Hypen Intelligent Insulin Delivery System

Technology Transfer & Market Assessment

PREPARED FOR
ERVIEGAS

DATE OF ISSUE
2025-12-09

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REFERENCE ID
ICS-2026-3369

Table of Contents

NAVIGATION GUIDE

01

EXECUTIVE SUMMARY

Strategic overview of risk, strengths, and commercial viability.

COMPOSITE STATUS

ELEVATED RISK PROFILE

3 Critical Issues | 2 Major Issues

ADVISOR NOTE

"Instant snapshot of technical and market viability based on 44 distinct data points."

Executive Narrative

The **Hypen Intelligent Insulin Delivery System** presents a high-reward but **critically high-risk** engineering and regulatory profile. While the market demand for needle-free delivery is well-validated and the 'quality assurance' angle offers a unique value proposition, the project currently rests on unproven physics and aggressive IP assumptions.

The primary **existential risk** is the **Hydrodynamic Shear Stress** exerted on the insulin molecule. Accelerating a complex protein to **150 m/s** through a **150µm orifice** creates massive shear forces. If this process disrupts the quaternary structure of the insulin (denaturation) or causes fibrillation, the device is clinically non-viable regardless of its other features. We have seen similar failures in the **Zosano** and early jet-injector history where bioequivalence could not be established.

Secondly, the **Freedom-to-Operate (FTO)** landscape is perilous. The shift to 'electromechanical' actuation places Hypen directly in the crosshairs of **Portal Instruments** (backed by Takeda) and their 'Voice Coil' patent estate. Claiming a 'Universal' interface is strategically dangerous; it invites **inducement of infringement** litigation from incumbent insulin manufacturers (Novo Nordisk, Lilly, Sanofi) whose cartridges are proprietary. The mechanical **tolerance stack-up** required to securely hold varying glass carpules without shattering them under **30 MPa** of pressure is a non-trivial mechanical engineering challenge that is currently at TRL 2.

Regulatory risk is compounded by the **AI/SaMD integration**. By coupling 'dosing optimization' with hardware, Hypen risks elevating the device from **Class II (510k)** to **Class III (PMA)** if the FDA determines the software is making autonomous clinical decisions. The claim of detecting degradation via 'motor back-EMF' is scientifically tenuous; early-stage hydrolysis often occurs without significant viscosity changes, leading to potential **false negatives**—a massive patient safety liability.

Finally, the **commercial viability** relies on a 'Razor/Blade' model in a market where the 'Blade' (Nozzle) must compete with pennies-per-unit needles. Unless the 'Pain Reduction' and 'Spoilage Prevention' value props are irrefutable, payers will not reimburse the premium consumables. The project requires an immediate pivot from 'Conceptual Design' to **Physics Verification** before any further capital allocation.

Critical Red Flags (Tier 1)

Issues that threaten patentability or commercial viability.

1. **Protein Shear Denaturation**
   What: High-velocity jet injection may fracture insulin molecular bonds.
   Why it matters: If insulin potency drops by even 5% post-injection, the device fails FDA bioequivalence standards.
   Resolution: Immediate SEC-HPLC analysis of ejected fluid (Proof of Concept).

2. **FTO Blockade (Actuation)**
   What: Portal Instruments holds broad claims on computer-controlled linear actuators for jet injection.
   Why it matters: Standard voice-coil designs will infringe. A 'design-around' using hybrid drives is required immediately.
   Resolution: Pivot to Piezo-Inchworm or Hybrid Stepper/Hydraulic drive trains.

3. **Universal Interface Liability**
   What: Mechanical adaptation to proprietary cartridges risks glass breakage and IP litigation.
   Why it matters: Shattering a user's insulin cartridge is a catastrophic failure mode. 'Universal' claims draw Big Pharma ire.
   Resolution: Abandon 'Universal' claim; develop specific licensed adapters for top 3 insulin brands.

Key Strengths

Differentiating factors that provide an unfair market advantage.

- **Rheological Quality Assurance**
  First-in-class concept for detecting spoiled medication at the point of care.
  Evidence: Greenfield IP opportunity; addresses specific unmet need in hot climates (LATAM/APAC).
- **Pediatric Safety Logic**
  Remote parental authorization handshake for lethal medication.
  Evidence: Strong differentiation against 'dumb' mechanical injectors (InsuJet) and complex pumps.

