DE NOVO CLASSIFICATION REQUEST FOR

ENSOETM™™

REGULATORY INFORMATION

FDA identifies this generic type of device as:

Temperature regulation device for esophageal protection during cardiac ablation procedures. This device is placed in the lumen of the esophagus to reduce the likelihood of thermal injury or a specific adverse event during cardiac ablation procedures. The device uses temperature regulation to control the temperature of the esophagus during cardiac ablation.

NEW REGULATION NUMBER: 21 CFR 870.5720

CLASSIFICATION: Class II

PRODUCT CODE: QXV

BACKGROUND

DEVICE NAME: ensoETM™

SUBMISSION NUMBER: DEN230021

DATE DE NOVO RECEIVED: March 30, 2023

SPONSOR INFORMATION:

Advanced Cooling Therapy, Inc.
d/b/a Attune Medical
3440 S. Dearborn St. #215-South
Chicago, IL 60616

INDICATIONS FOR USE

The ECD01 model of ensoETM™ is indicated as follows:

The ensoETM™ is a thermal regulating device, intended to:

1. connect to a Gaymar Medi-Therm III Conductive Hyper/Hypothermia System or Stryker Altrix Precision Temperature Management System to control patient temperature,
2. connect to a Gaymar Medi-Therm III Conductive Hyper/Hypothermia System or Stryker Altrix Precision Temperature Management System to reduce the likelihood of ablation-related esophageal injury resulting from radiofrequency cardiac ablation procedures, and

3. provide gastric decompression and suctioning.

The ECD02 model of ensoETM™ is indicated as follows:

The ensoETM™ is a thermal regulating device, intended to:

1. connect to a Gentherm/Cincinnati Sub-Zero Blanketrol II or Blanketrol III Hyper-Hypothermia System to control patient temperature,
2. connect to a Gentherm/Cincinnati Sub-Zero Blanketrol II or Blanketrol III Hyper-Hypothermia Systemto reduce the likelihood of ablation-related esophageal injury resulting from radiofrequency cardiac ablation procedures, and
3. provide gastric decompression and suctioning.

LIMITATIONS

The sale, distribution, and use of the ensoETM™ are restricted to prescription use in accordance with 21 CFR 801.109.

PLEASE REFER TO THE LABELING FOR A COMPLETE LIST OF WARNINGS, PRECAUTIONS AND CONTRAINDICATIONS.

DEVICE DESCRIPTION

The ensoETM™ is a multi-lumen silicone tube that is placed in the esophagus in a manner similar to a standard orogastric tube. The primary function of the ensoETM™ is to connect to an external heat exchanger to either (1) cool or warm a patient or (2) cool the esophagus to reduce the likelihood of thermal injury after radiofrequency (RF) cardiac ablation procedures.

The external heat exchanger circulates warmed or chilled water through the two outer lumens of the ensoETM™. One outer lumen serves as the water inflow, while the other serves as the water outflow. The distal end of the ensoETM™ contains an opening between the two outer lumens, allowing the water to circulate back to the external heat exchanger without contacting the patient.

The central lumen of the ensoETM™ is open to the stomach to allow for gastric decompression and suction.
The ensoETM™ is primarily composed of standard medical-grade silicone. The ensoETM™ is a single-use, disposable, non-implantable device with an intended duration of use of 72 hours or less. Figure 1 shows a depiction of the ensoETM™ device placed in the esophagus.

The ensoETM™ may be individually packaged with a bite block and/or lubrication jelly packets. These accessories are legally marketed in the United States under their own name and are not manufactured by Attune Medical. The accessories are recommended for use with the ensoETM™ and may be included in unit packages as a convenience to the customer.

