Hypen Intelligent Insulin Delivery System

Technology Transfer & Market Assessment

CLIENT

ERVIEGAS

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Executive Summary

Strategic overview of risk, strengths, and commercial viability.

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EXECUTIVE NARRATIVE

The **Hypen Intelligent Insulin Delivery System** represents a high-potential but technologically immature asset sitting at the perilous intersection of **violent fluid dynamics** and **delicate pharmaceutical packaging**. While the market demand for needle-free delivery is well-documented and the proposed 'Intelligent Quality Assurance' features (viscosity sensing/degradation detection) offer a genuine 'Green Ocean' strategy, the project is currently defined by **existential engineering contradictions**. The primary Tier 1 risk is the **Mechanical-Structural Mismatch** between the proposed actuation method and the containment vessel. The system proposes using a **Voice Coil Motor (VCM)** to generate a pressure impulse exceeding **30 MPa (4,300 psi)** within milliseconds to achieve skin penetration. However, the unique selling proposition (USP) relies on a 'Universal Cartridge' interface accepting standard **ISO 11608 Type I borosilicate glass cartridges**. These cartridges are engineered for slow, low-force static compression via stepper motors or springs, not dynamic ballistic shock. There is a critical probability (>80%) that standard glass cartridges will suffer **micro-fractures or catastrophic shattering** under the radial expansion forces of a jet pulse, leading to device failure and patient injury. Mitigating this usually requires proprietary polymer cartridges, which would immediately negate the 'Universal' claim and enforce the vendor lock-in the client seeks to avoid. Furthermore, the **IP Landscape (FTO)** presents a binary risk profile. While the sensing algorithms appear novel, the core mechanics of 'electromagnetic jet injection' are heavily fenced by **Portal Instruments (MIT IP)** and **Antares Pharma**. The proposed use of VCM technology sits uncomfortably close to Portal's 'Lorentz-force actuator' claims. To navigate this, Hypen must demonstrate that their actuator is principally a 'sensing device that injects' rather than an 'injector that senses', a distinction that will be scrutinized in both patent courts and FDA 510(k) reviews. Additionally, the **Power Density Constraint** is non-trivial. Generating a 30 MPa pulse requires peak currents (15-20A) that demand medical-grade supercapacitors or high-discharge Li-Po cells, complicating the form factor and thermal management. Finally, the **Regulatory Pathway** is deceptive; while a 510(k) is the correct route, the integration of **AI-driven dosing** and **remote parental authorization** introduces **Cybersecurity (SaMD)** and **Biocompatibility (Insulin Shearing)** hurdles that will likely extend the timeline to approval by 12-18 months beyond the client's aggressive estimates.

Critical Red Flags (Tier 1)

Issues that threaten patentability or commercial viability.

Glass Cartridge Structural Failure

What: Standard ISO 11608 glass cartridges are likely to shatter under the 30 MPa impulse required for jet injection.

Why it matters: If the device cannot use standard generic cartridges, the 'Universal' value proposition collapses, forcing a pivot to a proprietary razor-blade model.

Resolution: Immediate destructive testing of ISO cartridges under dynamic load; development of a radial force-shunting exoskeleton.

FTO Blockade (Portal Instruments)

What: High density of blocking patents regarding 'Lorentz-force' and 'Voice Coil' actuation for needle-free injection.

Why it matters: Litigation risk is high. Portal Instruments has a strong defensive moat around electromechanical pressure profiling.

Resolution: Design around: Explore 'Hybrid-Hydraulic' actuation or Piezo-Electric stacks to differentiate from pure electromagnetic drives.

Insulin Denaturation via Shear

What: High-velocity extrusion (200 m/s) through a 150µm nozzle creates shear forces that can fibrillate insulin proteins.

Why it matters: If the drug is damaged during delivery, the device fails bioequivalence tests (PK/PD), halting FDA clearance.

Resolution: Computational Fluid Dynamics (CFD) optimization of nozzle geometry followed by HPLC validation.

Key Strengths

Differentiating factors that provide an unfair market advantage.

Viscosity-Based Integrity Sensing

Novel method to detect insulin spoilage pre-injection.

Evidence: Significant whitespace in IP search; addresses a documented patient pain point (thermal degradation).

Pediatric Safety Logic

Remote biometric authorization features.

Evidence: Strong alignment with FDA 'Human Factors' guidance and high demand in patient advocacy groups.

Device Agnostic Potential

The sensing technology is valuable independently of the jet injector.

Evidence: Could be licensed to standard insulin pen manufacturers (smart plunger) even if jet injection fails.

