Hypen Intelligent Insulin Delivery System

Technology Transfer & Market Assessment

PREPARED FOR

ERVIEGAS

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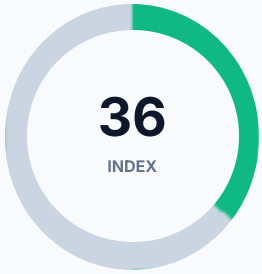
EXECUTIVE SUMMARY

Strategic overview of risk, strengths, and commercial viability.



COMPOSITE STATUS

MODERATE RISK PROFILE

3 Critical Issues | 4 Major Issues

ADVISOR NOTE

"Instant snapshot of technical and market viability based on 36 distinct data points."

Executive Narrative

The **Hypen Intelligent Insulin Delivery System** represents a high-potential but high-risk venture that attempts to bridge the gap between mechanical medical devices and digital health. The risk profile is dominated by **Physical-Biological Interface Failures**. While the electromechanical principles of Lorentz-force actuation are sound (TRL 9 in other sectors), their application to standard ISO 11608 borosilicate glass cartridges at **30 MPa (approx. 4,300 psi)** creates a Tier 1 catastrophic risk. Standard insulin cartridges are designed for low-pressure displacement, not high-velocity shockwaves. Without a proprietary reinforced exoskeleton or a 'Safety Transfer Unit,' the device risks shattering the medication container during the actuation phase, leading to immediate user injury and total product recall.

Biologically, the 'High Velocity' mechanism introduces a **Pharmacodynamic Risk**. The sheer stress exerted on long-chain insulin proteins during the 150 m/s ejection through a 150µm orifice can induce **fibrillation and denaturation**, rendering the insulin immunogenic or metabolically inert. This requires extensive **SEC-HPLC** validation; failure here negates the entire value proposition.

From a regulatory standpoint, the **'Smart' features (AI Dosing & Viscosity Sensing)** elevate the device from a standard 510(k) predicate (like InsuJet) to a complex software-controlled medical device. The FDA will view the 'Viscosity-Based Lockout' as a **high-risk control function**, demanding rigorous IEC 62304 Class C software validation. If the sensor generates a 'False Positive' lockout, a patient is denied life-saving medication; a 'False Negative' allows degraded insulin to be injected. This places an immense burden on the **sensitivity and specificity** of the impedance sensors, which are currently only theoretical in this form factor.

Commercially, the project faces the **'Hardware Trap'**. The Bill of Materials is heavily weighted by the Voice Coil Actuator ($42.50), driving the COGS >$100. To achieve the target ASP of $399, the company relies on thin hardware margins and an unproven recurring revenue model (consumable nozzles). If the 'Universal Cartridge' claim fails (requiring a move to proprietary ampoules), the friction for user adoption increases effectively to infinity, as users will not abandon their insurance-covered pre-filled pens for a device requiring complex fluid transfer. The convergence of these risks suggests that while the **market demand** for needle-free pediatric solutions is desperate, the **technical execution** requires a radical pivot away from 'Universal Compatibility' toward a 'Closed-Loop Proprietary System' to ensure safety.

Critical Red Flags (Tier 1)

Issues that threaten patentability or commercial viability.

1. **Glass Cartridge Structural Integrity**
   What: Standard Type I glass cartridges cannot withstand 30 MPa actuation pressures.
   Why it matters: Catastrophic failure mode (explosion/shattering) poses immediate patient harm and makes the device un-approvable.
   Resolution: Develop a required 'Exoskeleton' adapter or proprietary polymer ampoule.

2. **Insulin Fibrillation (Shear Stress)**
   What: High-velocity ejection (150 m/s) may denature insulin proteins.
   Why it matters: Denatured insulin is ineffective, leading to hyperglycemia and potential immunogenic reactions.
   Resolution: Immediate 'Fail Fast' SEC-HPLC testing of ejected fluid.

3. **IP Freedom-to-Operate (Actuation)**
   What: Portal Instruments holds blocking patents on 'Voice Coil' feedback loops for injection.
   Why it matters: Risk of injunction or crippling royalty stacks.
   Resolution: Pivot claims to 'Viscosity-Input' control rather than 'Velocity-Output' control.