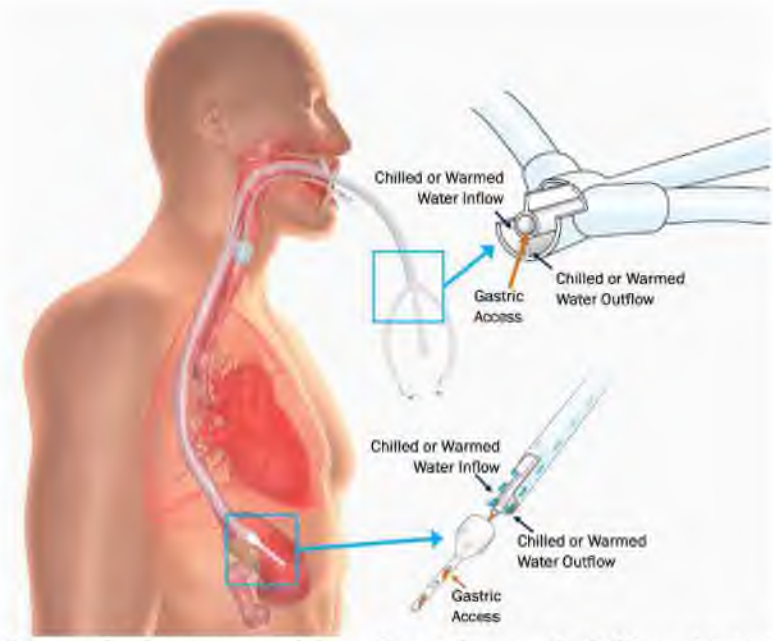

***Figure 1**: Depiction of the subject device. **Left** Placed into the Esophagus. **Right** Cross-sectional view of lumen arrangement and function.*

A version of the ensoETM™ was previously granted marketing authorization under DEN140018 for the following indication:

> The Esophageal Cooling Device is a thermal regulating device, intended to:
> - connect to a Gaymar Medi-Therm III Conductive Hyper/Hypothermia System to control patient temperature, and
> - provide gastric decompression and suctioning.

The indication granted under DEN140018 is incorporated by reference into the indication granted under this De Novo classification request.

SUMMARY OF NONCLINICAL/BENCH STUDIES

The subject device is identical in design and materials to the devices reviewed under DEN140018 (ECD01 model of the ensoETM™) and K170009 (ECD02 model of the ensoETM™). The following nonclinical/bench studies were performed and were used to support this De Novo classification request.

BIOCOMPATIBILITY/MATERIALS

Biocompatibility testing was originally performed under DEN140018. No changes have been made to the patient contacting aspects of the device.

The ensoETM™ is a surface device that contacts the mucosal membrane with prolonged exposure (≤ 72 hours). To assess the biocompatibility, the patient contact areas of the

device were tested. Devices were cut into pieces and extracted in appropriate media for the specific biocompatibility tests.

Biocompatibility evaluation has been completed according to FDA Guidance, Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process" (https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM348890.pdf).
The test articles were found non-cytotoxic per ISO 10993-5.
The test articles were found to be non-sensitizing in tests for skin sensitization per ISO 10993-10.
The test articles were found to be non-irritating in tests for irritation per ISO 10993-10.

SHELF LIFE/STERILITY

The device is provided non-sterile, which was determined to be acceptable based upon an evaluation of reports submitted to FDA under 21 CFR Part 803 and through an evaluation of complaints collected from Real-World Data (RWD) using the device for the proposed indication.

The shelf life for ensoETM™ is 3 years. Performance testing on devices which had completed 3-year accelerated aging was used to demonstrate that the device and packaging materials did not experience significant degradation.

Packaging testing was performed according to ASTM F2096-11 under DEN140018.

MAGNETIC RESONANCE (MR) COMPATIBILITY

Model ECD01: MR Safe
Model ECD02: MR Conditional

> Testing according to ASTM F2503 determined that for ECD02 model of the ensoETM:
>
> The magnetically induced displacement angle and magnetically induced torque results indicate that these effects do not pose significant risk to a patient in a clinical MR environment with a static magnetic field of 1.5 T or 3.0 T and a maximum magnetic spatial gradient of 12 T/m. The RF heating results establish that a patient with an Esophageal Cooling Device may be safely scanned in a 1.5 T or 3.0 T MR system at a whole body averaged specific absorption rate (SAR) of 2.0 W/kg for 15 minutes. The RF heating results indicate that the maximum temperature rise under these conditions is 2.61 °C. The maximum distance the image artifact extended from the test articles was measured to be 103 mm.