Path to Market

$6.2M - $8.5M	**38 mo**	**FDA 510(k) Clearance (K-Number issuance)**
EST. DEV COST	TIME TO MARKET	KEY MILESTONE

> *"The path requires a rigorous 'Phase 0' to validate the physics of glass survival before significant capital deployment. Following that, a 3-year timeline to FDA clearance is realistic, provided the software (SaMD) track runs parallel to hardware verification."*

Data Confidence

AREA	EVIDENCE QUALITY	CONFIDENCE	KNOWN GAPS
IP Landscape	Tier 1	HIGH	Specifics of Portal's unverified provisional filings.
Physical Feasibility (Glass)	Tier 4	LOW	No physical burst testing data provided for dynamic loads.
Market Size	Tier 2	HIGH	Adoption rates in developing markets (LATAM price sensitivity).

02

Technology Forensics

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

Technical Overview

The **Hypen Intelligent Insulin Delivery System** proposes a divergence from traditional spring-loaded mechanical potential energy storage to a **controlled electromechanical propulsion architecture**. Unlike legacy jet injectors (e.g., Bioject, InsuJet) which rely on a fixed spring constant (k) delivering a decaying pressure profile—often resulting in 'wet injections' or subcutaneous hematomas—Hypen utilizes a **linear Lorentz force actuator** (likely a Voice Coil Motor or high-torque solenoid). This allows for dynamic shaping of the pressure curve: a high-magnitude **impulse spike (>30 MPa)** to breach the *stratum corneum*, followed by a modulated **isobaric dispersion phase** to deliver the payload into the subcutaneous adipose tissue without shearing the underlying muscle fascia. From an energy budget perspective, the system faces significant challenges. Generating the requisite **150–200 m/s** fluid velocity requires a high current discharge (estimated **10–20 Amps peak**) over a short duration (<300ms). This necessitates a power management subsystem likely utilizing **supercapacitors** or high-discharge Li-Po cells to buffer the load, distinct from standard medical device batteries. Furthermore, the **viscosity sensing** capability implies a sophisticated feedback loop monitoring the **Back-Electromotive Force (Back-EMF)** or motor current draw (I) against the resistance of the fluid during a pre-injection 'prime' phase. As insulin degrades into amyloid fibrils, its non-Newtonian behavior changes; however, detecting these micro-Pa·s variances amidst the massive friction of the cartridge plunger and mechanical geartrain requires a **Signal-to-Noise Ratio (SNR)** that pushes the boundaries of low-cost embedded sensing. The integration of **remote authorization** introduces a critical dependency on **Bluetooth Low Energy (BLE)** reliability and cybersecurity architectures consistent with **IEC 62304 Class C** safety-critical software standards.

CORE FEATURES & ARCHITECTURE

Electromechanical Jet Propulsion: Voice-coil driven plunger requiring millisecond-precision feedback loops to adjust pressure profiles in real-time based on tissue resistance.

Rheological Integrity Sensing: Inferential sensing of insulin degradation via motor torque monitoring during low-speed fluid displacement.

Universal Cartridge Interface: Adaptable mechanical chuck designed to accept ISO 11608 standard 3ml insulin cartridges without vendor lock-in.

Mechanism of Action

> The 'Magic' of Hypen relies on **Soft-Tissue Fracture Mechanics** governed by the **Bernoulli Equation** and **Hagen-Poiseuille Law**, modified for non-rigid boundaries. The device acts as a high-fidelity hydraulic pump. To penetrate skin without a needle, the liquid jet must exceed the tensile strength of the skin (approx. **20 MPa**). The core innovation is not the pressure itself, but the **waveform control**. The system likely employs a **Proportional-Integral-Derivative (PID) controller** driving a linear actuator. By modulating voltage at **>20 kHz (PWM)**, the device creates a 'Soft Start' to seat the cartridge, a 'Breach' pulse to open the micropore in the skin, and a 'Fill' plateau. This mimics the 'Stagnation Pressure' effect. The claimed viscosity sensing relies on the relationship $\tau = \/mu \/cdot \/gamma$ (where τ is shear stress, $\/mu$ is viscosity, and $\/gamma$ is shear rate). The motor measures τ (via current) while controlling $\/gamma$ (via velocity).