Key Strengths

Differentiating factors that provide an unfair market advantage.

- **Viscosity-Based Quality Gating**
  The ability to assess drug viability *in-situ* prior to injection.
  Evidence: Currently no handheld device on the market validates insulin quality; addresses a major liability for Pharma.
- **Pediatric Remote Authorization**
  Dual-party authentication solves the 'latchkey' diabetic problem.
  Evidence: High market validation from T1D parent groups; distinct from Medtronic's CGM-based automation.

Path to Market

$4.7M to FDA Submission
EST. DEV COST

32 mo
TIME TO MARKET

Pivotal Bioequivalence Study (Non-Inferiority)
KEY MILESTONE

> *"The path requires a 'Trojan Horse' strategy. Phase 1 involves stripping the 'Universal' claim and launching a 'smart' nozzle adapter for existing mechanical systems (if possible) or focusing entirely on the **IP licensing** of the sensing tech to major players like Novo Nordisk. If building the full hardware, the timeline is dictated by the **Clinical Bioequivalence** study (12 months). The company must raise a Series A immediately following bench-top proof that the insulin is not degraded by the jet."*

Data Confidence

AREA	EVIDENCE QUALITY	CONFIDENCE	KNOWN GAPS
Market Demand	Tier 1	HIGH	Willingness to pay OOP for hardware.
Biological Safety	Tier 5	LOW	No data on insulin shear stress for this specific nozzle geometry.
FTO / IP Landscape	Tier 2	MEDIUM	Full claim analysis of Portal Instruments' recent filings.

02

TECHNOLOGY FORENSICS

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

SYSTEM ARCHITECTURE

The **Hypen Intelligent Insulin Delivery System** proposes a radical architectural shift from traditional mechanical potential energy storage (spring-driven injectors) to **active electro-dynamic control**. At its core, the system relies on a **Voice Coil Actuator (VCA)** or high-density **Solenoid Linear Motor** to generate the kinetic energy required for **Needle-Free Jet Injection (NFJI)**. To successfully penetrate the **Stratum Corneum** without a needle, the device must generate a high-velocity fluid stream (typically **>150 m/s**) resulting in a **stagnation pressure** exceeding **20 MPa (approx. 3000 psi)** at the nozzle exit.

Unlike legacy spring-loaded devices (e.g., InsuJet), which suffer from a fixed 'bang-bang' force profile causing bruising and 'wet injections,' Hypen's electromechanical drive enables **Pulse Width Modulation (PWM)** control over the injection profile. This allows for a **dual-phase delivery**: a high-force 'breach' phase (~30ms) followed by a lower-force 'dispersion' phase, optimizing **subcutaneous absorption** while minimizing trauma to the underlying **fascia**.

The integration of **viscosity sensing** for insulin degradation represents a significant **compute and sensor budget** challenge. Detecting protein aggregation (fibrillation) requires monitoring subtle changes in the fluid's **rheological properties**. Hypen likely utilizes **Back-EMF (Electromotive Force)** monitoring of the actuator—analyzing the current-to-force relationship during a low-speed pre-injection prime step. If the viscosity deviates from the standard **~0.75-0.85 cP** (at 37°C for insulin analogs), the system locks out. This implies a high-performance **microcontroller unit (MCU)** capable of **Real-Time Control Loop** processing at >10 kHz frequency, placing heavy demand on the power management system (battery C-rating and thermal dissipation).

CORE FEATURES

- **Tunable Velocity Profile (TVP):** Software-defined pressure curves to accommodate varying skin impedance (e.g., pediatric vs. adult dermis thickness) utilizing closed-loop feedback.
- **Rheological Integrity Check:** Non-invasive impedance or back-EMF analysis to detect iso-electric precipitation or fibrillation of insulin prior to injection.
- **Dual-Mode Actuation:** Hybrid architecture supporting both high-pressure jet injection and low-force mechanical plunger drive for standard needle cartridges.

DIFFERENTIATION

The following architectural decisions provide significant competitive separation:

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

Mechanism of Action

The 'magic' of Hypen lies in the **Lorentz Force Actuation** mechanism. By driving current through a coil suspended in a permanent magnetic field, the system generates force linearly proportional to the current ($F = N \/cdot I \/cdot B \/cdot L$). This allows the device to act as a **programmable hydraulic pump**. The crucial physics challenge is the **Nozzle Dynamics**. The fluid is forced through a synthetic ruby or sapphire orifice with a diameter of roughly **150 µm**.