PERFORMANCE TESTING – BENCH

ensoETM™ underwent the following bench performance tests under DEN140018:

- Tensile Test: Acceptance criterion was bond strength of ≥15 N
- Burst Strength Test: Acceptance criterion was ≥15 psi
- Ultimate Material Strength Test: Acceptance criterion was ≥ 5 Mpa
- Leakage Test: Acceptance criterion was no visible evidence of leaks
- Vacuum Resistance Test: Acceptance criterion was device does not collapse under 200 mmHg of negative pressure.
- End Cap Axial Deflection Test: Acceptance criterion was required force to bend is less that that needed for NeoMed enteral feeding connector
- Dimensional testing confirming accurate dimensions of:
    - Extruded Tube
    - Extension Tube
    - Proximal End Cap
    - Distal End Cap

- Compatibility Testing was performed under DEN140018 and K170009 with relevant External Heater/Coolers with acceptance criteria of:
    - Flow Rate: ≥ 31 L/hr
    - Temperature Accuracy: Within ± 1.0 ºC
    - Alarm Trigger: Alarms at ≤ 29 ºC and ≥ 45 ºC and when flow occluded
    - System pressures under Occlusive situation: ≤ 9.0 psi

All tests met the specified acceptance criteria.

PERFORMANCE TESTING – ANIMAL

The following preclinical animal testing was performed to evaluate the safety and effectiveness of the device when used to control body temperature under DEN140018:

CONTROL OF BODY TEMPERATURE WITH AN ESOPHAGEAL DEVICE IN SWINE (GLP)

Purpose: The objective of this study was to demonstrate the safety and efficacy of the Esophageal Cooling Device (ECD) in controlling swine body temperature.

- Primary Outcome: Integrity of esophageal mucosa tissue and adjacent organs after experimental temperature modification, determined by gross pathological and histological analysis at necropsy.

- Secondary Outcome: Success in:

    - reducing swine body temperature by 4°C from baseline,
    - maintaining reduced body temperature for a period of 24 hours, and

- subsequently rewarming to baseline temperature at a rate of up to 0.5°C per hour, with success defined as attaining, and maintaining, goal body temperatures (39 °C at baseline, and 35°C at reduced temperature)

The results of the study demonstrated no impact on the esophageal mucosa tissue or adjacent organs. There was no direct effect of the device on the epithelial lining of the esophagus or the deeper layers of the esophagus (submucosa, muscularis layers) when the device was used to control core body temperature.

SUMMARY OF CLINICAL INFORMATION

The clinical information submitted to support this De Novo classification request included both data from preliminary randomized controlled trials (RCTs) and data cross-sectional study from reported clinical use of the subject device during electrophysiology procedures.

CLINICAL TRIAL DATA

The sponsor presented the protocols and results for three randomized controlled trials (RCTs) conducted at three different sites to evaluate esophageal cooling in RF cardiac ablation. The sites, ClinicalTrials.gov references, and number of subjects are presented below.

1. Riverside Medical Center (Riverside, NCT03481023) - 6 patients
2. University of Pennsylvania (Penn, NCT03691571) - 70 patients
3. St. George's University Hospitals (St. George's, NCT03819946) - 120 patients

All three studies evaluated the esophagus with endoscopy at 1-2 days post-ablation. Table 1 describes the scoring methodology for each of the sites and the common score which was used to combine the results for overall analysis.

Original Study Definitions			Injury Severity (Common Outcome Labels)
Riverside	Penn	St George's	
Grade 0: Normal examination	**Grade 0**: Normal mucosa	**Grade 0**: Normal mucosa	**Grade 0**: No injury
Grade 1: Edema and hyperemia of the mucosa	**Grade 1**: Erythema	**Grade 1**: Erythema **Grade 2**: Linear erosion <5mm **Grade 3**: Linear erosion(s) >5mm	**Grade 1**: Mild injury
Grade 2a: Superficial ulceration, erosions, friability, blisters, exudates, hemorrhages, whitish membranes	**Grade 2**: Superficial ulceration	**Grade 4a**: Superficial ulceration (clean) **Grade 4b**: Superficial ulceration (visible clot)	**Grade 2**: Moderate injury
Grade 2b: Grade 2a plus deep discrete or circumferential ulcerations **Grade 3a**: Small scattered areas of multiple ulceration and areas of necrosis with brown-black or greyish discoloration **Grade 3b**: Extensive necrosis	**Grade 3**: Deep ulceration **Grade 4**: Fistula/perforation	**Grade 5a**: Deep ulceration (clean) **Grade 5b**: Deep ulceration (visible clot) **Grade 6**: Perforation	**Grade 3**: Severe injury

Table 1:The esophageal injury grading scheme which was used in each of the randomized controlled studies (RCT) and the combined scoring scheme used for the combined analysis

The Riverside study of 6 patients showed: In the 3 control patients, 1 had no evidence of esophageal mucosal damage, 1 had diffuse sloughing of the esophageal mucosa and multiple ulcerations, and 1 had a superficial ulcer with a large clot. Both patients with lesions were classified as 2a cases using the Zargar grading scheme for caustic injury. In the 3 patients treated with the cooling device, 1 had no evidence of esophageal mucosal damage, 1 had esophageal erythema (Zargar grade 1), and 1 had a solitary Zargar grade 2a lesion. At 3 months of follow-up, 1 patient in each group had recurrence of atrial fibrillation.

