CHAZTRONICS, INC.

SubQ-Confirm

A delivery-confirmation subsystem for wearable insulin pumps, developed for integration by pump manufacturers.

Chaz Stephens / Executive pitch / Medical Device Product Management / August 2026

Silent infusion-site failures go undetected

Need a way to **detect when programmed insulin is not reaching the subcutaneous tissue** in people using wearable insulin pumps, so it can be corrected before hyperglycemia or ketoacidosis develops.

$5.25B

TAM · GLOBAL

3.5M pump users worldwide × ~$1,500/yr of confirmation disposables

$2.25B

SAM · UNITED STATES

1.5M US pump users; the closed-loop beachhead is ~900K ≈ $1.35B

$110M

SOM · 5 YEAR

5% of the US pump base — ~75,000 users on subscription sets

Limitations of the current standard of care

Site failures run 18–36 h into wear: insulin leaks at the cannula instead of being delivered, dosing goes uncertain — and no device alarms. Pump occlusion alarms (21 CFR 880.5730, QFG) are pressure-threshold only, so leakage and displacement are silent.

MedTech triad

Clinician — separates device failure from patient dosing at follow-up

Patient — alerted before DKA, not hours later by a high glucose

Buyer / VAC — one averted DKA admission ≈ $27,000

Dual-modality sensing in the infusion set

Disposable infusion set

Pressure sensor in the fluid line at the cannula hub; two electrodes under the adhesive, resistance falling when liquid bridges them.

Consumable · 72 h · SAL 10^{-6}

→

Reusable module

Snaps on with keyed, latching geometry. Battery, processor running the detection logic, authenticated radio, one indicator light.

Capital · ≤ 5 g · ≥ 96 h

→

Partner pump (OEM)

Has the fault code within 500 ms and alarms on its own cleared alarm system; carries the log for clinic review.

Integration · no delivery command

Detection logic — the four states

STATE	PRESSURE	SITE
Occlusion	High	Dry
Site leak	< 60% normal	Wet
Cannula out	Low	Dry
Working	Normal	Dry

REQ-FUN-01 shall sample pressure ≥ 10×/s and moisture ≥ every 5 s. REQ-FUN-02 shall report a leak only on 3 of 5 consecutive deliveries within 30 s while pressure stays < 60% of normal, which rejects sweat and showering. REQ-FUN-03 shall send the fault code ≤ 500 ms and resend every 30 s until acknowledged.

Constraints, standards, verification

REQ-NON-01/02 shall mass ≤ 5 g, add ≤ 3 mm height, and seal to 1 m for 30 min — IEC 60529

REQ-NON-03/04 shall run ≥ 96 h and signal low battery at ≥ 8 h left — IEC 60601-1 / -1-11

REQ-NON-05 skin contact ≤ 30 d — ISO 10993-1/-5/-10 ; set sterile to SAL 10^{-6}

Gel-block rig, all four states, n = 30 each — correct state in every trial

Two sweat arms, n = 30 — zero leak reports ; 100 induced faults — every code ≤ 500 ms

A sequenced pathway for two components

	UNITED STATES · FDA	EU · MDR 2017/745	CANADA · MDB
Component A disposable set	Class II, code FPA, 21 CFR 880.5440	Class IIa, Annex VIII Rule 7 — surgically invasive, short-term	Class II, Schedule 1 Rule 11
Component B electronics module	No matching code: Accessory Request §513(f)(6) or De Novo	Class IIa, Annex VIII Rule 10 — active monitoring	Class II, Schedule 1 Rule 5
Route	Track A: 510(k) citing K181718 · Track B: accessory or De Novo. §524B applies to both	Notified Body assessment, Class IIa	Class II MDL application
Fee & time	510(k) $28,653 / $7,163 SB · 513(g) $8,596 · De Novo $191,020. Track A 4–8 mo · Track B 9–18 mo	≈ €70K–220K all-in · 18–24 months	$632 CAD + $460/yr · 15-day target

Predicate & substantial equivalence

Predicate K181718 (BD FlowSmart / MiniMed Pro-Set) — same class, code and regulation. The hub sensor alters no lumen dimension or delivery accuracy ; electrodes are surface-contact only.

Reimbursement architecture

No new code: sets bill under the existing pump-supply pathway A4225 , pump under E0784. Diagnosis E10.10 / E10.65 / T85.614 ; averted admission MS-DRG 637–639; coverage under the Part B DME infusion-pump LCD. No CPT applies — self-applied at home, no billable procedural work; payment is taken OEM-side in the $10–12 premium.

Evidence sized to event incidence, not enrollment

Substantial equivalence rests on bench verification — **no powered trial gates clearance** . Accuracy evidence accrues post-market against a blinded, clinician-adjudicated reference standard.