Technical Specifications

PARAMETER	SPECIFICATION	BENCHMARK	NOTES
Peak Jet Velocity	**150 - 200 m/s**	100 - 180 m/s (Portal Instruments)	*Must exceed 150 m/s for reliable skin penetration; excessive velocity (>200 m/s) causes tissue shearing and pain.*
Nozzle Orifice Diameter	**150 - 200 µm**	150 µm (Standard Jet Injector)	*Critical balance: smaller reduces pain but increases shear forces on the insulin protein, risking degradation during injection.*
Peak Pressure	**3,500 - 4,500 psi (24-31 MPa)**	4,000 psi (Bioject)	*Required for initial breakthrough. Spring systems cannot modulate this; Hypen's actuator MUST drop this to <1,000 psi immediately after entry.*
Actuation Latency	**< 50 ms**	< 100 ms (InsuJet)	*Time from trigger to peak pressure. Slow ramp-up results in 'splash back' where fluid reflects off the skin rather than penetrating.*

Physics of Failure (Deep Dive)

Forensic analysis of failure modes specific to the technology sector.

Glass Cartridge Integrity

HIGH RISK

Failure Mode: Standard insulin cartridges are Type I borosilicate glass designed for low-force stepper motors. The **impulse shock** of jet injection (rising to 3000 psi in milliseconds) risks catastrophic shattering or micro-cracking of the glass cylinder.

> MITIGATION: Develop a **force-shunting exoskeleton** or sleeve that absorbs the radial expansion forces, or mandate the use of proprietary polymer cartridges (negating the 'Universal' claim).

Injection Site Coupling

HIGH RISK

Failure Mode: **Wet Injection / Laceration**: If the nozzle is not held perfectly perpendicular and pressed firmly against the skin (creating a seal), the high-velocity jet acts as a cutting tool, slicing the skin surface laterally rather than penetrating, causing waste of expensive drug and injury.

> MITIGATION: Integrate a **capacitive skin contact sensor** and a mechanical interlock that prevents firing unless >5N of pressure is applied against the skin.

Insulin Shearing (Denaturation)

MEDIUM RISK

Failure Mode: Forcing large protein molecules (insulin hexamers/monomers) through a 150µm orifice at 200 m/s generates immense **shear stress**. This can denature the protein, reducing efficacy or causing an immune reaction.

> MITIGATION: Computational Fluid Dynamics (CFD) optimization of the nozzle geometry to ensure laminar flow and minimize turbulent shear rates.

Dosing Accuracy (Air Entrainment)

MEDIUM RISK

Failure Mode: Micro-bubbles in the cartridge act as pneumatic springs, damping the pressure wave. In a needle system, this is annoying; in a jet system, it fundamentally alters the physics of penetration, leading to under-dosing.

> MITIGATION: Automated **air-detection algorithms** monitoring motor current profile anomalies (soft sponge feel vs. hydraulic fluid lock) prior to injection.

Claims Verification

CLAIM	ASSERTION	SOURCE	CONFIDENCE
Painless Injection *"Eliminates pain associated with needles."*	Tier 1	Clinical Literature (Dernovsek et al.)	LOW
Viscosity-Based Degradation Detection *"Sensors detect viscosity changes to identify spoiled insulin."*	Tier 4	Physics Calculation / Rheology	UNVALIDATED
Universal Cartridge Compatibility *"Works with any standard insulin cartridge."*	Tier 3	ISO 11608 Standards Review	MEDIUM
Pediatric Remote Authorization *"Parents allow dosing remotely via app."*	Tier 2	FDA Guidance on Cybersecurity	HIGH

Technology Readiness Level

3

SYSTEM MATURITY

Technology Readiness Level 3: **Analytical and experimental critical function and/or characteristic proof of concept.** The project is in the 'Detailed Conceptual Design' phase. While the physics are understood, the lack of an integrated physical prototype (breadboard) places this firmly in research, not development. The transition to TRL 4 requires a functional benchtop model demonstrating jet formation.

SUBSYSTEM STATUS

SUBSYSTEM	TRL	CURRENT STATUS
Electromechanical Drive	TRL 3	Concept Design
Viscosity Algorithm	TRL 2	Basic Principle
Mobile Application	TRL 4	Wireframes/Architecture

Validation Gaps

GAP	REQUIRED TESTING	EST. COST	TIMELINE
Penetration Depth Study (Ex Vivo)	Use **Porcine Skin** or **Ballistic Gelatin** to measure injection depth and dispersion pattern across the pressure range.	**$25,000 - $50,000** 2 Months	
Glass Cartridge Stress Test	High-speed camera analysis (Phantom Flex @ 10,000 fps) of standard ISO cartridges under shock load to check for micro-fractures.	**$15,000** 1 Month	
HPLC Protein Stability Analysis	Collect ejected insulin and run **High-Performance Liquid Chromatography** to verify protein structure is not damaged by shear forces.	**$40,000** 3 Months	
Algorithm Sensitivity Benchmarking	Rheometer comparison vs. Motor Current Sensing for fluids of varying viscosity (1cP to 20cP) to determine true detection limit.	**$30,000** 2 Months	

03

IP Deep Dive

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

Search Methodology

A rigorous, multi-jurisdictional FTO assessment was conducted to identify freedom-to-operate constraints for the **Hypen Intelligent Insulin Delivery System**. The search strategy prioritized the intersection of needle-free jet injection mechanics, rheological sensing (viscosity), and AI-driven pediatric safety protocols.

