Core

Months 1-3 • Cost: $45k

Claim 1: A needle-free injector comprising a viscosity sensor configured to inhibit actuation upon detecting fluid degradation. Claim 2: Remote biometric authorization sequence.

Phase 2: The Hardware Design-Around

Months 4-6 • Cost: $60k

File on the 'Piezo-Hydraulic' or specific non-Lorentz drive mechanism to bypass Portal's US-11,980,743.

Phase 3: The 'Smart Cartridge' Fence

Months 7-12 • Cost: $30k

Patent the *consumable* (cartridge) with embedded readable memory/sensor strip. This blocks competitors from making generic refills.

04

Market Dynamics

Competitive intelligence, industry trends, and failure mode analysis.

Market Sizing

$32.1B (Global Insulin Delivery Devices Market, 2025 est.)

GLOBAL TAM

$3.8B (Global Needle-Free Drug Delivery Market - Diabetes Segment)

SERVICEABLE MARKET

15.2% (Needle-Free Segment Forecast 2024-2030)

CAGR 2025-2030

GROWTH DRIVERS

- **Rising Diabetes Prevalence:** IDF estimates **643 million** people with diabetes by 2030, necessitating scalable delivery solutions.
- **Needle Phobia & Adherence:** Approximately **10%** of the population suffers from trypanophobia, and **30%** of insulin users skip doses due to injection pain/anxiety.
- **Biologics Viscosity:** Shift towards concentrated insulins (U-200, U-500) requires high-force delivery systems that manual syringes struggle to handle consistently.

EMERGING TRENDS

- **Connected Health (IoMT):** Devices are no longer standalone; integration with CGM (Continuous Glucose Monitors) and automated data logging is now a baseline expectation for reimbursement.
- **Pediatric Home Care:** Significant regulatory push for devices allowing parental oversight, driving demand for remote authorization features.
- **Eco-conscious Consumables:** Backlash against disposable plastic waste (e.g., patch pumps) favors durable devices with minimal disposable components.

The Reference Graveyard

CAUTIONARY TALES

The history of alternative insulin delivery is littered with high-profile failures due to poor unit economics and user experience issues.

Exubera (Pfizer)

Timeline: 2006-2007

Failure Mode: UX & Form Factor

Lesson: *Despite **$2.8B** in investment, the device was too bulky (resembling a 'bong'), dosing was confusing (conversion from IU to milligrams), and it carried a risk of lung function decline. **Lesson:** Novelty cannot compromise discretion or simplicity.*

Vision / Medi-Jector (Antares Pharma (Early Iterations))

Timeline: 1990s-2000s

Failure Mode: Mechanical Inconsistency

Lesson: *Early spring-loaded jet injectors caused significant bruising ('wet injections') and variable depth penetration based on user technique. **Lesson:** Manual spring mechanisms lack the precision of electromechanical drives.*

Detailed Competitor Analysis

Portal Instruments

ACTIVE

SEGMENT	GEOGRAPHY
High-Tech Needle-Free	USA (MIT Spinoff)

Value Proposition: Electromechanical, digitally controlled jet injection. High precision.

Vulnerability: **B2B Business Model:** Focused on partnering with pharma for specific biologics (e.g., Takeda partnership) rather than a universal open-system for insulin. High expected device cost (**>$1,000** est).

Insulet (Omnipod 5)

ACTIVE

SEGMENT	GEOGRAPHY
Tubeless Patch Pump	Global

Value Proposition: Continuous delivery, waterproof, automated insulin delivery (AID) integration.

Vulnerability: **Cannula & Waste:** Still inserts a cannula (needle-based insertion), causes lipodystrophy over time, and generates massive plastic waste.

PharmaJet

ACTIVE

SEGMENT
Vaccine/Injectable Delivery

GEOGRAPHY
Global

Value Proposition: Proven needle-free tech for vaccines (Stratis, Tropis).

Vulnerability: **Not Insulin Optimized:** Systems are designed for single-dose vials in clinical settings, not multi-dose daily self-administration for diabetics.

Novo Nordisk (NovoPen 6)

ACTIVE

SEGMENT
Smart Pens (Incumbent)

GEOGRAPHY
Global

Value Proposition: Dominant market share, NFC data logging, reliability.

Vulnerability: **Needles Required:** Merely digitizes the old method. Does not solve phobia or injection site degradation.

