SECTION 5: 510(k) SUMMARY

As required by 21 CFR 807.92(c)

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Device Information:

Trade/Proprietary Name:	Reprocessed Supreme Diagnostic Electrophysiology Catheters
Common Name:	Diagnostic Electrophysiology Catheter
Classification Name:	Catheter, Recording, Electrode, Reprocessed
Classification Number:	Class II, 21 CFR 870.1220
Product Code:	NLH

Predicate Device:

510(k) Number	510(k) Device	Manufacturer
K151622	Supreme Electrophysiology Catheter	St. Jude Medical
K161769	Reprocessed Supreme Diagnostic Electrophysiology Catheter	Innovative Health, LLC.

Device Description:
The Reprocessed Supreme Diagnostic Electrophysiology Catheters are manufactured in various fixed curves and electrode spacing for electrophysiological mapping for the evaluation of a variety of cardiac arrhythmias from endocardial and intravascular sites.

The item numbers in scope of this submission are as follows:

Description	Item Number	French Size	Electrode Spacing (mm)	Curve Type	Usable Length (cm)	Number of Electrodes
Supreme Fixed Diagnostic EP Catheter	401978	6	2-2-2	CSL	65	20
	402033	6	2-2-2-2-2-2-2-2-2-45-2-2-2-2-2-2-2-2-2-2	CSL	120	20
	402020	6	2-5-2-5-2-5-2-5-2-60-2-10-2-10-2-10-2-10-2	CRD	120	20
	401956	6	10	CRD	120	2
	402010	6	2-5-2	CRD-2	120	6
	402011	6	5-5-5	CRD-2	120	6

	401876	6	5-5-5-175-175	CRD-1	120	6
	401877	6	5-5-5-175-175	JSN	120	6
	401434	6	10	CRD	120	4
	401436	6	10	JSN	120	4
	401438	6	10	DAO	120	4
	401442	6	5	CRD	120	4
	401474	6	5	CRD-1	120	4
	402004	6	5	CRD-2	120	4
	401430	6	5	JSN	120	4
	401475	6	5	JSN-1	120	4
	401445	6	5	DAO	120	4
	401449	6	2-5-2	CRD	120	4
	401451	6	2-5-2	JSN	120	4
	401453	6	2-5-2	DAO	120	4
	401950	6	5	CRD	120	4
	401951	6	5	JSN	120	4
	401952	6	10	CRD	120	4

Table 5.1: Device Scope

Indications for Use:
The Reprocessed Supreme Diagnostic Electrophysiology Catheters can be used in the evaluation of a variety of cardiac arrhythmias from endocardial and intravascular sites.

Technological Characteristics:
The purpose, design, materials, function, and intended use of the Reprocessed Supreme Diagnostic Electrophysiology (EP) Catheters are identical to the predicate devices. There are no changes to the claims, clinical applications, patient population, performance specifications, or method of operation. In addition, Innovative Health's reprocessing of these devices includes removal of visible soil and decontamination. Each device is inspected and function tested prior to packaging and labeling.

Functional and Safety Testing:
Bench and laboratory testing was conducted to demonstrate performance (safety and effectiveness) of the Reprocessed Supreme Diagnostic EP Catheter. This included the following:

- Biocompatibility
- Cleaning Validation
- Sterilization Validation
- Functional Testing
    - Visual Inspection
    - Dimensional Verification
    - Electrical Continuity and Resistance
    - Simulated Use
    - Mechanical Characteristics
- Electrical Safety Testing
    - Dielectric and Current Leakage
- Packaging Validation

The Reprocessed Supreme Diagnostic EP Catheters are reprocessed no more than three (3) times. Each device is marked and tracked. After the device has reached the maximum number of reprocessing cycles, the device is rejected from further reprocessing.

Reprocessing is performed only by Innovative Health. Innovative Health restricts its reprocessing to exclude devices previously reprocessed by other reprocessors.

Conclusion:
Innovative Health concludes that the Reprocessed Supreme Diagnostic EP Catheters are as safe and effective as the predicate devices described herein.