Solving the nurse shortage

with Ella AI Nurse Assistant

An always-on, contactless care system for memory care. Ella senses movement 24/7 and turns everyday activity into early insight, so every nurse can safely care for more residents.

University of Minnesota

Ambient Intelligence

MN CUP

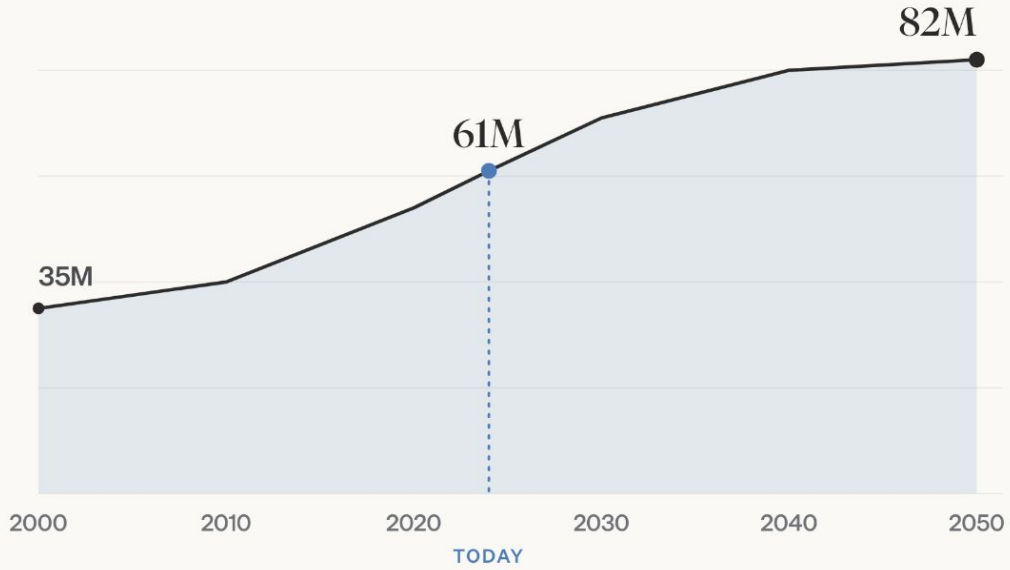
2026 Semifinalist Pitch Deck

01 The Problem

The global shortage of nurses

Americans aged 65 and older

U.S. population, in millions



1 in 4

seniors falls every year

260,000

U.S. nurse positions unfilled

The residents who need watching most are watched over by no one.

Source: U.S. Census projections · HRSA health workforce supply & demand

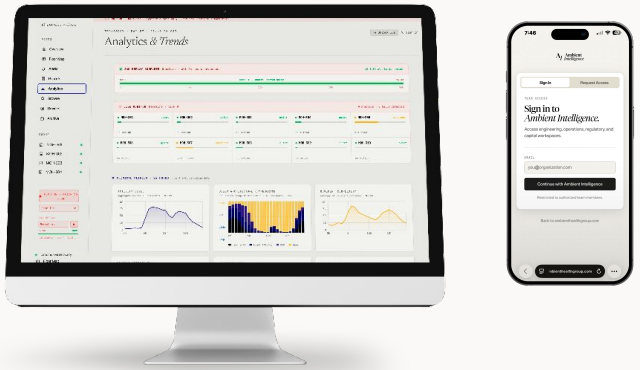
02 The Solution

Ella AI Nurse Assistant

Running quietly in the background **24/7,** Ella AI detects movement and sends alerts for falls and other events.

→ Ella AI learns each resident's patterns over time and informs nurses where **earlier intervention may improve care.**

Ella AI is powered by **Ambient Intelligence**, contactless sensing with no camera and no wearable.



Ella AI Nurse Dashboard
Desktop and mobile

Ella AI Device
3 per resident

03 Ella AI Mobile and Desktop

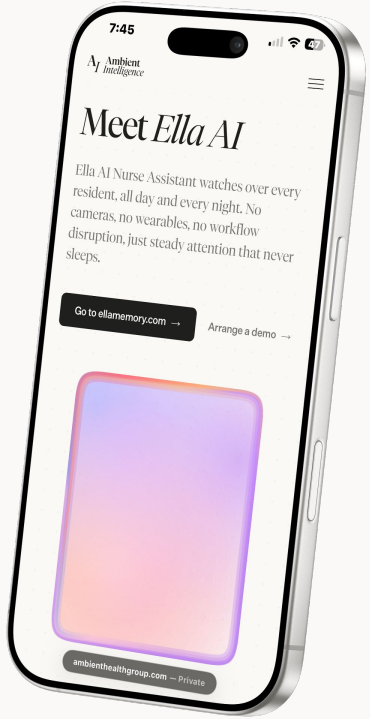
Mobile alerts and deeper desktop data

The Ella dashboard gives caregivers a **single, live view of every room** on the floor, flagging active concerns like falls or unusual nighttime activity so staff know where to focus first.

Nurses use it to

- → Prioritize rounds.
- → Back clinical judgment with **objective data**.
- → Catch gradual changes **early enough to act**.

Over time, it becomes a running record of each resident's baseline.



04 Ella AI Nurse Assistant

Ella writes daily nurse notes for each resident

Ella AI *Nurse Assistant*

Ella Today · 8:15 PM

Good evening, Sarah. Here is how Margaret did today.