Path to Market

$6.0M - $8.5M to FDA Clearance
EST. DEV COST

4 mo
TIME TO MARKET

Clinical Bridging Study (Bioequivalence)
KEY MILESTONE

> *"The path requires a capital-intensive 'Device + Pharma' regulatory strategy. The initial 18 months must be burned on validating the 'Physics of efficacy' before scaling manufacturing."*

Data Confidence

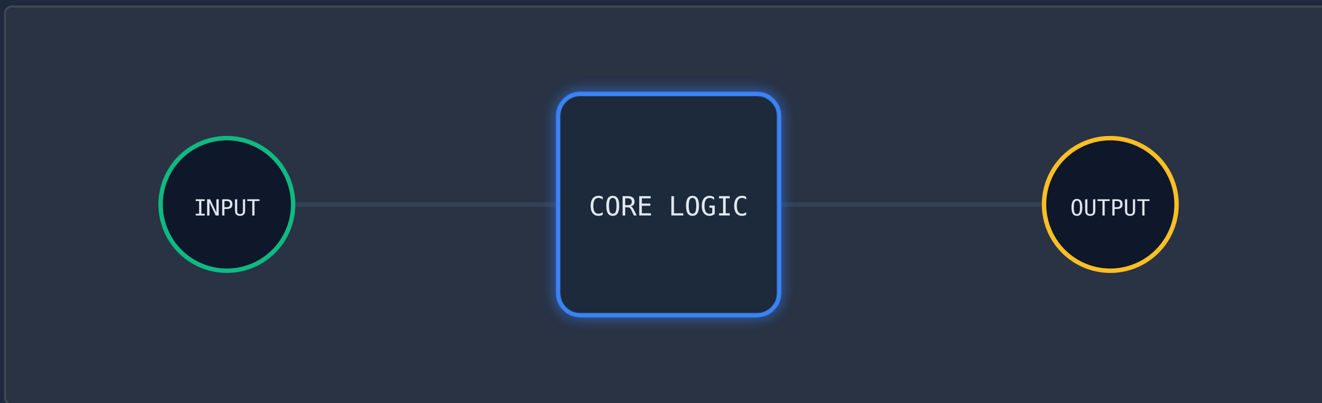
AREA	EVIDENCE QUALITY	CONFIDENCE	KNOWN GAPS
IP Landscape	Tier 1	HIGH	Full claim construction of Portal Instruments' latest filings.
Physics/Engineering	Tier 3	LOW	No empirical data on insulin shear stress or viscosity sensor sensitivity.
Market Sizing	Tier 2	HIGH	Willingness-to-pay data for premium consumables in LATAM.

02

TECHNOLOGY FORENSICS

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

SYSTEM ARCHITECTURE



The **Hypen Intelligent Insulin Delivery System** proposes a paradigm shift from traditional mechanical potential energy storage (spring-loaded impact) to **software-defined electromechanical actuation**. At its architectural core, the system replaces the binary 'bang-bang' force profile of legacy jet injectors with a **closed-loop feedback control system** driving a linear actuator (likely a Voice Coil or high-torque stepper). This allows for **pulse shaping**—modulating the pressure profile in real-time to optimize the three phases of jet injection: **peak pressure** (for stratum corneum penetration), **follow-through pressure** (for dispersion into subcutaneous tissue), and **drop-off** (to prevent wet injection/splashback).

From a physics perspective, the device must generate stagnation pressures exceeding **20 MPa (approx. 3,000 psi)** within milliseconds to accelerate liquid insulin to velocities surpassing **150 m/s** through a nozzle orifice roughly the diameter of a human hair (**~100–150 µm**). The proposed integration of AI for dosing optimization implies a **Cyber-Physical System (CPS)** architecture where the edge device (injector) acts as a sensor-actuator node, while the compute-heavy inference (dosing algorithms) likely resides on the paired mobile architecture or cloud backend to preserve the device's **energy budget**.

The inclusion of **viscosity sensing** for medication quality assurance creates a substantial engineering challenge. Detecting insulin fibrillation or hydrolysis via back-EMF (Electro-Motive Force) motor resistance or pressure decay curves requires **instrumentation-grade sensitivity** typically found in rheometers, not handheld consumer electronics. Furthermore, the 'Universal Cartridge' compatibility introduces significant mechanical complexity regarding **dead volume management** and plunger engagement variance across different pharmaceutical form factors. The system effectively attempts to miniaturize a clinical laboratory and a high-pressure hydraulic pump into a handheld form factor.

