December 17, 2021

CIRCA Scientific, Inc.
Fred Piazza
Quality Assurance Manager
14 Inverness Drive East, Suite H-136
Englewood, Colorado 80112

Re: K200943
Trade/Device Name: Circa S-Cath M Esophageal Temperature Probe and Temperature Monitoring System
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL, IKD
Dated: November 18, 2021
Received: November 19, 2021

Dear Fred Piazza:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal

statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Aneesh Deoras
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K200943

Device Name
CIRCA S-CATH M Esophageal Temperature Probe and Temperature Monitoring System

Indications for Use *(Describe)*
The CIRCA Temperature Monitoring System is composed of CIRCA Temperature Monitor and CIRCA S-CATH M Probe and is intended for the continuous detection, measurement and visualization (in °C) of esophageal temperature. The intended environments of use are operating rooms and interventional electrophysiology rooms. The CIRCA Monitor must be used in conjunction with the CIRCA S-CATH M Probe.

The role of esophageal temperature monitoring using this device in reducing the risk of cardiac ablation-related esophageal injury has not been established. The performance of the CIRCA Temperature Monitoring System in detecting esophageal temperature changes as a result of energy delivery during cardiac ablation procedures has not been evaluated.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

I. SUBMITTER

CIRCA Scientific, Inc.
14 Inverness Drive East, Suite H-136
Englewood, CO 80112
Phone: (303) 951-8767
Contact: Fred Piazza
Date Prepared: November 18, 2021

II. DEVICE INFORMATION

Name of Device: CIRCA S-CATH M Esophageal Temperature Probe and Temperature Monitoring System

Common or Usual Name: Clinical electronic thermometer

Classification Name: Clinical electronic thermometer (21 CFR 880.2910)

Regulatory Class: II

Product Code(s): FLL, IKD

Predicate Device: ESOTEST MULTI Esophageal Temperature Probe and Temperature Monitoring System, K192210

Reference Device: S-Cath Esophageal Temperature Probe and Temperature Monitoring Probe, K112376

III. DEVICE DESCRIPTION

The CIRCA Scientific Temperature Monitoring System consists of a touch-screen monitor, interconnect cables, and an esophageal temperature probe.

The monitor displays 12 temperature probe sensor readings (°C), the minimum and maximum temperature of all sensors, and contains an alarm system with user-selected levels. The measured temperatures can be stored in the internal memory of the device and examined at a later time on an external personal computer (after exporting the corresponding data file to an USB flash drive).

The S-CATH M Esophageal Temperature Probe provides continuous temperature measurement (°C) and operates in direct mode (operating mode of a clinical thermometer where the output temperature is an unadjusted temperature that represents the temperature of the measuring site to which the probe is coupled). The probe contains 12 thermistor sensors located along an s-curve. The sensors measure temperature by a resistor that is sensitive to temperature changes. The probe is connected to the CIRCA Scientific monitor by using an interconnect cable. The 10Fr diameter probe is placed inside the esophagus.

The Probe is also equipped with 4 electrode sensors. By connecting the S-CATH M Probe to a 3D cardiac mapping system through the optional component Mapping Interconnect Cable, the probe can be visualized inside a 3D model of the patient's body for optimal placement.

IV. INDICATIONS FOR USE

The CIRCA Temperature Monitoring System is composed of CIRCA Temperature Monitor and CIRCA S-CATH M Probe and is intended for the continuous detection, measurement and visualization (in °C) of esophageal temperature. The intended environments of use are operating rooms and interventional electrophysiology rooms. The CIRCA Monitor must be used in conjunction with the CIRCA S-CATH M Probe.

The role of esophageal temperature monitoring using this device in reducing the risk of cardiac ablation-related esophageal injury has not been established. The performance of the CIRCA Temperature Monitoring System in detecting esophageal temperature changes as a result of energy delivery during cardiac ablation procedures has not been evaluated.

V. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

ELEMENT OF COMPARISON	SUBJECT DEVICE: CIRCA S-CATH M Esophageal Temperature Probe and Temperature Monitoring System	PREDICATE DEVICE: K192210 FIAB-ESOTEST MULTI Esophageal Temperature Probe and Temperature Monitoring System	COMMENTS
Thermometer type	Esophageal	Esophageal	Same
Product Code	FLL, IKD	FLL, IKD	Same
Regulation	880.2910 Clinical Electronic Thermometer 890.1175 Cable, Electrode	880.2910 Clinical Electronic Thermometer 890.1175 Cable, Electrode	Same

510(k) SUMMARY

ELEMENT OF COMPARISON	SUBJECT DEVICE: CIRCA S-CATH M Esophageal Temperature Probe and Temperature Monitoring System	PREDICATE DEVICE: K192210 FIAB-ESOTEST MULTI Esophageal Temperature Probe and Temperature Monitoring System	COMMENTS
Indications for Use	The CIRCA Temperature Monitoring System is composed of CIRCA Temperature Monitor and CIRCA S-CATH M Probe and is intended for the continuous detection, measurement and visualization (in °C) of esophageal temperature. The intended environments of use are operating rooms and interventional electrophysiology rooms. The CIRCA Monitor must be used in conjunction with the CIRCA S-CATH M Probe. The role of esophageal temperature monitoring using this device in reducing the risk of cardiac ablation-related esophageal injury has not been established. The performance of the CIRCA Temperature Monitoring System in detecting esophageal temperature changes as a result of energy delivery during cardiac ablation procedures has not been evaluated.	The ESOTEST MULTI Temperature Monitoring System is composed of ESOTEST MULTI Monitor and ESOTEST MULTI Probe and is intended for the continuous detection, measurement and visualization (in °C) of esophageal temperature. The intended environments of use are operating rooms and interventional electrophysiology rooms. The ESOTEST MULTI Monitor must be used in conjunction with the ESOTEST MULTI Probe. The role of esophageal temperature monitoring using this device in reducing the risk of cardiac ablation-related esophageal injury has not been established. The performance of the ESOTEST MULTI system in detecting esophageal temperature changes as a result of energy delivery during cardiac ablation procedures has not been evaluated.	Same (except for the trade name)
Components	Temperature probe, Patient cable, Monitor. The package includes an external power supply and hospital-grade power cord. Optional component: Mapping Interconnect Cable	Temperature probe, Patient cable, Monitor. The package includes an external power supply and an equipotential cable. Optional component: ESOTEST MULTI ADAPTER CABLE	Similar, predicate device includes additional equipotential cable. Equipotential cable is not required per IEC 60601-1; it is an accessory provided by predicate manufacturer.

510(k) SUMMARY

ELEMENT OF COMPARISON	SUBJECT DEVICE: CIRCA S-CATH M Esophageal Temperature Probe and Temperature Monitoring System	PREDICATE DEVICE: K192210 FIAB-ESOTEST MULTI Esophageal Temperature Probe and Temperature Monitoring System	COMMENTS
Temperature measurement range (°C)	0 – 45	0 – 75	Rated output range is lower for the subject device. Consensus standard ISO 80601-2-56 states in section 201.12.1.101: *The output temperature of clinical thermometers should cover the minimum rated output range from 34,0 °C to 43,0 °C.*
Number of temperature sensors	12	5 or 7	Subject device has more sensors allowing additional coverage within the esophageal area.
Temperature sensor type	NTC Thermistor (system accuracy ± 0.3°C)	T-type thermocouple (system accuracy ± 0.3°C)	Similar, a thermistor is a temperature-sensitive resistor, whilst a thermocouple generates a voltage proportional to the temperature. The same accuracy is ensured by the respective signal process and display.
Measurement presentation / User Interface	LCD monitor Touch screen monitor	LCD monitor Touch screen monitor	Same
Alarm temperature range (°C)	Upper threshold (Alarm and Warning High) Lower Threshold (Alarm and Warning Low) Low threshhold cannot be set higher than upper threshold.	37-41 upper threshold (Tmax) 12-24 lower threshold (Tmin)	Similar, subject device allows user to select values within the same ranges.
Alarm signal	Visual (flashing yellow or red on the LCD display) Audible (intermittent sound)	Visual (flashing red circles on the LCD display) Audible (intermittent sound)	Similar, subject device includes yellow visual for warning level and red for alarm level.
Power requirements	100 – 240 Vac	100 – 240 Vac	Same