She slept about seven hours, with one brief wake-up near 2 a.m., which is typical for her. Her resting heart rate and breathing stayed in their normal range overnight. She was up and moving by 8:15 and had a steady, active morning.

No falls, no concerns, and nothing the care team needed to step in on. A calm, good day. I will check in again tomorrow, and reach out right away if anything changes overnight.

Ella

A note from Ella

No cameras. No wearables.

Privacy-first by design.

Contactless radar senses movement, falls, and vitals. No one is watched, recorded, or asked to wear a device.

Privacy-First

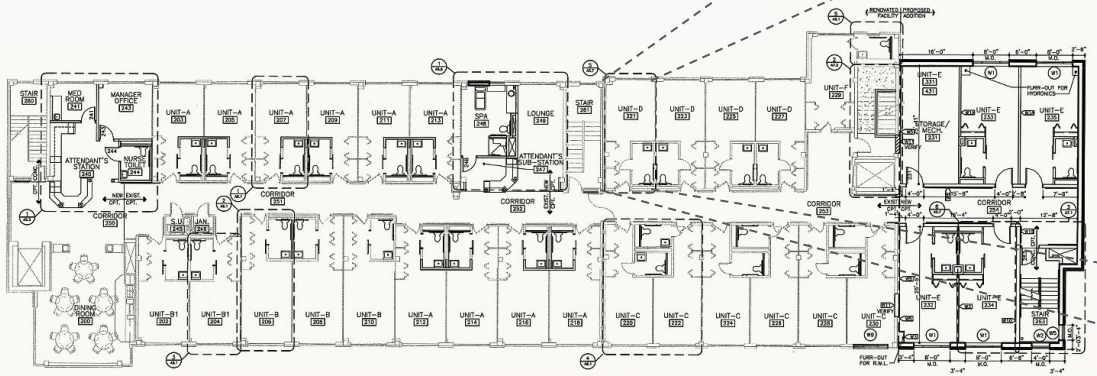
05 Ella AI for Campuses

The whole campus, One platform. Every resident.

Ella AI is the **intelligence layer** that informs care decisions today while building future understanding of mobility, cognitive decline, and treatment outcomes across aging populations.

Every resident room runs **three contactless sensors** (over the bed, in the living area, in the bath). Using ambient radio waves, they sense movement continuously and privately: **no cameras, no wearables**.

→ **More than a sensor.** Always-on room awareness that helps nurses see **what is happening now, and what may be changing next**.



Pilot Facility

Senior care room layout

06 Impact

One care team, connected across the continuum

Ambient Intelligence

STAGE 01
In-home
Aging in place at home, with early insight for family.

STAGE 02
Independent living
Active and independent, with minimal support.

STAGE 03
Assisted living
Daily support, with dignity and privacy preserved.

STAGE 04
Skilled nursing
Round-the-clock clinical care and monitoring.

STAGE 05
Hospice
Comfort and dignity through end of life.

Ella AI puts *nurses, caregivers, and families* on one live view of each resident, so a change one person sees reaches the whole team in seconds. That shared picture follows the resident across the continuum of care, and no hand-off falls are missed.

07 Market

Our beachhead is memory care

Ambient Intelligence

Memory care is our beachhead: the one segment where *every alternative fails.*

Residents living with dementia cannot be relied on to:

- → **Wear a pendant.**
- → **Charge a device.**
- → **Press a button.**

It is also the highest-acuity, highest-willingness-to-pay slice of a **1.5M**-resident, **$1.8B** SAM, focused on falls, wandering, and overnight decline.

08 Competition

No wearable, no camera, no compromise

Ambient Intelligence

CAPABILITY	Ambient Intelligence DUAL RADAR	Vayyar Care RADAR	SafelyYou CAMERA	Sensi.AI AUDIO	CarePredict WEARABLE
No wearable to charge or press	✓	✓	✓	✓	–
No cameras, works in bathrooms	✓	✓	–	✓	✓
Works with zero resident cooperation	✓	✓	✓	✓	–
Fall and long-lie detection	✓	✓	✓	○	○
Continuous vitals, heart and breathing	✓	○	–	–	○
Gait and mobility biomarkers	✓	–	–	–	○
Predicts decline, not just reacts	✓	○	–	○	✓
Whole-room, every room, not bedside only	✓	✓	✓	○	○
Built for memory care	✓	○	✓	○	○
Routes the right alert to the right caregiver	✓	○	○	○	○

09 Data and Clinical Evidence

Innovation in digital biomarkers

The most advanced aging-care sensing system in the world.

25+ **digital biomarkers** from one contactless install

ACROSS FIVE BIOMARKER DOMAINS

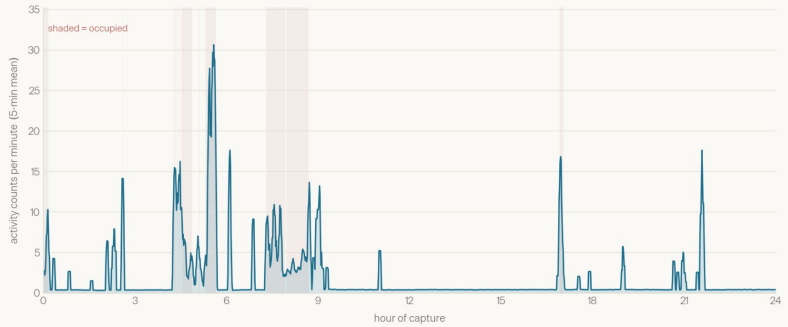
1. **Cardiac and respiratory**
2. **Sleep**
3. **Gait and mobility**
4. **Behavior and routine**
5. **Safety events**

Measured passively, with no wearable and no camera. Validated on the bench and in physical-therapy testing, and measured longitudinally in an IRB-approved pilot at Mount Olivet Home.