The Penn study had 44 patients who completed the study (22 device group, 22 control group). Adjunctive posterior wall isolation was performed more frequently in the device group (11/22, 50% vs. 4/22, 18%). Endoscopically-detected esophageal lesions (EDELs) through upper endoscopy by 48 hours were detected in 5/22 (23%) control group patients, with mild or moderate injury in 2/5 patients (40%) and severe thermal injury in 3/5 patients (60%). In the device group, EDELs were detected in 8/22 (36%) patients, with mild or moderate injury in 7/8 (87%) patients and severe thermal injury in 1/8 (12%) patients. There were no acute perforations or atrioesophageal fistulas (AEF) identified during follow-up.

In the St. George's study (IMPACT), endoscopic examination was performed at 7 days post-ablation and, of 188 patients, 120 underwent endoscopy (the remaining 66 withdrew consent for esophagogastroduodenoscopy (EGD) but were not lost to follow up). EDELs

to the mucosa were significantly more common in the control group than in those receiving esophageal protection (12/60 vs. 2/60; p=0.008). There was no difference between groups in the duration of RF or in the force applied (p-value range=0.2 to 0.9). Procedure duration and fluoroscopy duration were similar (p=0.97, p=0.91, respectively).

The sponsor pooled the available data from the three studies. Differences in patient demographics and clinical protocols adds uncertainty to the representativeness of the pooled results. Demographics are shown in Table 2:

	Riverside		Penn		St. George's	
	Control (n=3)	EnsoETM (n=3)	Control (n=22)	EnsoETM (n=22)	Control (n=60)	EnsoETM (n=60)
Age (avg) (years)	55–71 (61.3)	58–70 (64.7)	63.6 ± 9.3	62.8 ± 9.6	65 ± 9	65 ± 10
Sex male, n (%)	67	100	16 (73)	14 (64)	37 (61.7)	36 (60)
BMI	NR		31.0 ± 5.1	30.5 ± 7.3	29.8 ± 6.98	28.5 ± 5.3
Obesity (n)	1	2	NR		NR	
Paroxysmal AF, n (%)	100		14 (64)	11 (50)	30 (50)	27 (45)
Left atrial size (avg) (cm)	3.8–4.2(3.9)	4.1–5.7 (4.7)	NR		4.2 ± 0.6	4.1 ± 0.9
LVEF (%)	NR		55.8 ± 9.4	54.7 ± 11.4	52 ± 8	55 ± 9
EF <50% (avg)	0 (0)	2 (67)	NR		NR	
CHA2DS2-VASc score	NR		2.2 ± 1.6	2.2 ± 1.4	NR	
Hypertension, n (%)	2 (67)	3 (100)	13 (59)	12 (55)	NR	
CAD, n (%)	1 (33)	1 (33)	4 (18)	1 (5)	NR	
Diabetes mellitus, n (%)	1 (33)	0 (0)	2	1	4	10
Prior Stroke, n (%)	0 (0)	1 (33)	2 (9)	3 (14)	3	1

Table 2: Baseline characteristics for each of the 3 randomized controlled studies

Results of endoscopy in the pooled data showed a nonsignificant difference between the odds of esophageal injury (odds ratio = 0.55, 95% CI = (0.22, 1.35), p = 0.22), presented in Table 3:

		Combined	
		LET	EnsoETM
# of Patients Completed		83	83
Severity of Esophageal Injury	No Injury	65 (78%)	72 (87%)
	Mild injury	7 (8%)	5 (6%)
	Moderate injury	7 (8%)	5 (6%)
	Severe injury	4 (5%)	1 (1%)

Table 3: Combined esophageal lesion rates for pooled RCT data using the combined scoring scheme found in Table 1

In total 4 serious adverse events and 95 other adverse events occurred in the combined LET arms while 3 serious adverse events and 101 other adverse events occurred in the ensoETM™ arm. Detailed adverse events were as presented in Table 4:

Adverse Event	Riverside		Penn		St. George's		Combined	
	LET	EnsoETM	LET	EnsoETM	LET	EnsoETM	LET	EnsoETM
Serious Adverse Events								
All-cause mortality*	0	0	0	0	1	0	1	0
Bradycardia	0	0	0	0	0	1	0	1
Hematuria	0	0	1	0	0	0	1	0
Pericardial effusion	0	0	0	0	1	0	1	0
Prolonged hospital stay due to previous heparin allergy	0	0	0	0	1	0	1	0
Pseudoaneurysm	0	0	0	0	0	2	0	2
Other Adverse Events								
Abdominal bloating	0	0	0	0	6	4	6	4
Abdominal pain	0	0	0	0	5	5	5	5
Acid reflux	0	0	0	0	3	5	3	5
Arrhythmia	0	0	4	3	0	2	4	5
Chest Pain/ Pericarditis	0	0	3	2	7	11	10	13
Difficulty Swallowing	0	0	0	1	0	0	0	1
Early satiety	0	0	0	0	6	7	6	7
Esophageal candida	0	0	0	0	2	5	2	5
Esophagitis	0	0	1	0	4	3	5	3
Gastric polyps	0	0	0	0	3	0	3	0
Gastritis	0	0	0	0	11	10	11	10
Headache	0	0	1	3	0	0	1	3
Hemoptysis	0	0	1	0	0	0	1	0
Hiatus hernia	0	0	0	0	4	6	4	6
Insomnia due to chest discomfort	0	0	0	0	3	5	3	5
Knee Pain	0	0	1	0	0	0	1	0
Leg Edema	0	0	0	1	0	0	0	1
Lip Sore	0	0	1	0	0	0	1	0
Nausea	0	0	0	0	5	4	5	4
Presyncope/ Palpitations	0	0	0	1	13	9	13	10
Sinus Infection	0	0	0	1	0	0	0	1
Sore throat/ Cough/ Phlegm	0	0	8	10	0**	0**	8	10
Vomiting	0	0	0	0	3	3	3	3

Table 4: Adverse event rates in the three RCT using the ensoETM™ device

CROSS-SECTIONAL STUDY

The sponsor conducted a cross-sectional study using retrospective cohorts of patients undergoing RF ablation with esophageal cooling from the ensoETM™ device. The primary endpoint study was hypothesis driven while the secondary endpoint study was a descriptive study. For the primary study endpoint, a retrospective review of data from 25 hospital systems to quantify the effect of active esophageal cooling by (1) measuring AEF rates across hospital systems with the highest use of this method (use of

ensoETM™ during RF ablation for AF ablation) and then (2) comparing these rates before and after the adoption of active esophageal cooling. The 25 hospital systems included a total of 30 separate hospitals. Data were extracted by site investigators to determine the total number of RF catheter ablations performed for the treatment of atrial fibrillation over the study time frame and the number of AEFs that occurred over this time frame.

At each site, the number of reported fistulas developing after the adoption of active cooling with ensoETM™ was compared with the number reported during an equivalent period before the adoption of cooling. The total number of patients at each site undergoing pulmonary vein isolation (PVI) before and after the adoption of cooling were used for statistical analysis.

For a secondary study endpoint, a retrospective data review was performed with Institutional Review Board approval from two healthcare systems subset from the primary dataset and analysis. All patients who underwent PVI performed by any of four electrophysiologists in two healthcare systems encompassing 3 different hospitals over the study timeframe from January 2018 to March 2020 were included in this analysis. No patients who underwent PVI were excluded from this review. The purpose of this study was to determine the recurrence rates of AF after PVI and compare these between patients before and after the introduction of active esophageal cooling.

For the primary analysis the sample size was 25,186 (10,962 before and 14,224 after adoption of the ensoETM™ cooling device).

Figure 2: Graph demonstrating the reported number of PVI ablation procedures during equivalent time periods before and after adoption of the ensoETM™ Cooling Device. Reported Atrialesophageal Fistula (AEF) are indicated by a black dot and centers with reported AEFs are highlighted in red. Please note FDA concerns for this data related to relevance and reliability below which suggest that the above results may not be fully representative.

The secondary analysis was a retrospective review of patients who underwent PVI in two healthcare systems (three hospitals) comparing recurrence rates of AF after PVI before and after adoption of the subject device. The sample was a subset of the primary analysis, and included 513 patients (253 before, and 260 after adoption).