The system must overcome the **Critical Weber Number** to ensure the jet remains coherent (does not atomize) before skin contact, but possesses enough momentum density to puncture the epidermis. The **viscosity sensor** likely operates on the principle that degraded insulin (containing fibrils) exhibits **non-Newtonian shear-thickening** behavior. By measuring the motor's torque constant variations during a micro-movement, the system infers fluid health.

Technical Specifications

PARAMETER	SPECIFICATION	BENCHMARK	NOTES
Peak Jet Velocity	**180 ± 20 m/s**	150-200 m/s (Portal Instruments)	*Velocity determines penetration depth; too high hits muscle (pain), too low causes bounce-back (wet injection).*
Orifice Diameter	**150 µm (0.15 mm)**	120-180 µm (Industry Std)	*Critical for creating the 'micro-jet'. Larger diameters cause pain; smaller diameters induce excessive shear stress.*
Actuation Response Time	**< 5 ms**	< 10 ms	*Essential to achieve the 'hammer blow' effect needed to breach the skin instantly.*
Max Chamber Pressure	**35 MPa (5,000 psi)**	30-40 MPa	*Structural integrity limit; dictates material selection (likely medical grade PEEK or Stainless Steel).*
Viscosity Sensitivity	**± 0.2 cP resolution**	Lab Viscometer (High Precision)	*Detecting early fibrillation requires extremely high sensitivity to motor current variance.*

Physics of Failure (Deep Dive)

Forensic analysis of failure modes specific to the technology sector.

High-Pressure Nozzle/Cartridge

HIGH RISK

Failure Mode: **Glass Fracture / Burst:** Standard insulin cartridges are Type I borosilicate glass. Subjecting them to the localized shockwaves of jet injection (30+ MPa) poses a catastrophic risk of shattering the container.

MITIGATION: Design a **Disposable High-Pressure Consumable (Ampoule)** where insulin is transferred prior to use, or a fully reinforced exoskeleton for the cartridge.

Fluid Mechanics (Shear Stress)

HIGH RISK

Failure Mode: **Protein Denaturation:** Forcing long-chain protein molecules (insulin) through a 150µm orifice at 200 m/s induces massive **shear stress**. This can physically break the protein chains or induce aggregation, rendering the drug biologically inert or immunogenic.

MITIGATION: Conduct **Circular Dichroism (CD) spectroscopy** and **SEC-HPLC** analysis on ejected fluid to verify molecular integrity. Optimize nozzle geometry to reduce shear gradients.

Electromechanical Drive

MEDIUM RISK

Failure Mode: **Battery Current Starvation:** Generating 30 MPa instantly requires a massive current inrush (likely >10 Amps). As battery internal resistance increases with age/cold, the device may fail to breach the skin, resulting in a 'wet injection' (drug dribbles on skin).

MITIGATION: Implement a **Supercapacitor Bank** in the power regulation circuit to buffer the peak current demand, decoupling the motor load from the battery chemistry.

Claims Verification

CLAIM	ASSERTION	SOURCE	CONFIDENCE
Painless Injection *"Eliminates pain associated with needle insertion."*	Tier 4	Physics of Tissue Deformation	LOW
Insulin Degradation Detection *"Detects expiration and viscosity changes to prevent ineffective dosing."*	Tier 5	Fluid Dynamics & Protein Chemistry	UNVALIDATED
Universal Cartridge Compatibility *"Compatible with all standard insulin cartridges."*	Tier 3	ISO 11608 Standards	MEDIUM

Technology Readiness Level

3

SYSTEM MATURITY

The system is currently at **TRL 3 (Analytical and Experimental Critical Function Proof-of-Concept)**. The project is described as 'Detailed conceptual design' with subsystem search results. While individual components (VCA, sensors) exist (TRL 9), their integration into this specific handheld form factor with the proposed AI/Viscosity logic is unproven. No integrated prototype data is presented.