Activity over 24 hours

VITALS NODE, BENCH

Per-minute ambient activity with presence, contactless and continuous



Spatiotemporal gait

MICRO-DOPPLER

Standard clinical gait parameters recovered from a single radar walk

Gait speed	Cadence	Step length	Stride length
0.63 m/s	100 steps/min	0.38 m	0.76 m
normal 1.2 to 1.4	normal 100 to 120	normal 0.6 to 0.7	normal 1.2 to 1.4

10 Patent Pipeline

Defensible by design

Intellectual property

Patent pending, filed as a PCT application through the University of Minnesota. The moat is dual-radar sensing paired with on-device AI, compounding with every install.

Patent filed
Foundational platform coverage.

Filed · PCT

Filings in preparation
Ahead of each new capability.

Drafting

Roadmap of filings
Mapped to the product roadmap.

Planned

Held as trade secrets
Where secrecy protects best.

Protected

Cardiac & Respiratory
6
BIOMARKERS

Heart rate · HRV · Breathing rate

Sleep
4
BIOMARKERS

Duration · Interruptions · Restlessness

Gait & Mobility
6
BIOMARKERS

Gait speed · Transfers · Unsteadiness

Behavior & Routine
5
BIOMARKERS

Activity · Routine deviation · Wandering

Safety Events
4
BIOMARKERS

Falls · Long-lie · Distress

Every feature updates over the air.
New biomarkers roll out to the entire fleet as software, no new hardware.

25+ validated digital biomarkers across five domains

11 Timeline

From bench to bedside

MN CUP

Foundation	Detection validated	PCT patent filed	MVP device built	Pilot · Minneapolis	First paying customer	Cash-flow positive
the R&D years	at 94% accuracy	University of Minnesota	and bench-tested	Care Facility	commercialization	self-funding
2019 *to* 2023	2023	2024	2025	2026	2027	2028

Founded on a contactless senior-care concept; **fall & vitals algorithms** matured to working on-device detection.

READING THE CHART
- Secured or in hand
- Planned

Funding

- Founder-funded R&D
- Minnesota Partnership $248K
- Pre-seed $500K
- Seed $2M
- Series A $5M
- Bakken ENDURE · accelerator
- gener8tor $100K
- R&D · new patents, 25+ biomarkers
- AWS credits $15K

Regulatory & go-to-market

- Prototype & bench test
- Wellness · ships now
- Class I · MDDS
- Class II · De Novo decline index
- Class II · 510(k) first clearance
- Pilot & commercial launch
- Scale

Publications & IP 9 peer-reviewed papers 1 PCT patent, UMN

2023 to 2025 · Alzheimer's & Dementia, AAIC, Design of Medical Devices

12 Business Model

Private pay today, reimbursement tomorrow

Family pays, with reimbursement upside.

Ella earns **$99 a month from families on day one**, with no clearance or claim needed. In Year 2 to 3, as Medicare and Medicaid reimbursement come online, revenue per resident stacks up to **$3,036 a year**.

Year 1 **Family pays**

$1,188 / resident / yr · $99/mo

Year 2–3 **With reimbursement**

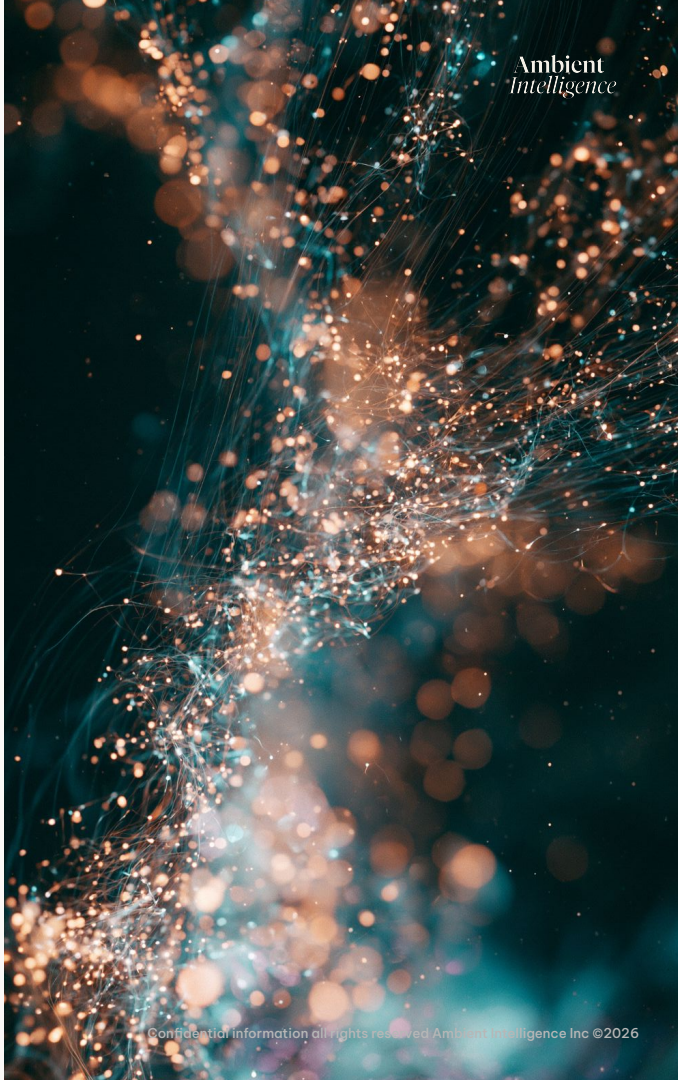
$3,036 / resident / yr · $253/mo 2.5× Year 1