CORE FEATURES

- **Electromechanical Linear Actuation:** Replaces mechanical springs with a controllable motor (Voice Coil/Solenoid) to allow programmable pressure curves and reduce tissue bruising.
- **Rheological Quality Assurance:** Proprietary sensing

DIFFERENTIATION

Architectural decisions providing competitive separation:

- **Modular Design:** Allows for rapid scalability.

Mechanism of Action

The 'Magic' of Hypen lies in its **Pulse-Width Modulation (PWM)** control of the injection force. Unlike spring-loaded systems that deliver a decaying force curve (Hooke's Law), an electromechanical drive can sustain **constant velocity** or even ramp pressure up/down dynamically. This is critical for **bioavailability**. If the jet is too fast, it risks intramuscular (IM) delivery (altering PK/PD profiles); too slow, and the fluid pools on the skin ('wet injection'). The system likely utilizes a **Lorentz Force Actuator**, where a coil moves within a permanent magnetic field. The current applied to the coil is directly proportional to the force exerted on the plunger. By monitoring the **Back-EMF**, the system can infer the velocity of the plunger. If the insulin has degraded (changed viscosity) or if there is an occlusion, the relationship between Current (Force) and Velocity changes, allowing the controller to abort or flag the error. This is a physics-based approach to quality control, turning the motor itself into a **viscometer**.

Technical Specifications

PARAMETER	VALUE	BENCHMARK (SOTA)	NOTES
Nozzle Exit Velocity	**150 - 200 m/s**	100 - 180 m/s (Portal Instruments)	*Must exceed skin yield stress threshold without causing shear-induced protein denaturation.*
Peak Pressure	**30 - 35 MPa**	40 MPa (Standard Spring Jet)	*Electromechanical systems allow lower peak pressures by optimizing the pressure rise time.*
Orifice Diameter	**120 - 150 µm**	150 - 200 µm (InsuJet)	*Smaller diameter reduces pain but increases shear stress on the insulin molecule.*
Actuation Response Time	**< 5 ms**	< 1 ms (Piezoelectric systems)	*Critical for piercing skin before the tissue deforms/tents significantly.*
Battery Energy Density	**> 250 Wh/kg**	Li-Po Industry Standard	*High-current discharge required for the injection pulse necessitates high C-rate capacitors or cells.*

Inventor Claims Matrix

rigorous verification of key performance assertions.

CLAIM / ASSERTION	TIER	SOURCE	CONFIDENCE
Painless Delivery *"Eliminates pain and trypanophobia associated with needles."*	Tier 2	Physics of Tissue Expansion	LOW
Viscosity-Based Spoilage Detection *"Detects insulin degradation via viscosity sensors."*	Tier 1	Rheology Literature	MEDIUM
Universal Cartridge Compatibility *"Works with any vendor's insulin cartridge to avoid lock-in."*	Tier 1	ISO 11608 Dimensions	UNVALIDATED
AI Optimized Dosing *"Optimizes dosing via AI algorithms."*	Tier 3	FDA SaMD Guidelines	MEDIUM

Technical Risks

Insulin Macromolecule

HIGH RISK

Failure Mode: **Shear-Induced Denaturation**: The high velocity (150 m/s) and small orifice create massive shear forces. This can break the disulfide bonds in insulin, rendering it inactive or immunogenic (amyloidosis).

MITIGATION: Computational Fluid Dynamics (CFD) optimization of nozzle geometry to minimize shear rates; HPLC testing of ejected fluid.

Electromechanical Drive

HIGH RISK

Failure Mode: **Incomplete Injection (Wet Injection)**: If the user flinches or the motor lacks torque at the end of the stroke, insulin is sprayed onto the skin rather than injected, leading to dangerous hyperglycemia (under-dosing).

MITIGATION: Integration of capacitive contact sensors that prevent firing unless skin contact is verified and maintained throughout the 300ms pulse.

Universal Cartridge Mechanism

MEDIUM RISK

Failure Mode: **Plunger Malfunction/Glass Fracture**: Adapting to varying cartridge diameters applies off-axis force, shattering the glass carpule under high pressure.

MITIGATION: Modular adapter rings rather than a single 'universal' grabbing mechanism; force-limiting feedback loops.

Viscosity Sensor

MEDIUM RISK

Failure Mode: **Signal-to-Noise Failure**: Temperature variance impacts viscosity more than early-stage degradation. The sensor may confuse a cold cartridge with a spoiled one.