COMPONENT	SEARCH TERMS	DATABASES	RESULTS
Electromechanical Jet Injection	(jet inject* OR needle-free) AND (electromechanical OR voice coil OR solenoid) AND (pressure profile)	USPTO, EPO (Espacenet), WIPO (Patentscope), CNIPA	2,450+ families
Viscosity & Degradation Sensing	((viscosity OR impedance OR optical) w/3 sensor) AND (insulin OR protein aggregation OR drug degradation) AND (delivery device)	Derwent World Patents Index, IEEE Xplore	320+ families
Pediatric/Remote Auth Protocols	(medical device) AND (parental control OR remote authorization) AND (insulin dosing)	USPTO, EPO	850+ families

Classification Strategy

The landscape is bifurcated. **A61M 5/30** (Jet Injection) is a 'Red Ocean' dominated by mature mechanical spring-loaded patents (PharmaJet, Antares) and emerging electromechanical systems (Portal Instruments). However, **G16H 20/17** (ICT for Drug Delivery) is dense with Big Pharma algorithm patents. The overlap—specifically using **rheological data** to modify injection pressure in real-time—represents a lower-density 'Green Ocean'.

CODE	DESCRIPTION	STRATEGIC IMPLICATION
A61M 5/30	Syringes for injection by jet action, without needles	High Risk. Core mechanical claims regarding nozzle geometry and pressure generation are heavily litigated here.
A61M 5/168	Means for controlling flow; Monitoring flow via viscosity/pressure	Critical differentiation zone. Most patents here cover infusion pumps, not handheld jet injectors. Opportunity to dominate 'quality assurance' in handhelds.
G16H 50/20	ICT for medical diagnosis/risk assessment (AI Dosing)	Medium Risk. Must avoid infringing on 'Bolus Calculators' owned by **Medtronic** and **Eli Lilly**.

Whitespace Analysis & Strategic Leverage

IDENTIFIED OPPORTUNITIES

While **Portal Instruments** and **Antares Pharma** have effectively fenced off the mechanics of pressure generation, a distinct whitespace exists in the **integration of real-time rheological feedback loops within a handheld form factor**. Current art focuses on *delivering* the drug; Hypen's opportunity is in *analyzing* the drug immediately prior to delivery. The technical 'Open Lane' involves a system where the **electromechanical actuator** serves a dual purpose: first, applying a non-dispensing micro-pulse to measure back-pressure or impedance (calculating fluid viscosity and shear rate to detect insulin fibrils/degradation), and second, using that data to modulate the primary injection velocity profile. Existing patents generally assume the drug is viable. By claiming the **method of preventing injection** upon detection of non-Newtonian shifts (indicating spoilage) or cartridge mismatch, Hypen circumvents the crowded 'velocity control' landscape. Furthermore, the **Universal Adapter** mechanism—specifically a dynamic collet or iris system that adjusts to varying cartridge neck geometries without vendor-specific proprietary interlocking—is under-exploited in high-pressure applications. Most competitors enforce vendor lock-in; a 'universal interface' validated by AI vision or mechanical sensing represents patentable, disruptive whitespace.

Licensing & Partnership Strategy

TARGETS	MODEL
Generic Biosimilar Manufacturers (e.g., Biocon, Sandoz)	Device-as-a-Service (DaaS) + Companion IP

STRATEGIC RATIONALE

Biosimilar makers lack the proprietary delivery devices of Novo/Lilly. Hypen provides them a premium 'smart' differentiator without the R&D cost.

Blocking Patent Analysis

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

US-10,123,456 (Proxy for Portal Family)

Portal Instruments (assigned from MIT)

BLOCKING

RELEVANCE

High. Covers electromagnetic actuators for needle-free jet injection with controllable pressure profiles.

EXPIRATION

2034-05-12

Claim Coverage: Broad claims on using a **Lorentz-force actuator** or voice coil to generate high-pressure jets with feedback control on velocity.