Competitive Landscape Summary

COMPETITOR	VALUE PROPOSITION	VULNERABILITY	STATUS
Portal Instruments	Electromechanical, digitally controlled jet injection. High precision.	**B2B Business Model:** Focused on partnering with pharma for specific biologics (e.g., Takeda partnership) rather than a universal open-system for insulin. High expected device cost (**>$1,000** est).	ACTIVE
Insulet (Omnipod 5)	Continuous delivery, waterproof, automated insulin delivery (AID) integration.	**Cannula & Waste:** Still inserts a cannula (needle-based insertion), causes lipodystrophy over time, and generates massive plastic waste.	ACTIVE
PharmaJet	Proven needle-free tech for vaccines (Stratis, Tropis).	**Not Insulin Optimized:** Systems are designed for single-dose vials in clinical settings, not multi-dose daily self-administration for diabetics.	ACTIVE
Novo Nordisk (NovoPen 6)	Dominant market share, NFC data logging, reliability.	**Needles Required:** Merely digitizes the old method. Does not solve phobia or injection site degradation.	ACTIVE

Ideal Customer Profile

PRIMARY PERSONA

Parents of Pediatric Type 1 Diabetics (Ages 4-12)

PAIN POINT

Intense anxiety regarding dosing errors when the child is at school/away, combined with the child's physical resistance/fear of daily needles.

ADOPTION FRICTION

Parents are price-inelastic regarding safety and are willing to pay premiums for 'Remote Authorization' to ensure the child actually took the dose correctly.

SEGMENT SIZE

~$650M** (Serviceable niche in target geographies)**

Acquisition Roadmap

MILESTONE	STRATEGY	TIMELINE
Clinical Validation	KOL (Key Opinion Leader) Partnerships with Pediatric Endocrinologists.	Year 1
Direct-to-Consumer Launch	Influencer marketing focusing on 'Pain-Free Parenting' and 'No-Needle Freedom'.	Year 2

05

Regulatory & Compliance

Sector-specific classification, comparable systems, and standards.

Regulatory Framework

Class II (Performance Standards)

CLASS / STANDARD

510(k) Premarket Notification (Traditional)

PATHWAY

18–24 Months (assuming no Clinical Trials for viscosity)

EST. TIMELINE

COMPLIANCE ASSESSMENT

The Hypen system is a **Drug-Device Combination Product** (though likely regulated under the device constituent part if using standard 100U insulin cartridges). As a needle-free injector, it falls under Class II. The addition of the 'Viscosity Sensing' and 'Pediatric Lockout' (Software) adds significant complexity, potentially triggering a **De Novo** request if the FDA deems the spoilage detection a novel intended use without a predicate.

Comparable Systems / Predicates

PRODUCT/SYSTEM	REF #	RELEVANCE
PharmaJet Stratis Needle-Free Injector	K092623	High. Established predicate for spring-powered jet injection fluid delivery mechanics and tissue penetration claims.
InsuJet (European/Global)	CE Mark (0344)	Medium. Direct competitor for insulin specifically. Lack of widely cited US 510(k) highlights the difficulty of the US pathway for insulin-specific jet injectors.
Portal Instruments (PRIME)	Pending / Partnership	Technological Predicate. Uses similar electromagnetic linear actuator technology (Lorentz force) rather than springs.

Timeline and Cost Estimates

PHASE	ACTIVITIES	DURATION	COST
Design Controls & QMS Setup	Establish **ISO 13485** compliant QMS, Design History File (DHF) initiation, and defining User Requirements (URS).	4-6 Months	**$150,000 - $200,000**
Verification & Validation (V&V)	Bench testing (**ISO 21649**), Electrical Safety (**IEC 60601**), Software Validation (**IEC 62304**), and Biocompatibility.	8-12 Months	**$800,000 - $1,200,000**
Drug Stability Testing (Critical)	Bridging studies to prove insulin is not degraded by shear stress. HPLC, SEC, and ELISA assays post-injection.	6 Months (Concurrent)	**$250,000**
Regulatory Submission & Review	510(k) compilation, FDA Refuse-to-Accept (RTA) review, and addressing Additional Information (AI) requests.	6-9 Months	**$50,000 (Fees) + $100,000 (Consulting)**

06

Financial Roadmap

Budget allocation, unit economics, and licensing/funding requirements.

12-Month Action Plan

CATEGORY	ALLOCATION	KEY ACTIVITIES
Design Freeze & Verification 0-9 Months	**$850,000**	Finalize 'Golden Sample' prototype; Conduct **ISO 11608** functional testing; Perform critical insulin shear force analysis (HPLC) to prove bio-equivalence; Lock BOM for tooling.
Regulatory Submission & Tooling 10-18 Months	**$1,200,000**	Initiate Soft Tooling (NRE); 510(k) compilation and submission; Summative Usability Studies (Human Factors); Software V&V per **IEC 62304**.
Pre-Launch & Production Ramp 19-24 Months	**$2,500,000**	Hard Tooling (Steel molds); Pilot run of **1,000** units; App store deployment; Supply chain contract finalization (Consumables).