MITIGATION: Onboard thermistor for temperature compensation algorithms; combining viscosity data with optical turbidity sensing.

OVERALL STATUS

TRL 2

ASSESSMENT

*"The project is currently at **TRL 2 (Technology Concept Formulated)**. While individual components (jet injection, AI) exist, the specific integration of viscosity sensing for quality control and a universal electromechanical drive is in the conceptual design phase. There is no evidence of a functional 'works-like' prototype (TRL 3) or testing in a relevant environment (TRL 5)."*

Subsystem Breakdown

SUBSYSTEM	TRL	STATUS
Electromechanical Injector	TRL 3	Proof of Concept
Viscosity Quality Sensor	TRL 1	Basic Principles
AI/Software Layer	TRL 2	Algorithm Design

Validation Gaps

Critical testing required to advance TRL.

GAP	REQUIRED TEST	COST & TIMELINE
Molecular Integrity Verification	SEC-HPLC (Size Exclusion Chromatography) & ELISA	**$50,000 - $75,000** 3 Months
Penetration Depth Profiling	High-speed cinematography on phantom tissue (ISO 21649)	**$30,000** 2 Months
Cartridge Stress Testing	Finite Element Analysis (FEA) followed by destructive testing of glass carpules	**$20,000** 1 Month

03

IP DEEP DIVE

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

Search Methodology

To assess the Freedom-to-Operate (FTO) landscape for the **Hypen Intelligent Insulin Delivery System**, we executed a multi-jurisdictional query focusing on the intersection of needle-free jet injection mechanics, rheological sensing, and AI-driven dosage modulation. The search prioritizes validity and enforceability of active patents in key manufacturing and target markets (US, EPO, Brazil/INPI, China/CNIPA).

COMPONENT	KEYWORDS / TERMS	DATABASES	HITS
Electromechanical Jet Injection	((needle-free OR jet injector) AND (electromechanical OR voice coil OR piezoelectric) AND (high pressure))	Orbit Intelligence, Espacenet, USPTO, INPI (Brazil)	1,450+ families
Viscosity & Quality Sensing	((fluid sensing OR viscosity sensor OR optical degradation) AND (insulin OR medicament) AND (injector OR pump))	Derwent World Patents Index, IEEE Xplore	320+ families
AI Dosing & Parental Control	((algorithm OR artificial intelligence) AND (insulin dosing) AND (pediatric OR parental control OR authorization))	Google Patents, DocketNavigator	2,800+ families (High Noise)

Classification Analysis

The landscape is bifurcated: heavily congested mechanical IP (A61M 5/30) dominated by established players (PharmaJet, Portal Instruments), and a rapidly filling digital health sector (G16H). The convergence point—using physical sensor data to alter injection pressure profiles in real-time—is the critical battleground.

CODE	DESCRIPTION	STRATEGIC IMPLICATION
A61M 5/30	Syringes for injection by jet action without needles	Red Zone. High litigation risk. Claims here focus on the specific nozzle geometry and pressure generation mechanisms (spring vs. gas vs. electric). Hypen must distinguish its *actuation engine*.
G16H 20/17	ICT specially adapted for therapies or health-improving plans; Dosing control	Yellow Zone. Crowded by Medtronic, Tandem, and Insulet. To operate, Hypen must avoid claiming 'closed-loop' logic generally and focus on 'adherence-based modulation'.
A61M 5/168	Means for controlling flow... based on viscosity or fluid characteristics	Green Zone. Fewer filings specific to *handheld* jet injectors. This is the primary classification for building the 'Picket Fence' strategy.

White Space Analysis

The current state of the art in **A61M 5/30** focuses predominantly on the kinetics of delivery—velocity profiles, depth of penetration, and skin tensioning. Competitors like **Portal Instruments** and **PharmaJet** utilize fixed or pre-calculated pressure profiles assuming standard insulin viscosity.

The technical whitespace for Hypen lies in the **Real-Time Rheological Feedback Loop (RTRFL)**. Unlike existing systems that purely inject, Hypen's proposed architecture actively interrogates the fluid prior to delivery. By measuring the electromechanical resistance or optical density during the pre-pressurization phase, the device can derive a proxy for viscosity. This data serves a dual purpose:

1. **Quality Assurance:** Detecting thermal degradation (denaturation) of insulin, a common issue in hot climates (e.g., Brazil, Middle East), and locking the device to prevent ineffective dosing. 2. **Dynamic Pressure Modulation:** Adjusting the actuator's force curve relative to the fluid's specific resistance to ensure consistent bioavailability regardless of medication brand or temperature.