At 12 months, 58.2% of pre-cooling patients were free of arrhythmia, and 72.2% of patients treated with esophageal cooling were free of arrhythmia, for an absolute difference in freedom from arrhythmia of 14% with active esophageal cooling (p=.03).

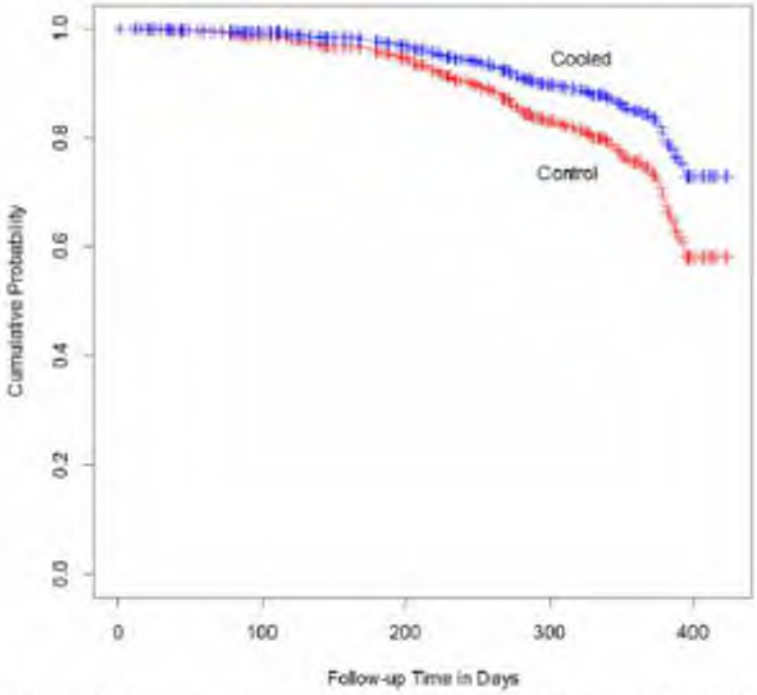

Figure 3: Graph demonstrating cumulative probability of atrial fibrillation (AF) recurrence in the two groups of patients before and after adoption of the subject device

Cross-Sectional Study Relevance and Reliability Assessment

FDA reviewed the cross-sectional study using Section A (Relevance) and Section B (Reliability) in the FDA guidance, "Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices," issued August 2017, and available at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-real-world-evidence-support-regulatory-decision-making-medical-devices. This review included the data elements of interest (device, endpoints/outcomes, covariates); study population; data collection and retrieval; study design and analysis; and patient protections. After careful consideration of these elements, FDA found that the cross-sectional study evidence had the following significant limitations:

1. Insufficient information on follow-up for 98%, limiting conclusions on the rate of a certain adverse event.

2. Insufficient information to identify the device used device exposure, limiting conclusions on device-related outcomes.

3. Insufficient information on covariates, limiting conclusions about the effect of potential bias on study outcomes.

Due to these limitations, FDA concluded that the cross-sectional study results would not be used as primary evidence of safety and effectiveness for the ensoETM™. However, the totality of evidence submitted to support this application (including both clinical trial data and cross-sectional study data) did support a conclusion that the subject device can be expected to reduce the likelihood of ablation-related esophageal injury resulting from RF ablation procedures.

Pediatric Extrapolation

In this De Novo request, existing clinical data were not leveraged to support the use of the device in a pediatric patient population.

LABELING

The labeling consists of the following: device description, indications for use, instructions for use including methodology of use during AF ablation, and the use of gastric suction, principles of device operation, identification of device materials, contraindications, warnings, precautions, a list of potential adverse effects, and special populations that the use of ensoETM™ has not been studied in. The labeling meets the requirements of 21 CFR 801.109 for prescription devices.

RISKS TO HEALTH

The table below identifies the risks to health that may be associated with the temperature regulation device for esophageal protection during cardiac ablation procedures and the measures necessary to mitigate these risks.