Family pays, $1,188/yr Reimbursement stack, Medicare RPM + CCM, +$1,848/yr

REIMBURSEMENT CODES

99454	Medicare RPM, device supply and data	$44/mo
99457	Medicare RPM, management, first 20 min	$48/mo
99490	Medicare CCM, first 20 min	$62/mo
S5161	MN Medicaid PERS, alternative path	~$40/mo

Medicare clinical stack is $154/mo on top of the $99 family-pay, for $253/mo combined. No reimbursement is required to reach the $50M ARR plan; it is upside.

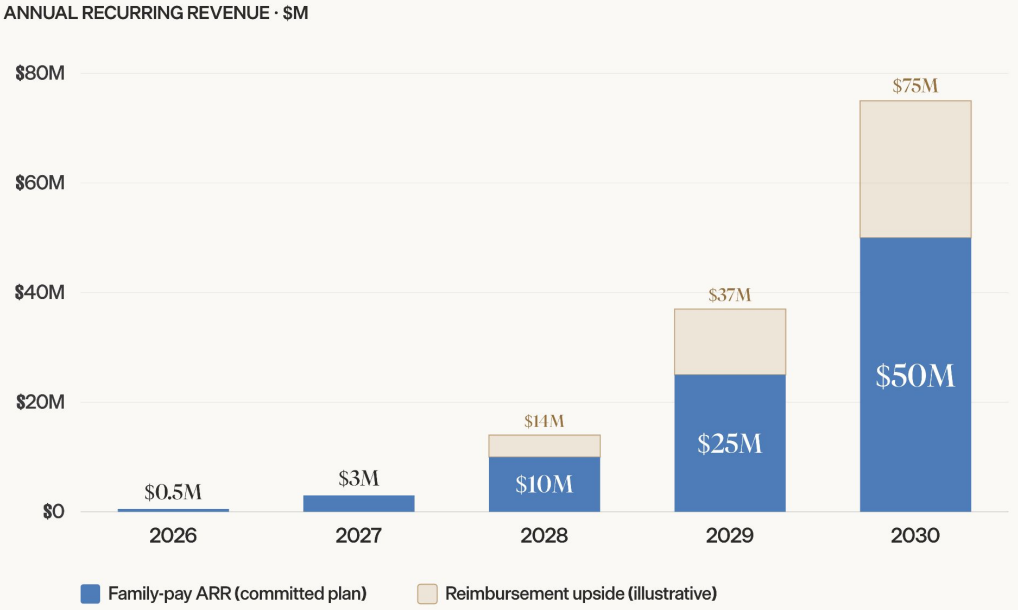


13 Financials

Recurring revenue, software margins, real profit

Ambient Intelligence

- → Ambient sells recurring software at **$99 per resident per month** ($1,188 per year) on multi-year agreements, growing ARR from **$500K in 2026 to $50M by 2030** on the family-pay floor alone.
- → Software **gross margin exceeds 85%** with hardware leased off balance sheet.
- → Medicare reimbursement of up to **$3,036 per resident per year** stacks as upside beyond that plan.
- → A single **$500K pre-seed** carries the company to cash-flow positive in 2028, scaling to roughly a **$21.5M operating profit (43% margin)** by 2030.



14 Team & Advisors

The team building Ella AI Nurse Assistant

FOUNDER

Brian Bradley Johnson

Founder & CEO

Biomedical engineer building the sensing hardware, the on-device AI, and the clinical science behind Ella.

TEAM

Greg Shultz

Marketing & Strategy

Leads brand, marketing, and go-to-market.

Gavin Phillips

Electrical Engineer

Designs the circuitry and power electronics.

Isaac Wodele

Data Science

Builds the on-device AI and data pipeline.

Abdul-Awwal Adesalu

Cybersecurity

Secures the platform and protects resident data.

Johannes Wintara

Mechanical Engineer

Designs the device enclosures and mounts.

ADVISORS

Dr. Simon Mittal

Chief Medical Officer

Clinical strategy, validation, and oversight.

Dr. Britni Bolstad

Nursing Advisor

Frontline nursing and care workflows.

Dr. Jaideep Srivastava

Technical Advisor

AI, data systems, and research at scale.

Kyle Rolfing

Strategic Advisor

Healthcare venture building and growth.

Dr. Randall Ross

Strategic Advisor

Leadership and organizational strategy.

Tim Hokanson

Healthcare Advisor

Senior-living operations and administration.

15 The Ask

From pilot to paying facilities

$500K pre-seed

USE OF FUNDS

Product and AI	$200K · 40%
Clinical and regulatory	$150K · 30%
Go-to-market	$100K · 20%
Operations	$50K · 10%

IN TWELVE MONTHS, THIS DELIVERS

01 Clinical pilot funded and sited

Grant-funded human-subjects study, IRB in process at the University of Minnesota, with contactless monitoring planned across 10 residents and 30 devices in a Minneapolis memory-care center.