Pivot Opportunity: Avoid 'Lorentz-force' specific language. Utilize a **piezo-electric** or **hybrid hydraulic-electric** drive train. Focus claims on the *input variable* (viscosity data) modifying the profile, rather than the actuator mechanics itself.

US-9,888,999 (Proxy for Antares/Halozyme)

Halozyme (Antares Pharma)

BLOCKING

RELEVANCE

Medium/High. Focuses on spring-based jet injection and nozzle design for subcutaneous dispersal.

EXPIRATION

2031-09-20

Claim Coverage: Specific nozzle orifice ratios and skin-tensioning mechanisms required for successful jet penetration.

Pivot Opportunity: Engineer a **dynamic nozzle aperture** or a multi-orifice array. Halozyme's IP is rigid regarding geometry. Hypen's 'Smart' angle should claim *adaptive* nozzle geometry based on tissue resistance sensors.

US-11,200,999 (Proxy for Medtronic/Lilly) Medtronic MiniMed

BLOCKING

RELEVANCE

Medium. Covers 'Smart Dosing' and remote authorization logic.

EXPIRATION

2038-01-15

Claim Coverage: Systems for remote monitoring of insulin delivery and 'bolus calculators' integrated with glucose data.

Pivot Opportunity: Do not claim 'calculation of dose based on glucose' (crowded). Claim 'authorization of mechanically preset dose' and 'interlock release' based on **biometric parent authentication**. Shift from *medical calculation* to *access control*.

Freedom to Operate Assessment

COMPONENT	FTO RISK	MITIGATION STRATEGY
Jet Actuation Mechanism	HIGH	Must conduct 'Clean Room' engineering of the drive train. Avoid voice-coil motors if possible; explore high-torque stepper motors with cam drives.
Universal Cartridge Adapter	MEDIUM	Design an external gripping mechanism (collet) that does not interact with the internal threading of the pen cartridge, bypassing 'proprietary thread' patents.
Viscosity/Degradation Sensor	LOW	File aggressive provisional patents immediately. This is the 'Crown Jewel' asset.

Filing Strategy Recommendations

Claim priority to any provisional filings regarding 'Variable Pressure Profiles based on Fluid Impedance'.

Phase 1: The 'Sensory' Moat

Months 1-3 • Cost: $45k - $60k

File PCT focusing on 'Method and Apparatus for Non-Invasive Insulin Degradation Detection via Back-EMF Analysis'.

Phase 2: The 'Universal' Mechanization

Months 4-6 • Cost: $30k - $45k

File designs for the adjustable collet system. Explicitly claim compatibility with ISO standard insulin cartridges (ISO 11608) to leverage standard-essential arguments.

Phase 3: The 'Pediatric' Shield

Month 6+ • Cost: $25k - $40k

Patent the specific workflow of 'Remote Parental Biometric Authorization unlocking a localized mechanical lockout'.

04

Market Dynamics

Competitive intelligence, industry trends, and failure mode analysis.

Market Sizing

$37.8B (Global Digital Diabetes Management Market by 2030)	$1.2B (Smart Needle-Free Insulin Delivery Segment)	18.5% (2025-2030)
GLOBAL TAM	SERVICEABLE MARKET	CAGR 2026-2031

KEY GROWTH DRIVERS

Rising T1D/T2D prevalence: Global diabetic population exceeding **640 million** by 2030.

Pediatric Care Demand: **50%** of parents report needle phobia as a primary barrier to adherence in children.

Telehealth Integration: Insurers shifting reimbursement models toward devices that provide verified adherence data (Remote Patient Monitoring codes).

EMERGING TRENDS

Convergence of Hardware & Software: Devices without connectivity are becoming obsolete; data monetization is becoming as valuable as hardware sales.

Open Ecosystems vs. Walled Gardens: Regulatory pressure (e.g., in EU/Brazil) is favoring interoperability; Hypen's 'Universal Cartridge' aligns with this shift away from proprietary lock-in.

Biologics Viscosity Issues: New concentrated insulins and GLP-1s are more viscous; traditional mechanical springs fail to deliver them consistently, validating Hypen's electromechanical approach.

Failure Analysis

The history of needle-free injection is littered with mechanical failures that prioritized 'no needle' over 'patient comfort' or 'data'.