Identified Risks to Health and Mitigation Measures

Risks to Health	**Mitigation Measures**
Failure to protect the esophagus during ablation leading to esophageal perforating complications	Clinical performance testing Animal performance testing Non-clinical performance testing Labeling
Device alters ablation procedure resulting in patient injury, improper catheter performance, or interruption of procedure	Clinical performance testing
Device malfunction leading to esophageal injury	Non-clinical performance testing Shelf life and packaging testing
Adverse tissue reaction	Biocompatibility evaluation
Infection	Sterilization validation Shelf life and packaging testing Labeling
Mechanical injury to esophageal or oral structures	Clinical performance testing Animal performance testing Non-clinical performance testing

	Labeling

SPECIAL CONTROLS

In combination with the general controls of the FD&C Act, the temperature regulation device for esophageal protection during cardiac ablation procedures device is subject to the following special controls:

(1) Clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use and include the following:
   (i) Evaluation of reduction of the incidence of esophageal injury during cardiac ablation procedures;
   (ii) Evaluation of any effects on the ablation procedure resulting in patient injury, improper catheter performance, or interruption of procedure; and
   (iii)Evaluation of any esophageal or oral injury from use of the device.
(2) Animal performance testing must demonstrate that the device performs as intended under the anticipated conditions of use, including evaluation of any esophageal injury from use of the device.
   (i) Evaluation of the device's capability to regulate the temperature of the esophagus; and
   (ii) Evaluation of any esophageal injury from use of the device.
(3) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use and include the following:
   (i) Mechanical integrity testing using clinically relevant forces;
   (ii) Testing to determine temperature change rate(s); and
   (iii)Compatibility testing with accessory devices.
(4) Performance data must demonstrate the sterility of any device components intended to be provided sterile.
(5) The patient-contacting components of the device must be demonstrated to be biocompatible.
(6) Performance data must support the shelf life of the device by demonstrating package integrity and device functionality over the identified shelf life.
(7) Labeling must include the following:
   (i) A summary of clinical performance testing with the device; and
   (ii) A shelf life.

BENEFIT-RISK DETERMINATION

The probable risks associated with ensoETM™ include complications related to instrumentation of the esophagus

- Minor risks associated with ensoETM™ device include:
  - Chest pain

- Gastritis
- Sore throat

The ensoETM™ device has been studied in multiple randomized controlled trials which demonstrated an overall positive but non-statistically significant benefit. Subjects in the ensoETM™ group had a lower rate of ablation-related esophageal lesions or all severities, and there were no unexpected safety findings. The ensoETM™ has also been used in over 25,000 ablation procedures with a signal of a lower rate of AEFs and with a very low overall complaint rate which did not reveal safety concerns. In a sub study the rates AF recurrence were found to be lower when the ensoETM™ device is used in conjunction with a PVI ablation procedure.

Based upon the totality of the various evidence sources presented to support the ensoETM™ device, FDA has determined that the benefits of ensoETM™, when used to regulate the temperature of the esophagus during an RF PVI ablation procedure to minimize the risk of esophageal injury, outweigh the risks.

PATIENT PERSPECTIVES

This submission did not include specific information on patient perspectives for this device.

BENEFIT/RISK CONCLUSION

In conclusion, given the available information above, for the following indication statement:

The ECD01 model of ensoETM™ is indicated as follows:

The ensoETM™ is a thermal regulating device, intended to:

1. connect to a Gaymar Medi-Therm III Conductive Hyper/Hypothermia System or Stryker Altrix Precision Temperature Management System to control patient temperature,
2. connect to a Gaymar Medi-Therm III Conductive Hyper/Hypothermia System or Stryker Altrix Precision Temperature Management System to reduce the likelihood of ablation-related esophageal injury resulting from radiofrequency cardiac ablation procedures, and
3. provide gastric decompression and suctioning.

The ECD02 model of ensoETM™ is indicated as follows:

The ensoETM™ is a thermal regulating device, intended to:

1. connect to a Gentherm/Cincinnati Sub-Zero Blanketrol II or Blanketrol III Hyper-Hypothermia System to control patient temperature,
2. connect to a Gentherm/Cincinnati Sub-Zero Blanketrol II or Blanketrol III Hyper-Hypothermia Systemto reduce the likelihood of ablation-related esophageal injury resulting from radiofrequency cardiac ablation procedures, and
3. provide gastric decompression and suctioning.

The probable benefits outweigh the probable risks for the ensoETM™. The device provides benefits, and the risks can be mitigated by the use of class II controls.

CONCLUSION

The De Novo for the ensoETM™ is granted and the device is classified as follows:

Product Code: QXV

Device Type: Temperature regulation device for esophageal protection during cardiac ablation procedures

Regulation Number: 21 CFR 870.5720

Class: Class II