HeartLink Health LLC – Algorithm v4.1-CL (ASE 1.3)

Document: FDA Readiness Cover Letter | Date: October 2025

# Subject: HeartLink v4.1‑CL (ASE 1.3) — Internal FDA Readiness Statement

This letter documents that HeartLink Health LLC has completed internal design control and validation activities for the HeartLink Adaptive Stability Engine (ASE) v1.3, Clinical‑Lock configuration (v4.1‑CL). The algorithm is intended for non‑diagnostic wellness and monitoring support and has been validated on synthetic datasets representative of home health monitoring.

Key documentation available upon request or included in the DHF:

• HL‑V4.1‑DHF‑001 — Design History File (traceability from inputs to validation)

• HL‑V4.1‑VAL‑002 — Validation Protocols (T1.0–T1.9) and results (Excel/CSV)

• HL‑V4.1‑CER‑003 — Clinical Evaluation Summary

• HL‑V4.1‑RMF‑004 — Risk Management File (ISO 14971)

• HL‑V4.1‑SRS‑006 — Software Requirements Specification

• HL‑V4.1‑SDS‑007 — Software Design Specification

• HL‑V4.1‑SDIP‑008 — Software Update & Data Integrity Plan

• HL‑V4.1‑PMP‑009 — Post‑Market Monitoring Plan

• calculateScore\_v41CL.js — Clinical‑Lock source with FDA metadata header

## Validation Summary (T1.0–T1.9)

• Accuracy 93.2 %; Surrogate AUC 0.961

• False‑alert rate 0.28 %; Ping‑pong rate 0.44 %

• Orthopnea trigger: 100 % correct escalation when paired with SOB

• EMA drift stability within ±0.04 normalized; Clamp held ≥5 calm days

Attestation: All metrics are reproducible from archived scripts and datasets. Any change to configuration constants or source code triggers a full re‑verification cycle under HL‑V4.1‑SDIP‑008.

Prepared by: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Reviewed by: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Approved by: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_