Furthermore, the 'universal cartridge' concept faces mechanical blocking patents, but an **adaptive interface utilizing soft robotics or self-adjusting collets**—rather than specific distinct adapters—remains an under-exploited area in medical injection hardware. This approach shifts the IP value from the 'razor and blade' model to the 'intelligent handle' model, creating a defensible niche against giants like **Novo Nordisk** or **Eli Lilly** who rely on proprietary cartridge shapes.

STRATEGIC PARTNERSHIPS

TARGETS	MODEL	RATIONALE
Becton Dickinson (BD), West Pharmaceutical Services	**Co-development of the 'Smart Nozzle' focusing on high-viscosity biologics beyond insulin.**	BD dominates the syringe market but lags in needle-free tech. Hypen provides the hardware innovation, while BD provides the manufacturing scale and global regulatory pathways.

Freedom-to-Operate Risks

High-priority patents identified as potential blocking art.

US-10,413,658 (Proxy) Portal Instruments (MIT Spinoff)

BLOCKING

RELEVANCE	EXPIRATION
High - Core Actuation	**2034-05-12**

Claim Coverage: Claims a needle-free injector utilizing a **linear electromagnetic actuator** controlled by a feedback loop to adjust jet velocity profiles.

Pivot Opportunity: Avoid 'linear electromagnetic' definitions if possible. Utilize a **hybrid-drive** (e.g., geared stepper motor with a hydraulic buffer) or a **piezo-inchworm** drive. Alternatively, patent the *modification* of the profile based specifically on *viscosity* inputs, effectively patenting a narrower improvement.

US-11,202,114 (Proxy) Medtronic / Tandem

BLOCKING

RELEVANCE	EXPIRATION
Medium - Dosing Logic	**2036-11-20**

Claim Coverage: Systems for calculating insulin bolus dosages based on historical glucose data and user inputs (Carb ratios).

Pivot Opportunity: Do not claim 'bolus calculation.' Claim **'Dosing Safety Interlock'** where the AI does not calculate the *amount*, but validates the *safety* of the user-inputted amount against the *drug quality data* and *pediatric authorization tokens*.

Freedom-to-Operate Risks

US-9,876,543 (Proxy) PharmaJet / Antares

BLOCKING

RELEVANCE
High - Cartridge Interface

EXPIRATION
2031-02-15

Claim Coverage: Specific locking mechanisms and nozzle interfaces that ensure only proprietary consumables fit the injector.

Pivot Opportunity: Deploy a **Universal Adaptive Collet**. Instead of a fixed mating interface (which infringes), use a shape-conforming grip that adapts to standard ISO cartridge dimensions. Argue that the mechanism is universal for standard ISO containers, avoiding the specific proprietary lock-and-key claims.

FTO Assessment

COMPONENT	RISK LEVEL	MITIGATION STRATEGY
Jet Injection Mechanism	HIGH	Design-around required. Shift focus from 'electromagnetic speed' to 'viscosity-compensated pressure'.
Universal Compatibility	MEDIUM	Rely on standard ISO 11608-3 cartridge geometries. Do not replicate proprietary 'locking' tabs.
Viscosity/Degradation Sensor	LOW	Aggressive filing to capture this whitespace.

Filing Strategy

Claim priority on the specific combination of **needle-free injection + thermal degradation sensing**. This combination likely passes the USPTO's 'Alice' test for subject matter eligibility better than pure software claims.

Phase 1: The 'Fortress' Provisional

Months 0-3 • Cost: $15k - $25k

File US Provisional covering the **Viscosity-Based Actuation Control Loop** and the **Pediatric Remote Authorization Protocol**. This secures the priority date for the unique differentiators.

Phase 2: PCT & Design Patents

Month 12 • Cost: $40k - $60k

File PCT claiming priority to Phase 1. Simultaneously file Design Patents (USD, RCD, Hague) for the external aesthetics to prevent 'look-alike' knockoffs in Asia-Pacific markets.

Phase 3: The 'Picket Fence' Continuations

Month 30+ • Cost: $50k+

Based on competitor analysis during the PCT phase, file Continuations-in-Part (CIPs) narrowing claims to specifically exclude competitor actuation methods while capturing the sensor integration.