02 First paying facilities

Recurring revenue on the $99 per-resident family-pay floor, starting with the pilot site and its referrals.

03 Reference site and case study

A validated memory-care site that anchors early sales and referral proof.

04 Commercial pipeline

A qualified pipeline of memory-care operators lined up for multi-site rollout.

1,000 residents reached

Year-one target on this raise

100 nurses assisted by Ella

Year-one target on this raise

Ambient Intelligence

The appendix, in three sections.

The detail behind the deck. Each page carries its number in the header, so any claim in the pitch can be cited directly, for example *see A04*.

Nine reference pages, one system. *Every page shares this palette, so the set reads as one appendix.*

Pre-clearance plan. No FDA clearance, listing, or QMS certification is represented as achieved. Milestones are candidate pathways to confirm with FDA via Pre-Submission.

Ambient Intelligence

Ship now, clear deliberately.

One dual-AoP contactless-radar platform, split across four FDA pathways of rising risk and burden. The low-risk features ship immediately to fund and de-risk the higher-clearance ones, standing up the quality system and the real-world data engine along the way.

Ships now Future clearance

01 Land

SHIPS NOW

NON-DEVICE + CLASS I

Ship **general-wellness** features, **MDDS** data services, and non-device caregiver notifications. Generates revenue, stands up the QMS, and starts the real-world data engine with the MOH pilot.

02 Clear

PRIMARY NEAR-TERM PUSH

FIRST 510(K)

Take contactless **vital-sign monitoring** through 510(k), the strongest predicate path. Builds an FDA track record and evidence pipeline, and unlocks alarm and monitoring claims.

03 Define

FUTURE CLEARANCE

DE NOVO FLAGSHIP

Take the cognitive and functional **decline index** through De Novo with Breakthrough and a PCCP, powered by Phase 1 to 2 data and QMS maturity. Creates the category and the predicate moat.

Four tiers, one platform, rising clearance burden

General Wellness	Class I MDDS	Class II 510(k)	De Novo
NON-DEVICE	510(K)-EXEMPT	CLEARED PREDICATE	NEW CATEGORY

LOWER RISK — RISK & BURDEN RISE, LEFT TO RIGHT →

Hold the line

Every tier has an explicit claim boundary. Add a **fall alarm**, a **numeric vital readout**, or a **disease-risk claim** and the feature jumps a tier. The boundary is enforced in code, not in policy.

Architecture as strategy

The regulated fall algorithm is a separate signed package, **ambientsamd**, consumed as a pinned dependency by the non-regulated device agent. Threshold and alerting policy live **outside** the regulated boundary to shrink the audit surface. Governance: protected main, two reviewers, signed commits, CI gates.

Sequenced, not simultaneous. *Phase 1 ships today as general-wellness and Class I to fund the program and seed the data engine; the Phase 2 510(k) and Phase 3 De Novo are planned, not achieved. The QMS is still being stood up.*

Pre-clearance plan. No FDA clearance, listing, or QMS certification is represented as achieved. Pathways are candidate routes to confirm with FDA via Pre-Submission.

Ambient Intelligence

The intelligence is the device.

Ella AI is a **Software as a Medical Device**. The fall, vitals, and decline intelligence is the **regulated component**; the contactless radar is the data front end. Each capability routes to the FDA tier its claim requires, so revenue does not wait on clearance.

Ships now Future clearance

IMDRF SAMD RISK MATRIX

Rows: healthcare situation · Columns: decision the software informs

	Treat or diagnose	Drive clinical management	Inform clinical management
Critical	IV	III	II
Serious	III	**II** ELLA AI	I
Non-serious	II	I	I

Category II: a serious situation where the software drives clinical management, which sets Class II and IEC 62304 Class B.

WORKING INTENDED-USE STATEMENT

Detect falls and alert caregivers.

INTENDED USER

Facility care staff, not medically trained

USE ENVIRONMENT

Memory-care and senior-living rooms

Formal indications, contraindications, and labeling are being finalized pending FDA Pre-Submission. No finalized indications are claimed today.

FEATURE-TO-TIER ROUTING

General Wellness — SHIPS NOW

Not a device

- Activity, mobility & sleep trends
- Presence notifications
- Wellness score

Class I MDDS — SHIPS NOW

Register + list

- MDDS store, display & transfer
- Care dashboards
- EHR export

Class II 510(k) — PRIMARY TARGET

Predicate equivalence

- Contactless respiration
- Contactless heart & pulse
- Fall detection + caregiver alarm
- Long-lie / immobility
- Absence-of-vitals alarm