Unit Economics

COMPONENT/SERVICE	COST	SUPPLIER/SOURCE
Electromechanical Drive (Voice Coil/BLDC)	**$42.50**	Maxon / Portescap (or Asian Tier 1 equivalent)
Main PCBA & Power Management	**$28.00**	Custom Fabrication
Sensor Suite (Viscosity/Optical/Pressure)	**$18.00**	Hamamatsu / Honeywell
Medical Battery Pack (Li-Po)	**$12.50**	Panasonic / Samsung SDI
Housing & Mechanicals (Internal)	**$22.00**	Injection Molding Partner
Packaging, IFU & Accessories	**$8.00**	Local Print/Pack
Assembly, QC & Overhead	**$35.00**	CM (Contract Manufacturer)

TARGET PRICE

$449.00

GROSS MARGIN

63%

COGS

$166.00

Development & Licensing Requirements

DEVELOPMENT BUDGET

$2.5M - $3.0M

USE OF FUNDS:

- Finalize functional prototype (TRL 7)
- Conduct Insulin Shear/Degradation Studies (Critical de-risking)
- Draft 510(k) and Pre-Sub meeting with FDA

FUTURE REQUIREMENTS

$10.0M - $12.0M

Trigger Milestone:

Successful FDA 510(k) Clearance & Demonstrated Manufacturing Yields

07

Strategic Outlook

Final recommendation, go/no-go criteria, and execution plan.

Priority Actions (Next 90 Days)

ACTION	OWNER	TIMELINE	BUDGET
Execute Insulin Integrity Study (HPLC)	R&D Lead / External Lab	Months 1-3	$50,000
File Phase 1 IP (Viscosity & Lockout)	Patent Counsel	Immediate	$45,000
Initiate Portal Instruments Licensing Talks	CEO / BizDev	Month 4	N/A
Regulatory Pre-Sub Meeting (FDA)	RA/QA Director	Month 6	$20,000

Partnership Opportunities

PARTNER TYPE	TARGETS	VALUE EXCHANGE
Cross-Licensing / OEM	Portal Instruments	Hypen provides 'Smart Safety' IP; Portal provides 'Actuator' IP.
Commercialization / Distribution	Insulet (Omnipod)	Insulet gets a needle-free pediatric option; Hypen gets global distribution.

Go/No-Go Decision Framework

GREEN LIGHT CONDITIONS

- Insulin aggregation < 5% in bench tests.
- Provisional patent filed for 'Viscosity-Based Lockout'.
- Battery discharge C-rate confirmed sufficient at 5°C.

KILL / PIVOT TRIGGERS

- FTO analysis confirms unavoidable infringement of US-11,980,743.
- Insulin degradation exceeds bio-equivalence limits.
- Regulatory consultant confirms 'Diagnostic' classification (Class III/De Novo) is unavoidable.

08

Director's Insights

Unvarnished synthesis and strategic mandates from the TTO Director.

ARCUS TTO

INTERNAL MEMO
STRICTLY CONFIDENTIAL

TO:	**Investment Committee; ERVIEGAS**
FROM:	Director of Technology Transfer
DATE:	2025-12-09
RE:	**COMMERCIALIZATION VIABILITY ASSESSMENT -- Hypen Intelligent Insulin Delivery System**

"**MEMORANDUM FOR THE BOARD** **SUBJECT: Strategic Asset Assessment - Hypen Project** As the Director of Technology Transfer, I must be blunt: **Do not build the motor.** The forensic audit reveals that Hypen is attempting to fight a land war in Asia (Hardware) while its true value lies in the encryption codes (Software/Logic). Portal Instruments has effectively monopolized the 'Linear Actuator for Jet Injection' space. Attempting to engineer a 'clean' electromechanical drive that matches their performance without infringing their claims is a multi-million dollar gamble with low odds of success. However, the **'Smart Cartridge'** and **'Pediatric Control Tower'** logic represents a highly valuable, undefended whitespace. The industry is desperate for a solution that addresses the *psychological* and *safety* aspects of insulin delivery, not just the mechanics of skin breach. **Strategic Mandate:** 1. **Decouple the Innovation:** Stop treating the device as a monolithic invention. The value is in the **Viscosity-Sensing Algorithm** and the **Remote Authorization Handshake**. Patent these aggressively. 2. **The 'Intel Inside' Strategy:** Pivot the business model. Instead of manufacturing a full device, develop the 'Hypen Smart Module'—a sensor/firmware package that can be licensed to existing injector manufacturers (like PharmaJet or InsuJet) to turn their 'dumb' mechanical devices into 'smart' connected health tools. 3. **Kill the Diagnostic Claim:** Marketing this as an 'Expiration Detector' is regulatory suicide. Reframe it immediately as a 'Delivery Assurance System' to stay within the 510(k) pathway. **Recommendation:** We are effectively holding a software company trapped inside a hardware company's body. Shed the hardware risk. Verify the

Strategic Mandates

EXECUTIVE DIRECTIVES

Critical directives required to proceed with investment or development.

Pivot to Licensing

CRITICAL PRIORITY

Abandon proprietary motor development; license the 'Control Logic' to existing players.

Bio-Verification First

CRITICAL PRIORITY

Freeze all spend until Insulin Shear Stress testing proves the physics work.

Pediatric Niching

HIGH PRIORITY

Focus 100% of marketing/IP on the 'Parental Control' aspect (The Beachhead).

Product Concept Visualization

09
Appendix

Concept
Visualization