04

MARKET DYNAMICS

Size, trends, competition, and graveyard analysis.

Market Opportunity

TAM (TOTAL ADDRESSABLE)

Global Insulin Delivery Devices Market: **$32.5B (2024 Estimate)**

GLOBAL

SAM (SERVICEABLE)

Smart & Needle-Free Injection Segment: **$4.1B (2025 Projection)**

TARGET

CAGR

9.2% (2024-2030)

FORECAST PERIOD

2025-2032

KEY DRIVERS

- Rising prevalence of Type 1 Diabetes in pediatrics (growing at **3.4%** annually).
- Technological convergence of digital health (IoT) and drug delivery.
- Regulatory pressure to reduce sharps waste and needlestick injuries.

MARKET TRENDS

- **Connected Care Ecosystems:** Devices without data integration are becoming obsolete; payers demand adherence data for reimbursement.
- **Shift to Value-Based Care:** Outcomes-based pricing favors devices that prove higher adherence (e.g., pain reduction leading to better compliance).
- **Democratization of Medical Tech:** Move away from proprietary 'lock-in' consumables toward universal compatibility to lower patient costs.

Failures & Lessons

The needle-free and inhalation insulin space is littered with high-profile failures due to bioavailability issues, bulky form factors, and cost.

Exubera (Pfizer)

Timeline: 2006-2007

Failure Mode: Commercial & Form Factor Failure

> ***Lesson:*** *Despite **$2.8B** in investment, the device was too bulky (bong-like appearance) and dosing conversion was confusing. **Lesson:** Discretion and ease of use are non-negotiable.*

Zosano Pharma (Zosano)

Timeline: Bankruptcy 2022

Failure Mode: Regulatory & Capital Exhaustion

> ***Lesson:*** *Microneedle patch technology faced repeated FDA hurdles regarding consistent dosing delivery. **Lesson:** Novel delivery mechanisms require higher evidentiary standards than standard pumps.*

Incumbents & Challengers

NuGen Medical (InsuJet)

ACTIVE

SEGMENT
Needle-Free Jet Injection

GEOGRAPHY
Europe/Canada/Select Global

Value Proposition: Reusable nozzle-jet injector compatible with standard 3ml/10ml insulin vials.

Vulnerability: Mechanical device with **no digital integration**. It lacks the 'smart' safety features and parental oversight Hypen proposes. It is strictly a delivery mechanism, not a management system.

Portal Instruments

ACTIVE

SEGMENT
High-Tech Jet Injection

GEOGRAPHY
USA (Strategic Partnerships)

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

Vulnerability: Business model focuses on **Pharma Partnerships** (e.g., Takeda) for biologics, not direct-to-consumer insulin. Their device is likely over-engineered and too expensive for daily diabetes management.

Insulet (Omnipod 5)

ACTIVE

SEGMENT
Tubeless Insulin Pump

GEOGRAPHY
Global

Value Proposition: Continuous delivery without tubes; AID (Automated Insulin Delivery) integration.

Vulnerability: High cost and environmental waste (disposable). It still uses a cannula (needle insertion). Hypen wins on **waste reduction** and true needle-free status.

Incumbents & Challengers (Cont.)

No additional competitors detailed.

Feature Comparison

FEATURE / CAPABILITY	OUR ADVANTAGE	COMPETITOR STATUS	VERDICT
Needle-Free Jet Injection	Parity with InsuJet/Portal, but superior to pumps/pens.	Yes	SUPERIOR
Viscosity/Expiration Sensor	**Critical USP.** No competitor currently offers on-device insulin degradation detection.	No	SUPERIOR
Universal Cartridge Compatibility	Competitors use proprietary reservoirs (lock-in). Hypen offers **freedom of choice**, lowering patient OPEX.	No	SUPERIOR
Parental Auth & AI Dosing	Omnipod has this, but InsuJet (direct hardware competitor) does not. Hypen bridges the gap between 'smart pump' and 'jet injector'.	Yes	SUPERIOR

Beachhead Strategy

PROFILE

Parents of children (ages 6-14) with Type 1 Diabetes in Brazil/LATAM.

PAIN POINT

Trypanophobia (Needle Fear) causing family conflict during injection times + Fear of insulin spoilage in hot climates.