30

PRE-MARKET

Tolerability and wear cohort, 2 sites, 4 weeks — skin response and false-positive rate, not powered accuracy

79

EVALUABLE

$N = (Z\alpha+Z\beta)^2\ p(1-p)/\delta^2$, $p = 0.85$, $\delta = 0.10$, $\alpha = 0.05$ one-sided, 80% power — 93 with a 15% attrition buffer

465

REGISTRY TARGET

Monitored subjects at a 20% event rate — reached in weeks at launch scale, OEM co-funded

Endpoints

Safety, pre-market: no electrode-attributable skin reaction through 30 d of wear, no failure-to-alarm. Efficacy, registry: sensitivity and specificity of the site-integrity alarm, one-sided 95% lower bound above 0.75.

Change control — Path B (ECC)

Fixed-threshold, non-adaptive logic — no PCCP applies . Gates: adhesive peel + aging n = 30, ISO 11607, IEC 60601-1/60529 on module change, firmware threshold change re-runs the bench protocol. Re-file on indications, new contact material, or autonomous pump coupling.

PMCF, RWE & HEOR

The registry is the accuracy study: alarm events against confirmed outcomes, MAUDE trending, DKA admissions per 1,000 user-years vs. baseline, cost per avoided admission, field sensitivity quarterly. Funded from revenue and OEM cost-share — they need it for their own claim.

Top hazards concentrate in silent failure modes

HAZARD	HAZARDOUS SEQUENCE	PRE	RISK CONTROL & STAGE	POST	RESIDUAL
HAZ-01 Usability	Module seated but not latched → monitoring never starts; the user believes it is active	S4 · P3	Stage 1 keyed snap that cannot seat wrong + tactile latch · Stage 2 seating-contact detection gates the active state	S4 · P1	ALARP
HAZ-02 Usability	Adhesive over hair, an old site or damp skin → electrodes out of contact, or pre-bridged	S4 · P4	Stage 2 power-on self-test of electrode continuity and pressure baseline; dual-modality confirmation with debounce	S4 · P1	ALARP
HAZ-03 Software	Link to the pump lost to range, interference or a firmware update → silent reversion to unmonitored use.	S4 · P3	Stage 2 authenticated paired link, keep-alive heartbeat, pump-side loss-of-monitoring alarm the user acknowledges	S4 · P1	ALARP
HAZ-08 Software	Electrode detachment reads high resistance, classified "no fault" → fail-danger false negative	S4 · P3	Stage 1 recessed electrodes, liner peel exposing them last · Stage 2 a third reported state, indeterminate	S4 · P1	ALARP

Full URRA carries eight hazards: HAZ-04 battery and HAZ-07 telemetry close at Stage 1, HAZ-06 at Stage 2–3, HAZ-05 dermatitis at Acceptable.

Hierarchy, traceability & RBA

Controls taken in order — inherent safety by design → protective alarms → IFU and training : six of eight close at Stage 1 or 2, never on labelling alone. Severity stays S4 (the harm is still DKA), only probability moves; RBA holds — the device is non-therapeutic.

Usability validation — IEC 62366-1

Formative n = 5–8 per group, 2–3 rounds pre-freeze on shells and screen mockups. Summative ≥ 15 per group (adolescents, adults, caregivers — 45 min.), production-equivalent in a simulated home: low light, interruption, out-of-range. Zero prompting, 100% critical-task success , root-cause debrief per error.

Commercialization through the OEM channel

A **$3.5M seed** to resolve the Component B pathway, then a **$12M Series A** to carry Component A through V&V, clearance and launch — no pre-market pivotal to fund.

Q4 2026	Q2 2027	Q4 2027	Q1 2028	Q3 2028	2029
Pre-Sub + 513(g)	**Design freeze**	**V&V + summative**	**510(k) filed**	**Commercial launch**	**Component B**
pathway resolved	PRD + firmware locked	n ≥ 15 per group	predicate K181718	OEM channel + 2 KOLs	accessory + MDR

Unit economics — razor-blade

Blade: $10–12 per-set premium to the OEM, $11 ASP. COGS ≈ $3.20 (sensor $0.90, electrode-adhesive $0.55, assembly and sterilization $1.05, pack and yield $0.70) → 71% gross margin. Razor: module placed as capital at $180, COGS $62 → 66%. At 122 sets per user-year, 75,000 users ≈ 9.2M sets ≈ $101M.

Go-to-market & VAC

No direct sales force — the set ships through the OEM's channel and reps. Two academic endocrinology centers anchor the registry and publish the detection data. VAC dossier: DKA admissions per 1,000 user-years — one averted $27K admission against ~$1,300 of annual sets.

Projections, ask & exit

Revenue $4M · $18M · $46M · $78M · $110M across 2028–32, EBITDA positive in 2031. Use of funds: $12M covers V&V, summative, the 30-subject cohort and launch; accuracy evidence is post-market and OEM co-funded. Exit to Medtronic Diabetes, Abbott, Dexcom.