

# Model Risk Assessment — Centrifugal Blood Pump

## MEMORANDUM

**To:** Regulatory Affairs, Device Engineering

**From:** Computational Modeling Team, FDA OSEL/CDRH

**Date:** March 15, 2019

**Re:** Model Risk Assessment — Centrifugal Blood Pump Hemolysis CFD Analysis

### 1. Purpose

This memorandum documents the model risk assessment for the computational fluid dynamics (CFD) analysis of hemolysis in a centrifugal blood pump, conducted in accordance with ASME V&V; 40-2018 Section 4. Two Contexts of Use are assessed independently.

### 2. Context of Use 1: Cardiopulmonary Bypass (CPB)

The CFD model evaluates hemolysis sensitivity to dimensional tolerances for short-term CPB use. Model influence is MEDIUM (testing confirms key results). Decision consequence is HIGH (incorrect tolerance decisions could cause patient injury requiring clinician intervention). Per the V&V; 40 risk matrix, model risk is Level 2 (MEDIUM).

### 3. Context of Use 2: Ventricular Assist Device (VAD)

The same CFD model is assessed for long-term VAD use where cumulative hemolysis is a primary safety concern. Model influence is HIGH (model output directly informs long-term design decisions with limited ability to confirm via short-term testing). Decision consequence is HIGH (chronic hemolysis in VAD patients can cause organ damage, stroke, or death). Per the risk matrix, model risk is Level 5 (VERY HIGH).

### 4. Risk Matrix Summary

	COU1 (CPB)	COU2 (VAD)
Device Classification	Class II	Class III
Model Influence	MEDIUM	HIGH
Decision Consequence	HIGH	HIGH
Model Risk Level	2 (Medium)	5 (Very High)
Required Credibility	Moderate	Extensive

### 5. Implications for Credibility Assessment

COU1 (MRL 2) requires moderate validation rigor. PIV velocity comparison and hemolysis MIH comparison against the predicate device are sufficient. Uncertainty quantification is recommended but not required at this risk level.

COU2 (MRL 5) requires extensive validation rigor including formal uncertainty quantification (Monte Carlo propagation of dimensional tolerances), sensitivity analysis across all tolerance parameters, and demonstration that the model's predictive accuracy is sufficient for long-term safety decisions. All 13 V&V; 40 credibility factors must be assessed.