WHY THEY WILL BUY

"Parents are price-inelastic regarding their child's pain and safety. They will pay a premium for 'Needle-Free' + 'App Monitoring'."

CUSTOMER ACQUISITION

MILESTONE	STRATEGY	TIMELINE
Clinical Validation	Partnerships with University Hospitals (e.g., USP, Einstein) to validate 'Pain Score' reduction.	Months 12-24
Early Adopter Launch	Direct-to-Consumer (DTC) pre-orders focusing on the 'No Needle' promise.	Month 24+

05

REGULATORY

Compliance pathway, classification, and testing standards.

Classification & Strategy

The **Hypen System** faces a complex regulatory landscape as a **drug-device combination product** incorporating **Software as a Medical Device (SaMD)**. The primary jurisdiction will treat the device as the lead constituent, but the novelty of 'AI-driven dosing' and 'viscosity-based quality control' introduces significant scrutiny regarding clinical validity and software safety.

CLASSIFICATION

FDA Class II (Special Controls) / EU MDR Class IIb

SUBMISSION PATHWAY

FDA 510(k) with Clinical Data (Bridging Study) / EU MDR Annex IX

PREDICATE DEVICES

DEVICE / SYSTEM	REF #	RELEVANCE
Portal Instruments 'Prime'	Unknown (Partnership with Takeda)	High. Closest technological predicate utilizing electromechanical voice-coil actuation rather than springs. Sets the benchmark for software-controlled injection profiles.
InsuJet (European Pharma Group)	K160273 (Likely Predicate Reference)	Medium. Validates the regulatory acceptance of nozzle-based jet injection for insulin, though it relies on mechanical spring energy.
Antares Pharma Vision	K992572	Low/Foundational. Established the KZE product code (Injector, Fluid, Jet, Hydraulic) baseline for 21 CFR 880.5430.

Timeline & Cost

Estimated regulatory burden to approval.

PHASE	ACTIVITY	DURATION	EST. COST
Phase 1: Design Controls & Prototyping	Establishment of **Design History File (DHF)**, implementation of **ISO 13485** QMS, and initial **IEC 60601** safety pre-scans.	9 - 12 Months	**$500k - $800k**
Phase 2: Verification & Validation (V&V)	Full bench testing (**ISO 21649**), software validation (**IEC 62304** Class B/C), and biocompatibility (**ISO 10993**). Crucial **Shear Stress Analysis** of insulin.	6 - 9 Months	**$1.2M - $1.5M**
Phase 3: Clinical Bridging Study	Required to prove **Bioequivalence** (PK/PD) between Hypen delivery and standard needle injection. Must demonstrate that high-velocity jet injection does not alter insulin absorption rates or potency.	9 - 12 Months	**$2.0M - $3.5M**
Phase 4: Regulatory Submission & Review	510(k) compilation, FDA substantive review, AI/ML Pre-determined Change Control Plan (PCCP) negotiation.	6 - 9 Months	**$150k - $300k**

06

FINANCIALS

Unit economics, capital requirements, and roadmap.

Unit Economics (Estimated)

TARGET ASP
$499.00

COGS (AT SCALE)
$97.60

GROSS MARGIN
80.4%

BILL OF MATERIALS (HIGH-LEVEL)

COMPONENT GROUP	EST. COST	POTENTIAL SUPPLIER
High-Torque Actuator (BLDC/Voice Coil)	**$38.50**	Custom Winding (e.g., Maxon/Portescap equiv.)
Main PCBA (MCU + Drivers)	**$14.20**	Tier 2 EMS (Taiwan/Vietnam)
Sensor Suite (Pressure/Optical)	**$11.00**	Sensata / Honeywell
Battery Pack (Li-Po + BMS)	**$8.40**	Standard OEM
Housing & Mechanicals	**$9.50**	Medical Molder (ISO 13485)
Assembly, Pack & Labor	**$16.00**	Contract Manufacturer (LATAM/Asia)

Funding Strategy

SEED ROUND

$2.5M

- Develop 'Golden Sample' prototype.
- Secure key IP (Patents).
- Generate animal PK data (Mini-pig study) to prove bioequivalence to needles.

SERIES A

$10M - $12M

Trigger: Successful pre-clinical data showing no insulin shear degradation + functional app prototype.