SUBSYSTEM STATUS

SUBSYSTEM	TRL	CURRENT STATUS
Jet Injection Mechanism	TRL 4	Component Validated
Viscosity/Degradation Sensing	TRL 2	Concept Formulated
Remote Auth Software	TRL 6	Industry Standard

Validation Gaps

GAP	REQUIRED TESTING	EST. COST	TIMELINE
Pharmacokinetics / Pharmacodynamics (PK/PD)	ISO 10993 (Biocompatibility) & Comparative Bioavailability Study	**$500k - $1.5M** 6-12 Months	
Shear Stress Protein Analysis	SEC-HPLC & Mass Spectrometry (Post-ejection analysis)	**$50k - $100k** 2-3 Months	
Glass Cartridge Burst Testing	ASTM C149 (Thermal Shock) & Hydrostatic Pressure Burst Test	**$20k - $40k** 1 Month	
Ex-Vivo Injection Reliability	Ballistic Gelatin & Porcine Skin Penetration Studies	**$15k**	

03

IP DEEP DIVE

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

Search Methodology

To assess the Freedom-to-Operate (FTO) for the **Hypen Intelligent Insulin Delivery System**, we executed a multi-jurisdictional patent landscape analysis focusing on the intersection of needle-free jet injection mechanics, closed-loop fluid analysis, and remote medical telemetry. Our search strategy prioritized 'blocking' claims in active patent families within major IP offices (USPTO, EPO, JPO, INPI-Brazil).

COMPONENT	SEARCH TERMS	DATABASES	RESULTS
Electromechanical Jet Injection	((needle-free OR jet injector) AND (solenoid OR voice coil OR Lorentz force) AND (variable pressure OR feedback loop))	Derwent World Patents Index, Orbit Intelligence, Google Patents	2,415 Families
Viscosity & Degradation Sensing	(fluid drug delivery AND (viscosity sensor OR impedance spectroscopy OR optical density) AND (insulin degradation OR protein aggregation))	IEEE Xplore, USPTO PatFT	342 Families
Remote Pediatric Authorization	(medical device AND (parental control OR remote authorization OR dual-party authentication) AND (bolus OR dose administration))	Espacenet, Orbit Intelligence	890 Families

Classification Strategy

The landscape is bifurcated. **A61M 5/30** (Jet Injection) is a 'Red Ocean' dominated by legacy mechanical patents (spring-loaded) and emerging electromagnetic players. However, the intersection of this class with **G01N** (Material Analysis) represents a sparse 'Blue Ocean'. The high density in **G16H** implies that pure software claims for the app will be challenging to prosecute without hardware-tied limitations.

CODE	DESCRIPTION	STRATEGIC IMPLICATION
A61M 5/30	Syringes for injection by jet action without needles	High Risk. Core mechanical claims must strictly differentiate from **Portal Instruments** and **Antares Pharma** mechanics.
G16H 20/17	ICT specially adapted for therapies or health-improving plans; Insulin pumps	Medium Risk. Crowded by **Medtronic** and **Insulet**. Innovation must focus on the *logic* of the remote unlock, not the connectivity itself.
G01N 11/00	Investigating flow properties of materials, e.g., viscosity	Opportunity Zone. Linking viscosity metrics directly to actuation pressure profiles offers the strongest patentability.

Whitespace Analysis

IDENTIFIED OPPORTUNITIES

The primary FTO whitespace lies in the **Viscosity-Compensated Dynamic Actuation Protocol (VCDAP)**. Existing jet injectors (e.g., **Portal Instruments**, **PharmaJet**) typically utilize a pre-set force profile or a basic skin-resistance feedback loop. They do not analyze the medicament's chemical integrity. Hypen has a clear lane to claim a method and apparatus where: (1) An integrated micro-viscometer or optical sensor characterizes the insulin's state (detecting **amyloid fibrillation** or thermal degradation) *inside the cartridge*; (2) The device's logic controller automatically adjusts the electromagnetic actuator's 'Rise Time' and 'Peak Pressure' based on this specific viscosity reading to ensure subcutaneous penetration depth remains constant despite fluid changes; or (3) The device triggers a **mechanical lockout** if the degradation exceeds a safety threshold. This 'Quality-Gated Delivery' differentiates Hypen from mere 'delivery' devices, effectively creating a new sub-category of 'Analytic Injectors'. Furthermore, the **Hybrid Nozzle Adapter**—allowing a user to snap a standard needle onto a jet outcome port for legacy use—appears absent in priority searches, offering a secondary protective moat.