De Novo — FUTURE CLEARANCE

Novel, reserved

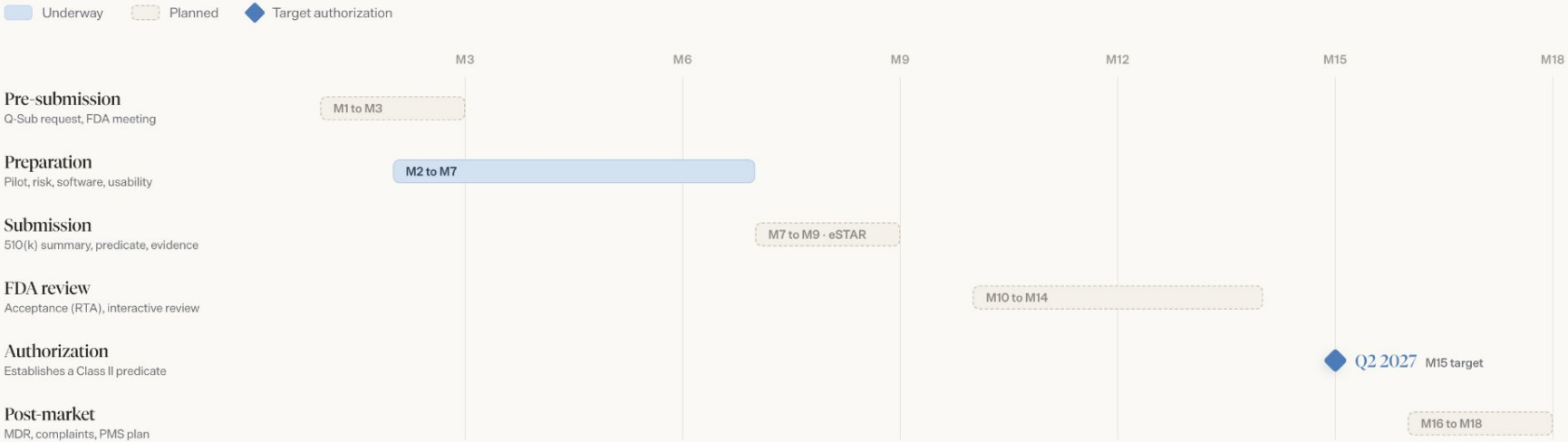
- Cognitive / functional decline index
- Neuro micro-Doppler markers
- Multi-parameter frailty index

Candidate pathways, not clearances. *No FDA clearance, listing, or QMS certification has been achieved. Every SaMD category and device class shown is a candidate regulatory pathway to confirm with FDA, and the working intended-use statement is not a finalized indication for use.*

Ambient Intelligence

Free FDA feedback before every gate.

The primary path is **510(k)** for contactless vitals and monitoring events; **De Novo** is reserved for the novel decline index. A Q-Submission precedes each gate to de-risk predicate, test plan, and protocol, so no evidence dollar is spent blind.



Q-Submission levers **Pre-Sub** free FDA feedback · **513(g)** classify decline index · **Breakthrough** · **PCCP** ML updates · **510(k) Third-Party** · **EU MDR / CE**

Two framings coexist in the record. *The current strategy routes vitals and events to 510(k) and reserves De Novo for the decline index; an earlier roadmap placed contactless-radar fall detection at De Novo. Both Pre-Sub items are planned, not confirmed, and the QMS is still being stood up.*

Pre-clearance plan. No FDA clearance, listing, or QMS certification is represented as achieved. Milestones are candidate pathways to confirm with FDA via Pre-Submission.

Ambient Intelligence

Every claim has a cleared predicate.

Ella AI routes each capability to a nearest cleared predicate device, by FDA product code. The cleared predicates are single-radar; our **dual-AoP two-sensor fusion** is the one technology difference argued in the substantial-equivalence rationale. Only the decline index has no predicate, which is the point of its **De Novo**.

Cleared predicate No predicate, De Novo

CAPABILITY	FDA CODE	CLASS & 21 CFR	NEAREST CLEARED PREDICATE
Data store, display & transfer MDDS	OUG	Class I · 880.6310	510(k)-exempt, no predicate required
Contactless respiration rate	BZQ	Class II · 868.2375	**Circadia C100** K200445 · **EarlySense** K131379
Contactless heart & pulse rate	DRT	Class II · 870.2300	**Xandar Kardian XK300** K202464 · **Circadia C200** K234003 · **Neteera 130H** K231733
Absence-of-vitals alarm	FLS / NPF	Class II · 868.2377 / 870.2300	Apnea monitor plus cardiac monitor with a rate alarm
Fall detection + caregiver alarm Primary near-term target	PJO / PJP	Class I · 880.2400	Fall-prevention alarm / sensor. No contactless-radar fall device cleared yet; confirm framing in Pre-Sub.
Long-lie & immobility alert	BZQ / IWE	Class I to II · 868.2375 / 892.5780	**EarlySense** movement and turn · light-beam position monitor (IWE)
Cognitive & functional decline index De Novo, no predicate	none	New classification	*No predicate, that is the point. Precedent: IDx-DR DEN180001, Cognoa Canvas Dx DEN200069.*

Cleared predicates are single-radar. *The dual-AoP two-sensor fusion is the technology difference argued in the substantial-equivalence rationale.*

Pre-clearance plan. No FDA clearance or listing is represented as achieved. Product codes and predicates are candidate pathways to confirm with FDA via Pre-Submission.

Ambient Intelligence

From a validated algorithm to a cleared claim.

The fall-detection algorithm is analytically validated at **94% sensitivity and specificity**. The MOH clinical pilot is underway, and each pathway has defined endpoints and statistical targets, so evidence is built to the exact bar each claim requires.