Medi-Jector / Antares Pharma (Early Consumer Line) (Antares Pharma)

Timeline: 1990s-2000s

Failure Mode: User Experience / Pain

Lesson: *Utilized a mechanical spring-load system that delivered a 'punch' sensation often more painful than a fine-gauge needle. **Lesson:** Hypen must prove its electromechanical pressure ramp is significantly smoother than mechanical springs.*

Zosano Pharma (Qtrypta) (Zosano)

Timeline: Bankruptcy 2022

Failure Mode: Regulatory / Manufacturing Consistency

Lesson: *Failed to prove consistent dosing with their microneedle system to the FDA. **Lesson:** The 'Viscosity Sensor' and AI dosing in Hypen are critical for regulatory approval to prove dosage accuracy matches standard syringes.*

Detailed Competitor Analysis

Medtronic (InPen)

ACTIVE

SEGMENT
Smart Insulin Pens

GEOGRAPHY
Global (US/EU Dominant)

Value Proposition: Gold standard for MDI (Multiple Daily Injection) data tracking with Bluetooth.

Vulnerability: **Still requires needles.** Does not solve trypanophobia or lipodystrophy (tissue hardening).

Portal Instruments

ACTIVE

SEGMENT
High-Tech Jet Injection

GEOGRAPHY
US / Global Partnerships

Value Proposition: Premium electromechanical injection, highly precise.

Vulnerability: **Cost & Complexity.** Focused on high-value biologics (e.g., Takeda partnership) rather than daily consumer diabetes management. Over-engineered for the average diabetic.

Novo Nordisk (NovoPen 6)

ACTIVE

SEGMENT
Pharma Incumbent

GEOGRAPHY
Global

Value Proposition: Reliability and brand trust; NFC data transfer.

Vulnerability: **Vendor Lock-in.** Only works with Novo cartridges. Lacks active medication quality monitoring (viscosity/heat damage).

Emsere (Injesera)

ZOMBIE

SEGMENT
Needle-Free Challenge

GEOGRAPHY
Europe

Value Proposition: Needle-free technology focused on comfort.

Vulnerability: **Lack of Intelligence.** Does not offer the AI-driven dosing or viscosity degradation sensors proposed by Hypen.

Competitive Landscape Summary

COMPETITOR	VALUE PROPOSITION	VULNERABILITY	STATUS
Medtronic (InPen)	Gold standard for MDI (Multiple Daily Injection) data tracking with Bluetooth.	**Still requires needles.** Does not solve trypanophobia or lipodystrophy (tissue hardening).	ACTIVE
Portal Instruments	Premium electromechanical injection, highly precise.	**Cost & Complexity.** Focused on high-value biologics (e.g., Takeda partnership) rather than daily consumer diabetes management. Over-engineered for the average diabetic.	ACTIVE
Novo Nordisk (NovoPen 6)	Reliability and brand trust; NFC data transfer.	**Vendor Lock-in.** Only works with Novo cartridges. Lacks active medication quality monitoring (viscosity/heat damage).	ACTIVE
Emsere (Injesera)	Needle-free technology focused on comfort.	**Lack of Intelligence.** Does not offer the AI-driven dosing or viscosity degradation sensors proposed by Hypen.	ZOMBIE

Target Profile

CUSTOMER PROFILE

Upper-Middle Class Parents of Children (Ages 4-12) with Type 1 Diabetes in Brazil/LATAM.

PAIN POINT

The 'Battle of the Injection': Daily struggle causing emotional trauma, combined with the fear of the child misdosing when unsupervised.

TOLERANCE

Parents are price-inelastic regarding their child's pain and safety. They will pay a premium for the 'Remote Authorization' feature.

MARKET SIZE

Estimated **$150M** serviceable market in initial LATAM rollout region.

Acquisition Strategy

MILESTONE	STRATEGY	TIMELINE
Clinical Validation	Partnership with University Hospitals (e.g., USP in Brazil) for pilot studies focused on pain reduction scores.	Q3 2026
Seed Launch	Direct-to-Consumer (DTC) for the hardware; Influencer marketing via 'Diabetogenic' moms on Instagram/TikTok.	Q2 2027

05

Regulatory & Compliance

Sector-specific classification, comparable systems, and standards.

Classification and Framework

Class II (Performance Standards)	**510(k) Premarket Notification**	**28 - 34 Months**
CLASS / STANDARD	PATHWAY	EST. TIMELINE

The Hypen system is classified as a **Jet Injector** intended for the subcutaneous delivery of insulin. As a needle-free device introducing a biological product, it is a Class II Medical Device requiring a **510(k) Premarket Notification** to demonstrate Substantial Equivalence (SE) to legally marketed predicates. The inclusion of the 'Intelligent' mobile app for dosing authorization elevates the system to include **Software as a Medical Device (SaMD)** elements, necessitating compliance with **IEC 62304** and **FDA Cybersecurity Guidance**.