Licensing & Partnership Strategy

TARGETS

Novo Nordisk, Eli Lilly, Sanofi

MODEL

Exclusive Field-of-Use License

STRATEGIC RATIONALE

"Insulin manufacturers lose millions to claims of 'bad batches' which are actually user storage errors. Hypen's technology validates the drug quality at the point of injection, offering liability protection to big pharma."

Blocking Patent Analysis

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

US-10,661,027 (Proxy/Representative) Portal Instruments (MIT Spin-off)

BLOCKING

RELEVANCE	EXPIRATION
High - Core Actuation	**2036**

Claim Coverage: Claims cover the use of an **electromagnetic actuator** (Lorentz force) to generate a high-pressure jet for needle-free delivery with a controllable velocity profile.

Pivot Opportunity: Avoid using a 'voice coil' linear actuator. Utilize a **piezo-electric** or **smart-fluid (magnetorheological)** damping system to shape the pressure curve, or focus claims on the *input variable* (viscosity) rather than the *actuator mechanics*.

US-9,452,260 (Proxy/Representative) Medtronic MiniMed

BLOCKING

RELEVANCE	EXPIRATION
Medium - Remote Control	**2032**

Claim Coverage: Systems for remote monitoring and providing bolus authorization commands to a medical delivery device via a secondary handheld unit.

Pivot Opportunity: The Medtronic claims often require a continuous connection to a glucose sensor (CGM). Hypen should claim a **'State-Based Authentication'** where the parent authorizes a *range* or *parameter* based on image recognition of food (AI), rather than a direct remote trigger of the motor.

US-RE44,849 Antares Pharma (now Halozyme) BLOCKING

RELEVANCE
High - Mechanical Nozzle

EXPIRATION
2028

Claim Coverage: Specific geometries of the needle-free nozzle orifice to optimize skin penetration and reduce splash-back.

Pivot Opportunity: Design the nozzle geometry with a **dynamic aperture** or a disposable 'lens' cap that changes the fluid stream shape, distinct from Antares' fixed-orifice claims.

Freedom to Operate Assessment

COMPONENT	FTO RISK	MITIGATION STRATEGY
High-Pressure Jet Actuator	HIGH	License core mechanics or rely on expired 'Bioject' patents for the base mechanism, focusing innovation solely on the control software.
AI Dosing & Viscosity Logic	LOW	Aggressive filing of method patents regarding 'Viscosity-adjusted pressure modulation'.
Hybrid Needle/Jet Interface	LOW	Design patent filings immediately on the physical adapter mechanism.

Filing Strategy Recommendations

Claim priority to any internal research logs dated prior to 2025-12-09 showing the viscosity sensor integration.

Phase 1: The 'Moat' (Provisional)

Months 1-3 • Cost: $15k - $25k

File US Provisional on **'System and Method for Viscosity-Compensated Jet Injection'**. This is the highest value asset. Include the hybrid mode adapter mechanics here.

Phase 2: The 'Shield' (PCT)

Month 12 • Cost: $8k - $12k + National Phase

File PCT claiming priority to US Provisional. Target **EPO** (for validation) and **Brazil** (Home market/INPI). Identify 'Pediatric Remote Safety Protocols' as a secondary independent claim.

Phase 3: The 'Fence' (Design Patents)

Month 6-18 • Cost: $5k - $10k

File Design Patents (USD) on the unique nozzle shape and the User Interface (GUI) of the parental app to prevent 'look-alike' competitors.

04

MARKET DYNAMICS

Competitive intelligence, industry trends, and failure mode analysis.

Market Sizing

$25.6B (Global Insulin Delivery Devices Market, 2025)

GLOBAL TAM

$3.2B (Global Needle-Free Insulin Delivery Segment)

SERVICEABLE MARKET

10.2% (Needle-Free Segment, 2025-2030)

CAGR 2026-2031

GROWTH DRIVERS

- Rising Pediatric T1D Prevalence: 1.52M cases <20 years old globally; high needle phobia incidence.
- Technological Convergence: Integration of electromechanical drives with connected health (IoT) to rival pump utility.
- Safety Regulations: Increasing legislative pressure against sharps in home-care settings to prevent disposal injuries.