Complete Planned

94% SENSITIVITY

94% SPECIFICITY

ANALYTICAL VALIDATION · CFAR FALL DETECTION

2,400 radar frames · 100 scripted fall events · ground-truth adjudicated

STUDY & METHOD	KEY RESULT	STATUS
Analytical validation CFAR FALL DETECTION, OFFLINE	Se 94% · Sp 94%, ground-truth adjudicated across 2,400 frames	Complete
Benchtop, range & angle DETECTION ENVELOPE	4.5 m range · ±15° azimuth · IWR6843AOP at 1 Hz: PASS	Complete
Clinical pilot, MOH PROSPECTIVE, IN-FACILITY · ODAT-FUNDED	90 days · 30 units · 10 residents · IRB review in process, ClinicalTrials.gov registration in progress	Active
Comparative vs EarlySense HEAD-TO-HEAD	6 rooms · 30 days · post-pilot	Planned
Post-market, real-world falls SURVEILLANCE	n=200 events · 3+ facilities · 12 months	Planned

510(k) VITALS + EVENTS

Primary near-term

- **Respiration** vs capnography / RIP → Bland-Altman, RMSD ≤ ~3 breaths/min
- **Heart / pulse** vs ECG / pulse-ox → within ~5 bpm or 10%
- **Fall detection**, video-adjudicated → Se ≥ ~85 to 90% (CI lower bound above goal), low false-alarm rate
- **Immobility** → sensitivity + time-to-detect

Likely Non-Significant-Risk · abbreviated IDE + IRB (21 CFR 812) · GCP per ISO 14155

De Novo DECLINE INDEX

Future

- **Three-layer validity** → analytical + concurrent + predictive
- **Concurrent** vs MoCA / MMSE → AUC ≥ ~0.80
- **Prognostic** → Cox time-to-event / hazard ratio
- **Cohort** in the hundreds, longitudinal (months to years)

Strategy · pursue Breakthrough Device + PCCP

Evidence is built to each claim's bar. *Analytical and benchtop validation are complete; the MOH pilot is active but not yet reported. Comparative and post-market studies are planned, and every target shown is a design goal to confirm with FDA before it becomes a cleared claim.*

Pre-clearance plan. No FDA clearance, listing, or QMS certification is represented as achieved. Endpoints and statistical targets are candidate study designs to confirm with FDA via Pre-Submission.

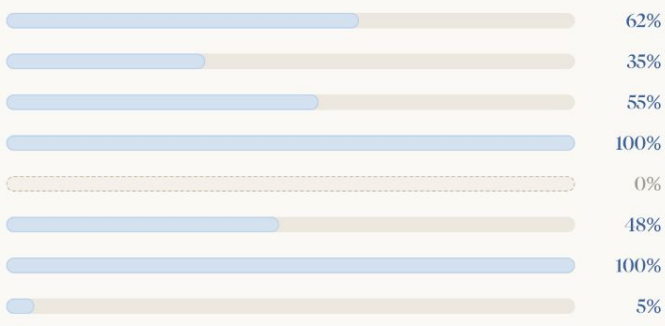
Ambient Intelligence

One quality system, mapped to the standards.

The QMS is built to **21 CFR 820 (QMSR)**, which since February 2 2026 incorporates **ISO 13485:2016** by reference. It is being stood up now as the Phase-1 gating deliverable, tracked openly against every governing standard.

Complete In progress / pending

STANDARDS COMPLIANCE MATRIX



QMSR · 21 CFR 820

ISO 13485 adopted by reference.

§820.7 adopts ISO 13485:2016 by reference

Clauses 4 to 8 hold the core QMS requirements

§820.10 · §820.35 · §820.45 add FDA records and labeling

In force since 2026-02-02

~30% overall QMSR conformance being stood up now

IEC 62304 CLASS B SOFTWARE LIFECYCLE

7 Requirements
SRS-001 to 007 VERIFIED

11 Verification tests
Coverage 100%

6 SOUP entries
Third-party components logged

1 Release
v0.1.0 DRAFT

DESIGN & DEVICE RECORDS

DHF DRAFT	**DMR** PENDING	**DHR** TEMPLATE	**RMF** DRAFT	**Part 11** 45%
Design History File	Device Master Record	Device History Record	Risk Management File	Electronic records

The QMS is being stood up as the Phase-1 gating deliverable. *Bars show current, self-assessed conformance against each standard, not certification. IEC 60601-1 electrical safety and HIPAA safeguards are in place; EMC testing and MDR reporting procedures have not yet started.*

Pre-clearance plan. No FDA clearance, listing, or QMS certification is represented as achieved. Conformance percentages are internal self-assessments to confirm through audit and FDA Pre-Submission.

Ambient Intelligence

Safety and security, engineered in.

Risk is managed across the full lifecycle under **ISO 14971:2019**, controls applied in priority order. Cybersecurity is anchored in **FD&C Act §524B**, with a secure development framework, a software bill of materials, and a STRIDE threat model.

Verified · In progress

Risk management

ISO 14971:2019

HAZARD REGISTER		SEVERITY 1 LOW TO 5 HIGH
HAZ-1	**Missed fall** *false negative* DRIVING HAZARD → Resident not aided, injury worsens	5
HAZ-2	**False alert** → Alarm fatigue	3
HAZ-3	**PHI exposure** → Privacy breach	3
HAZ-4	**Device offline** → Gap in monitoring	4
HAZ-5	**Single-radar failure, fusion desync** *dual-AoP* → Degraded coverage	4
HAZ-6	**Radar-to-radar interference** *~4 per room* → Degraded detection	3

RISK CONTROLS		RC-001 TO RC-006
RC-001	Algorithm validated to sensitivity and specificity	Verified
RC-002	Multi-frame confirmation, tunable thresholds	In progress
RC-003	No imaging, coded data, encryption, HIPAA	Verified
RC-004	Self-heal supervisor, watchdog, offline alert	In progress
RC-005	Dual-sensor fault detection, degraded mode, frame-sync	In progress
RC-006	Per-unit chirp config, time-slotting, interference monitor	In progress

Control priority: Inherent safety → Protective measures → Information for safety

Cybersecurity

FDA PREMARKET 2023

§524B — FD&C ACT · CYBER DEVICES

FDA may **refuse to accept** a cyber-device submission that lacks the required cybersecurity information.