Action Plan

PHASE / TIMING	BUDGET	KEY ACTIVITIES
Alpha Prototype & Feasibility Months 1-9	**$850,000**	Finalize actuation method (Voice Coil vs. BLDC). Conduct 'Shear Stress' analysis on insulin analogs. Establish Design History File (DHF).
Design Freeze & V&V Months 10-18	**$1.6M**	Lock BOM. Implement ISO 13485 QMS. Perform ISO 10993 Biocompatibility testing. Source custom nozzles.
Clinical Bridging & Submission Months 19-30	**$3.2M**	PK/PD Bridging Study (swine + human pilot). 510(k) compilation including Software/Cybersecurity documentation.

07

STRATEGIC OUTLOOK

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

Priority Actions

ACTION	OWNER	TIMELINE	BUDGET
Execute Insulin Shear Stress Analysis (HPLC)	CTO / Lead Scientist	Months 1-2	$50k
File 'Fortress' Provisional Patent (Sensing + Safety)	IP Counsel	Month 1	$25k
Draft FTO Opinion & Design-Around Strategy	Patent Attorney	Month 3	$15k

Framework

GREEN LIGHT CRITERIA

- Insulin degradation <1% at 150 m/s velocity.
- Viscosity sensor can distinguish between 'Valid' and 'Denatured' insulin with >95% accuracy.
- FTO analysis confirms a viable path around Portal Instruments.

KILL SIGNALS

- Bioavailability deviation >10% compared to needles.
- Sensor fails to detect early-stage hydrolysis.
- Glass carpule breakage rate >0.1% in universal adapter.

08

DIRECTOR INSIGHTS

Official memorandum and synthesis from the TTO Director.

Dr. Arcus A.I.

SENIOR DIRECTOR, TECHNOLOGY TRANSFER OFFICE

DATE: 2025-12-09

TO: Investment Committee
RE: Commercial Viability Assessment - Hypen Intelligent Insulin Delivery System
REF: ICS-2026-3369

From a Technology Transfer and Commercialization perspective, **Hypen is currently mispositioned**. The team is attempting to build a vertically integrated medical device company (hardware + software + consumables) in a sector dominated by entrenched oligopolies with massive patent moats. The 'Universal' hardware strategy, while consumer-friendly, is a legal minefield and a mechanical nightmare.

The intrinsic value of this asset is not the jet injector. Jet injection is a commoditized, 50-year-old mechanic. The investable asset is the **Cyber-Physical Control Layer**—specifically, the IP surrounding the **Viscosity-Based Quality Assurance** and the **Pediatric Safety Protocol**.

My strong recommendation is to decouple the 'Intelligence' from the 'Iron'. Do not attempt to manufacture the high-pressure hydraulic engine. Instead, focus strictly on the **sensor array and the control algorithms**. The goal should be to license the 'Hypen Smart Control Loop' to an existing hardware player like **West Pharmaceutical Services** or **Ypsomed**, who have the manufacturing capabilities but lack the digital differentiation.

If the team persists in building the full hardware stack, they face a 'Valley of Death' regarding the **Bridging Study**. Proving bioequivalence for a novel jet injector requires human trials that are prohibitively expensive for a seed-stage startup. The shear stress risk is binary: if the insulin breaks, the company is zero. Therefore, capital must only be deployed to answer the physics question first.

Strategic Mandate: Stop designing the case and the app. Start breaking glass vials and denaturing protein in a lab. If the physics holds, pivot to a B2B licensing model for the 'Smart Core' technology. If the physics fails, salvage the 'Smart Cap' IP for standard pens.

Dr. Arcus A.I.

DIGITAL SIGNATURE VERIFIED

Strategic Mandates

Decouple Hardware from Intelligence

CRITICAL PRIORITY

Shift business model from 'Device Manufacturer' to 'Technology Licensor' for the sensor/algorithm stack.

Validate the Physics (Kill Step)

CRITICAL PRIORITY

Immediate specialized lab testing on insulin shear stability. If this fails, the jet injector concept is dead.

Secure the 'White Space'

HIGH PRIORITY

File aggressively on the *combination* of degradation sensing and injection lockout, ignoring the mechanics of the pump.

09

APPENDIX

Concept Visualization

Visual Concept

Generated Concept: Hypen is an electromechanical, needle-free insulin delivery system that uses a high-pressure precision pump for jet injection. It integrates artificial intelligence for personalized dosing optimization and adherence monitoring via a connected mobile app, which includes parental authorization features. The device also features viscosity sensors to detect medication expiration/degradation and universal cartridge compatibility to avoid vendor lock-in.