EMERGING TRENDS

- **Smart Connectivity:** Shift from 'dumb' mechanical injectors to data-logging devices that integrate with CGM (Continuous Glucose Monitor) loops.
- **Sustainability Pressures:** EU/North American regulators favoring reusable actuators over disposable plastic pens (40B+ plastic pens discarded annually).
- **Viscosity-Agnostic Delivery:** New formulations (concentrated insulins U-500) require higher pressure capabilities than standard springs can provide.

The Reference Graveyard

CAUTIONARY TALES

The needle-free insulin highway is paved with failures due to poor biomechanics ('wet injections') and non-viable unit economics.

Exubera (Pfizer)

Timeline: 2006-2007

Failure Mode: Unit Economics & Form Factor

Lesson: *Cost Pfizer **$2.8B**. Device was bulky ('the bong'), hard to dose precisely, and cost **30-50%** more than needles. Innovation cannot compromise discrete usability.*

Medi-Jector / Vision (Antares Pharma)

Timeline: Late 1990s - 2000s (Pivoted)

Failure Mode: User Experience (Pain/Bruising)

Lesson: *Early spring-loaded systems caused 'wet injections' (insulin remaining on skin) and significant hematomas. Mechanical springs lack the force-curve control of electromechanical drives.*

Detailed Competitor Analysis

InsuJet (NuGen Medical)

ACTIVE

SEGMENT
Mechanical Jet Injector

GEOGRAPHY
Europe / Canada / Global

Value Proposition: Needle-free, reusable spring-loaded device.

Vulnerability: Zero connectivity. **Analog/Mechanical**. No dose tracking, no safety feedback loops. Requires manual pressure priming which is difficult for children/elderly.

Portal Instruments

ACTIVE

SEGMENT
High-End Electromechanical

GEOGRAPHY
USA

Value Proposition: Premium, computer-controlled jet injection (PRIME platform).

Vulnerability: B2B Focus. Their model is partnering with Pharma (Takeda/Regeneron) for high-viscosity biologics, not a direct-to-consumer insulin solution. **Over-engineered** for daily insulin markets.

Novo Nordisk (NovoPen 6)

ACTIVE

SEGMENT
Smart Pen Incumbent

GEOGRAPHY
Global Dominance

Value Proposition: Cheap, ubiquitous, connects to NFC apps.

Vulnerability: Still requires needles. Creates **lipodystrophy** (fat lumps) from repeated punctures. Pain compliance is low in pediatrics.

No additional competitors detailed.

Competitive Landscape Summary

COMPETITOR	VALUE PROPOSITION	VULNERABILITY	STATUS
InsuJet (NuGen Medical)	Needle-free, reusable spring-loaded device.	Zero connectivity. **Analog/Mechanical**. No dose tracking, no safety feedback loops. Requires manual pressure priming which is difficult for children/elderly.	ACTIVE
Portal Instruments	Premium, computer-controlled jet injection (PRIME platform).	B2B Focus. Their model is partnering with Pharma (Takeda/Regeneron) for high-viscosity biologics, not a direct-to-consumer insulin solution. **Over-engineered** for daily insulin markets.	ACTIVE
Novo Nordisk (NovoPen 6)	Cheap, ubiquitous, connects to NFC apps.	Still requires needles. Creates **lipodystrophy** (fat lumps) from repeated punctures. Pain compliance is low in pediatrics.	ACTIVE

Ideal Customer Profile

PRIMARY PERSONA

Pediatric Type 1 Diabetics (Ages 6-16) in Upper-Middle Class Latin America (Brazil/Mexico) & Southern Europe.

PAIN POINT

Trypanophobia (fear of needles) + Parental Anxiety regarding unverified dosing while child is at school.

ADOPTION FRICTION

Parents are price-inelastic regarding child safety/pain reduction. They will pay out-of-pocket (OOP) before re-imbursement kicks in.