SPDF
SECURE DEVELOPMENT LIFECYCLE

Secure product development framework, aligned to **IEC 81001-5-1**.

SBOM
SOFTWARE BILL OF MATERIALS

Generated via **CycloneDX** in CI on every release.

STRIDE
THREAT MODEL

Assets: algorithm source, model artifacts, FallEvent outputs, SBOM, release artifacts.

CVSS
VULNERABILITY MANAGEMENT

Triage SLAs, Critical **24h / 72h** to Low **30d**. Coordinated disclosure.

PROGRAM STATUS

Cloud controls	Device SBOM, threat model	Penetration test
Mature	In progress	Planned

6 SOUP items tracked under IEC 62304 §8.1.2. No dependency ships without a SOUP entry first.

Probabilities and residual risk are pending. *Severity is assessed; occurrence, residual risk, and the benefit-risk conclusion are TBD pending MOH pilot data. Cloud security controls are mature, while the device SBOM, threat model, and penetration test are still in progress.*

Pre-clearance plan. No FDA clearance, listing, or QMS certification is represented as achieved. The risk file, threat model, and security testing are candidate deliverables to confirm with FDA via Pre-Submission.

Ambient Intelligence

Grounded in University of Minnesota research.

The company is built on a University of Minnesota research pedigree, a grant-funded clinical pilot in a real memory-care setting, and a growing library of passively measured digital biomarkers.

01 RESEARCH PEDIGREE

- **$248K research grant**
  Minnesota Partnership for Biotechnology and Medical Genomics · University of Minnesota, Mayo Clinic, and the State of Minnesota
- **PCT patent, UMN-filed**
  University of Minnesota Technology Commercialization
- **ENDURE accelerator**
  Earl E. Bakken Medical Devices Center, UMN · 2024 to 2026
- **M.S., Medical Device Innovation**
  Founder · University of Minnesota

02 CLINICAL PILOT

30 CONTACTLESS DEVICES

10 RESIDENTS

- **Ranked #1 memory care in Minnesota**
  Mount Olivet Careview Home, Minneapolis · Newsweek America's Best Nursing Homes 2025
- **Non-dilutive, grant-funded**
  Real rooms, a working memory-care setting
- **IRB review in process at UMN**
  ClinicalTrials.gov registration in progress
- **Measures falls, long-lie, mobility, and vitals**

03 DIGITAL BIOMARKERS

26 **biomarkers** across five domains, measured from a single contactless sensor

Measured passively, no wearable and no camera.

A research pedigree, not yet a cleared product. *The pilot is grant-funded and pre-clearance; IRB review in process and ClinicalTrials.gov registration is in progress. Biomarkers are measured for research use and are not diagnostic claims.*

Pre-clearance research. No FDA clearance, listing, or diagnostic claim is represented as achieved. Pilot results are not yet reported; figures reflect the study design and are to be confirmed with FDA via Pre-Submission.

Ambient Intelligence

Publications and references.

The founder research record and the external market sources behind the deck.

FOUNDER PUBLICATIONS

Brian Bradley Johnson · ORCID 0000-0002-4799-6007 · Nine works, 2023 to 2025.

1. *Contactless fall detection using RF sensors for aging adults.*
   Alzheimer's & Dementia · 2023
   PEER-REVIEWED JOURNAL
2. *Classifying elderly falls and reducing long-lie events with contactless RF sensors.*
   AAIC Advancements · 2023
3. *Predicting mild cognitive impairment from movement via cyclomatic complexity and machine learning.*
   AAIC · 2024
4. *Contactless pulse and respiration monitor using FMCW radar.*
   Design of Medical Devices Conference · 2025
5. *Detecting sundowning in dementia via ambient movement-complexity analysis.*
   AAIC · 2024
6. *A framework for fusing biosensor data with a minimum data set to improve Alzheimer's care.*
   AAIC · 2025
7. *Remote patient monitoring infrastructure with Starlink in Indonesia for aging populations.*
   AAIC · 2024
8. *Integrating noninvasive RF monitoring into clinical decision-making.*
   AAIC · 2024
9. *Noninvasive ambient-sensor monitoring of physical and cognitive health in Alzheimer's patients.*
   Design of Medical Devices Conference · 2024

REFERENCES AND SOURCES

Market and reimbursement figures cited across the deck, with the source of record.

260,000+ U.S. nursing positions unfilled
HRSA

Global shortage of 5.8 million nurses
WORLD HEALTH ORGANIZATION

U.S. memory-care market $6B, reaching $8.6B by 2030
GRAND VIEW RESEARCH

Remote patient monitoring market $29B by 2030
MARKETSANDMARKETS

Aging-in-place technology $120B by 2030
AARP

Medicare RPM and CCM reimbursement CPT 99453 / 99454 / 99457 / 99490
CMS / CPT

Mount Olivet Careview Home, #1 in Minnesota
NEWSWEEK, AMERICA'S BEST NURSING HOMES 2025

Publication titles are paraphrased from the ORCID record. *Confirm exact titles and years before print.*

Pre-clearance plan. No FDA clearance, listing, or QMS certification is represented as achieved. External market figures are cited to the sources shown and should be confirmed before publication.