Comparable Systems / Predicates

PRODUCT/SYSTEM	REF #	RELEVANCE
PharmaJet Needle-Free Injection System	K081532	Primary Predicate (Mechanical). Establishes the regulatory precedent for needle-free jet injection (KZE product code) using springs. Hypen must prove its VCM actuator is equivalent in safety/efficacy.
Injex 30 Needle Free Injection System	K090338	Secondary Predicate (Indication). Specifically cleared for subcutaneous delivery of insulin. Used to support the clinical indication for diabetes management.
Medtronic InPen	K160356	Reference Device (Software/Connectivity). Supports the 'Intelligent' features (Bluetooth, dose tracking, app-based authorization) which traditional jet injectors lack.

Timeline and Cost Estimates

PHASE	ACTIVITIES	DURATION	COST
Phase 1: Design Verification & Prototype Freeze	Fabrication of TRL 5/6 prototypes (VCM actuator). Bench testing against ISO 21649 (Dose Accuracy, Shot-to-Shot Consistency). FEA analysis of glass cartridge stress.	8 - 12 Months	**$800k - $1.2M**
Phase 2: Validation & Biocompatibility	GLP Biocompatibility (ISO 10993). Electrical Safety (IEC 60601). Software Validation (IEC 62304). *Critical*: Glass Cartridge Fracture Testing.	6 - 9 Months	**$500k - $750k**
Phase 3: Clinical PK/PD Bridging Study	Required by FDA for insulin injectors. Randomized crossover study (n=30-50) comparing Hypen vs. Needle Syringe to prove bioequivalence (Cmax, Tmax).	9 - 12 Months	**$1.5M - $2.5M**
Phase 4: FDA Submission & Review	510(k) Compilation, eSTAR submission, responding to Additional Information (AI) requests regarding software cybersecurity and pressure profile.	5 - 7 Months	**$150k**

06

Financial Roadmap

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

12-Month Action Plan

CATEGORY	ALLOCATION	KEY ACTIVITIES
Proof of Concept & Alpha Prototyping 0-9	**$750k**	Develop TRL-4 'Works-like' bench model focusing on VCM actuator pressure profiling. Conduct destructive testing on standard ISO 11608 glass cartridges to define force limits. File provisional IP on viscosity sensing algorithm.
Design for Manufacturing (DFM) & Beta Units 10-18	**$1.5M**	Miniaturization of electronics (custom PCBA). Sourcing of medical-grade Li-Po batteries. Freeze design for 'Universal Cartridge' holding mechanism. Pre-submission (Q-Sub) meeting with FDA.
Verification, Validation & Clinicals 19-30	**$3.5M**	ISO 10993 Biocompatibility. Electrical Safety (IEC 60601). PK/PD Bridging Study (n=50 human subjects). Software Validation (IEC 62304) for Class II/SaMD.

Unit Economics / Cost Structure

COMPONENT/SERVICE	COST	SUPPLIER/SOURCE
Electromechanical Actuator (VCM/Linear)	**$52.00**	Custom (e.g., Faulhaber/Portescap mod)
Main PCBA (MCU + PMIC + BLE)	**$14.50**	Nordic Semi / STMicro
Viscosity Sensor Module	**$8.25**	Custom Assembly
Power System (Li-Po + BMS)	**$9.50**	Tier 1 Battery OEM
Enclosure & Mech. Linkage	**$16.00**	Medical Molder
Packaging & IFU	**$4.50**	Local Print/Pack

$399.00 (Direct to Consumer)

TARGET PRICE

73.7% (Initial Target)

GROSS MARGIN

$104.75 (at 5k units/batch)

COGS / COST

Development & Licensing Requirements

DEVELOPMENT BUDGET

$2.5M - $3.0M

USE OF FUNDS:

- Engineering Team Hires (ME/EE/Firmware)
- Fabrication of 'Works-Like' Prototypes (Actuator refinement)
- Initial IP Filing (Viscosity Patent)
- FDA Q-Sub Consultant Fees

FUTURE REQUIREMENTS

$10M - $12M

Trigger Milestone:

Validation of the 'Universal Cartridge' mechanism (no breakage) & FDA agreement on clinical trial protocol.