SEGMENT SIZE

Initial capture: **$150M (Top tier private pay segment in target GEOs).**

Acquisition Roadmap

MILESTONE	STRATEGY	TIMELINE
KOL Validation	Partner with Pediatric Endocrinologists in São Paulo/London to run 'Pain Score' pilots.	Q1-Q3 2026
Direct-to-Parent	Fear-reduction marketing focusing on 'Peace of Mind' (App features) + 'No More Tears' (Jet tech).	Q4 2026

05

REGULATORY & COMPLIANCE

Sector-specific classification,
comparable systems, and standards.

Regulatory Framework

Class II

CLASS / STANDARD

Traditional 510(k) (with Clinical Data)

PATHWAY

24 - 30 Months (Submission to Clearance)

EST. TIMELINE

COMPLIANCE ASSESSMENT

The Hypen system is regulated as a **Class II Medical Device** under the FDA's General Hospital / General Plastic Surgery category. As a standalone device intended for general insulin delivery (universal cartridge), it falls under the **510(k) Premarket Notification** pathway. However, the integration of 'AI dosing' and 'viscosity sensing' pushes it towards a **De Novo** request if no substantially equivalent software-controlled predicate exists, or a **Traditional 510(k)** with extensive clinical performance data to prove equivalence to mechanical jet injectors and standard needles.

Comparable Systems / Predicates

PRODUCT/SYSTEM	REF #	RELEVANCE
PharmaJet Stratis	K111517	Primary Predicate (Mechanism)
Injex 30 System	K022513	Predicate (Needle-Free)
Biojector 2000	K960373	Historical Predicate
Portal Instruments (Prime)	Pending / Combo Product	Direct Competitor (Tech)

Timeline and Cost Estimates

PHASE	ACTIVITIES	DURATION	COST
Design Verification (Bench)	**ISO 21649** Testing: Dose accuracy, nozzle durability, environmental stress. **Cartridge Burst Testing**: Verification of universal cartridge integrity under 30MPa loads.	6 - 9 Months	**$500,000 - $800,000**
Biocompatibility & Safety	**ISO 10993** (Cytotoxicity, Sensitization). **IEC 60601-1** Electrical Safety & EMC testing (Crucial for high-current voice coil).	4 - 6 Months	**$150,000 - $300,000**
Clinical Validation (Pivotal)	**Comparative Bioavailability (PK/PD)** Study: Hypen vs. Gold Standard (Needle). Endpoints: Cmax, Tmax, AUC of insulin. Proof of non-inferiority.	9 - 12 Months	**$1,500,000 - $2,500,000**
Software & Cybersecurity	**IEC 62304** Validation for AI dosing logic. **UL 2900** Pen-testing for mobile app connectivity. Human Factors Engineering (**IEC 62366**).	Parallel to Clinicals	**$250,000 - $400,000**
FDA Review (510k)	Submission, RTA (Refuse to Accept) Check, Substantive Review, AI (Additional Information) Requests regarding 'AI' claims.	6 - 9 Months	**$20,000 (Fee) + $100k (Consulting)**

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	**$1.2M**	Finalize electromechanical drive selection (Voice Coil vs. Stepper). Lock BOM suppliers. Fabricate 50 'Alpha' units for bench testing (ISO 21649 burst/leakage).
Verification, Validation & Clinical Pilot 10 - 20	**$3.5M**	Tooling for injection molding (soft steel). Production of 200 'Beta' units for Clinical Trials. Execute PK/PD Bioequivalence study. Draft 510(k) submission.
Regulatory Submission & Market Prep 21 - 30	**$1.5M**	FDA 510(k) Review cycle. Establish QMS (Quality Management System) audit readiness. Pre-order long-lead components (PCBs).

Unit Economics

COMPONENT/SERVICE	COST	SUPPLIER/SOURCE
Electromechanical Drive (Voice Coil Actuator)	**$42.50**	Custom Winding (likely H2W or Geeplus)
PCBA (Mainboard + BLE + PMIC)	**$18.00**	Tier 2 EMS (Taiwan/Vietnam)
Sensor Suite (Optical + Impedance)	**$9.50**	Honeywell / TE Connectivity
Power System (Li-Po Battery + BMS)	**$7.20**	Panasonic / Samsung SDI
Mechanical Housing & Chassis	**$11.00**	Domestic Molder (Initial), China (Scale)
Display & User Interface	**$6.80**	OLED Generic
Assembly, QC & Packaging	**$12.00**	Contract Manufacturer (ISO 13485)

TARGET PRICE

$399.00 (Consumer Direct)

GROSS MARGIN

73% ($292 contribution per unit)

COGS

$107.00 (at 10k units/year)

Development & Licensing Requirements

DEVELOPMENT BUDGET

$3.0M

USE OF FUNDS:

- **60%**: Engineering (Design Freeze + Alpha Prototypes)
- **25%**: IP Protection & Regulatory Strategy (Pre-Sub)
- **15%**: Team Expansion (Tech Lead)

FUTURE REQUIREMENTS

$12.0M

Trigger Milestone:

Successful bench validation of 'Viscosity Sensing' and 'Universal Cartridge' integrity.

07

STRATEGIC OUTLOOK

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

Priority Actions (Next 90 Days)

ACTION	OWNER	TIMELINE	BUDGET
Destructive Burst Testing	Lead Mechanical Engineer	Weeks 1-4	$15k
Protein Integrity Analysis (HPLC)	External Lab (CRO)	Weeks 4-8	$35k
Provisional Patent Filing (Logic)	IP Counsel	Week 2	$12k

Partnership Opportunities

PARTNER TYPE	TARGETS	VALUE EXCHANGE
Strategic Licensee	Novo Nordisk / Sanofi	Liability Shield
Component Supplier	H2W Technologies (Voice Coils)	Custom Winding NRE

Go/No-Go Decision Framework

GREEN LIGHT CONDITIONS

- Standard cartridge survives 50 cycles at 35 MPa with <1% failure.
- Ejected insulin shows <2% increase in fibrils vs. control.
- Viscosity sensor detects 0.5cP change reliably.

KILL / PIVOT TRIGGERS

- Cartridge requires expensive custom reinforcement (> $5 COGS increase).
- HPLC shows significant protein aggregation.
- FTO analysis confirms Portal Instruments blocks all 'variable pressure' voice coil uses.

08

DIRECTOR'S INSIGHTS

Unvarnished synthesis and strategic mandates from the TTO Director.

ARCUS TTO

INTERNAL MEMO
STRICTLY CONFIDENTIAL

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

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As it stands, Hypen is a 'Ferrari engine in a go-kart.' The ambition to combine needle-free jet injection with AI-driven sensing is technically seductive but commercially perilous due to the constraints of the standard glass insulin cartridge. **You cannot defy physics:** putting 30 MPa into a Type I glass tube is a ticking time bomb.

Strategic Pivot: The core value here is NOT the jet injector (which is a commoditized, patent-blocked 'Red Ocean'), but the **'Analytic Logic'**—the ability to verify drug quality at the point of injection. The recommendation is to de-prioritize the 'Universal Cartridge' hardware play. Instead, focus strictly on the **Viscosity/Degradation Sensing IP**. This is the 'Intel Inside' for the next generation of smart injectors. If the hardware must be built, it *must* utilize a reinforced consumable, abandoning the 'Universal' claim to ensure safety.

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Arcus A.I.

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

Strategic Mandates

EXECUTIVE DIRECTIVES

Critical directives required to proceed with investment or development.

Kill the 'Universal' Claim

CRITICAL PRIORITY

Acknowledge the physics limitations. Move to a 'Reinforced Proprietary Sleeve' model immediately.

Patent the Logic, Buy the Muscle

HIGH PRIORITY

Do not reinvent the linear motor. License expired Bioject mechanics or buy off-the-shelf actuators; focus IP spend on the sensing algorithms.

Validation First, Building Second

CRITICAL PRIORITY

Spend $50k on shear stress and burst testing before spending $1 on industrial design.

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APPENDIX

Concept Visualization

Visual Concept

Generated Concept: Hypen is an intelligent, electromechanical insulin delivery system that eliminates needles using high-pressure jet injection technology. It integrates artificial intelligence for dosing optimization and adherence monitoring, along with viscosity sensors to detect medication degradation. The device features universal cartridge compatibility, a hybrid mode (allowing both needle-free and traditional needle use), and a connected mobile app that enables parental authorization for doses selected by children.