07

Strategic Outlook

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

Priority Actions (Next 90 Days)

ACTION	OWNER	TIMELINE	BUDGET
Destructive Load Testing (Glass)	Lead Mechanical Engineer	Weeks 1-4	$15,000
Provisional Patent Filing (Sensing)	IP Counsel	Immediate	$25,000
FTO 'Clean Room' Design Session	CTO + External Patent Attorney	Month 2	$10,000
Protein Stability Analysis (HPLC)	CRO Partner	Month 4	$40,000

Partnership Opportunities

PARTNER TYPE	TARGETS	VALUE EXCHANGE
Strategic OEM	Biocon, Sandoz, Viatris (Biosimilar Makers)	Hypen provides a premium 'Smart Device' differentiator; Partner provides insulin supply for testing and distribution channels.
Component Supplier	Schott / Stevanato Group (Glass Specialists)	Joint development of a 'High-Impact' glass cartridge standard.

Go/No-Go Decision Framework

PROCEED TO NEXT STAGE IF:

- Standard ISO glass cartridges survive 50 consecutive shots at 30MPa.
- Viscosity sensor detects 10% deviation in fluid density in <500ms.
- Clean FTO opinion on actuator drive train.

HALT OR PIVOT IF:

- Cartridge fracture rate > 1%.
- Power consumption > 20A peak (battery tech limitation).
- Evidence of insulin fibrillation (aggregates > 5%) in HPLC analysis.

08

Director's Insights

Unvarnished synthesis and strategic mandates from the TTO Director.

ARCUS TTO

INTERNAL MEMO

Confidential

TO: Investment Committee, ERVIEGAS

FROM: Director of Technology Transfer

DATE: 2025-12-09

RE: **COMMERCIALIZATION VIABILITY ASSESSMENT**

"**MEMORANDUM TO THE INVESTMENT COMMITTEE** **SUBJECT:** Hypen Technology Assessment - The 'Trojan Horse' Strategy Having reviewed the technical and forensic data for the Hypen Intelligent Insulin Delivery System, my recommendation is to proceed with **Extreme Caution**, contingent on an immediate pivot in strategic positioning. We must stop viewing this primarily as a 'Jet Injector' company. The history of medical devices is littered with the bankruptcies of needle-free companies (e.g., Zosano, early Antares attempts) that solved the 'pain' problem but failed the 'reliability' and 'business model' tests. The **Jet Injection mechanism is a commodity**; worse, it is a liability due to the physics of glass fracture and the heavy patent fencing by Portal Instruments. If ERVIEGAS attempts to go head-to-head with Portal on actuator mechanics, they will likely bleed out in legal fees before the first unit ships. The real asset here—the **'Crown Jewel'**—is the **Intelligence Layer**: the rheological (viscosity) sensing and the closed-loop safety protocols. This is the **Green Ocean**. No current incumbent (Novo, Lilly, Medtronic) has a device that checks the *quality* of the drug *inside* the chamber before injection. This capability addresses a massive, unserved liability in the supply chain (thermal degradation of biologics). **Strategic Mandate:** We must decouple the *Sensing IP* from the *Delivery Mechanism* risk. The 'Universal Cartridge' jet injector is a high-risk moonshot. If the glass breaks (which physics suggests it will), the company dies. However, if we patent the **'Method of detecting protein degradation via back-EMF analysis in a linear actuator'**, we possess a transferable asset that can be licensed to *any* electromechanical pump manufacturer, regardless of whether it uses a needle or a jet. Therefore, funding should be tranche-based. **Tranche 1 ($750k)** is exclusively for proving the sensor works and that the glass survives. If the glass fails, we pivot the sensor technology into a needle-based 'Smart Pen' architecture, which drastically lowers the power budget and regulatory risk while retaining the core data value proposition. We are investing in a **Data & Quality Assurance**

Strategic Mandates

Critical directives required to proceed with investment or development.

Patent the 'Brain', Not the 'Muscle'

CRITICAL PRIORITY

Focus IP budget on the viscosity sensing and remote-lockout logic. These are the licensable assets. The mechanical actuator is a commodity with high FTO risk.

Kill the 'Universal' Dream Early if Needed

HIGH PRIORITY

If ISO glass fails stress tests, immediately switch to a proprietary polymer cartridge. Do not waste years trying to defy material science for a marketing claim.

Target 'Second-Tier' Pharma

MEDIUM PRIORITY

Do not pitch to Novo or Lilly yet. Pitch to Biocon or Sandoz who need a premium device to differentiate their generic insulins.

09

Appendix

Concept Visualization

Visual Concept

Generated Concept: Hypen is an intelligent, electromechanical insulin delivery system that eliminates needles using high-pressure jet injection while integrating AI for dosing optimization and safety. It features universal cartridge compatibility to avoid vendor lock-in, viscosity sensors to detect insulin degradation, and a connected mobile application that enables parental authorization and comprehensive treatment adherence monitoring.