510(k) SUMMARY

ELEMENT OF COMPARISON	SUBJECT DEVICE: CIRCA S-CATH M Esophageal Temperature Probe and Temperature Monitoring System	PREDICATE DEVICE: K192210 FIAB-ESOTEST MULTI Esophageal Temperature Probe and Temperature Monitoring System	COMMENTS
Monitor classification	Class I Medical Electrical Equipment Type CF Applied Part, Defibrillation-Proof	Class I Medical Electrical Equipment Type CF Applied Part, Defibrillation-Proof	Same
Dimensions (cm)	Monitor: 26W x 19H x 9D Patient cable length: 460 Temperature Probe: 65L; 10Fr	Monitor: 34W x 25H x 6.5D Patient cable length: 290 Temperature probe: 83L; 7Fr body, 11Fr sensors	Similar in size, minor differences that do not affect device placement or use.
Introduction	Esophageal (nose / throat)	Esophageal (nose / throat)	Same
Signal processing and display:	Actual temperature is a function of the thermistor resistance. Temperature displayed in 0.1°C increments. 1 input (single probe) available. 12 sensors per probe measurements and user-selected alarm limits are displayed on LCD monitor.	Actual temperature is a function of the thermocouple voltage. Temperature displayed in 0.1°C increments. 1 input (single probe) available. 5/7 sensors per probe measurements and user-selected alarm limits are displayed on LCD monitor.	Similar, temperature sensor technology (thermocouple and thermistor) are standard for temperature measurement. The same accuracy is ensured. Subject device has 5 more sensors per probe and therefore displays 12 temperatures.
Patient contacting materials	Flexible Polyether and Rigid Polyamide PEBAX® Tecothane® Urethane and Gold Electrode Bands	Polyurethane and Stainless Steel (SST) AISI 304	Similar, both use thermoplastics and metals commonly used for medical device applications. To bridge the difference, subject device was tested under ISO 10993-1.
Operating conditions	0°C to 40°C Non-condensed relative humidity: 30% to 75%	+10°C to +40°C Non-condensed relative humidity: 30% to 75%	Similar, subject monitor has a lower limit; devices are used in the same hospital setting.
Accuracy	0.3°C within rated output range (ISO 80601-2-56 requirements for clinical thermometers)	0.3°C within rated output range (ISO 80601-2-56 requirements for clinical thermometers)	Same
Precision and repeatability (°C)	0.1	0.1	Same

ELEMENT OF COMPARISON	SUBJECT DEVICE: CIRCA S-CATH M Esophageal Temperature Probe and Temperature Monitoring System	PREDICATE DEVICE: K192210 FIAB-ESOTEST MULTI Esophageal Temperature Probe and Temperature Monitoring System	COMMENTS
Response time	Heating transient response time is approximately six seconds and cooling transient response time is approximately eight and a half seconds. Response time is for probe plunged from reference water bath to a water bath with a 2°C differential, ISO 80601-2-56 requirements for clinical thermometers.	Both heating and cooling response time are approximately 1 second. Response time is defined as the mean value of the measured time intervals associated to temperature increase (tr) or to temperature difference (tf) necessary to cover 63.3% of the total temperature excursion.	Response time testing between FIAB ESOTEST and CIRCA S-CATH M using the same test methodology was conducted. The actual testing showed substantial equivalence, with the predicate device heating transient response time an average of only 2 seconds faster and also cooling transient response time an average of 2 seconds faster.
Probe sterilization	ETO Sterilized	ETO Sterilized	Same
Biocompatibility of the patient contacting part	Compliance to ISO 10993-1	Compliance to ISO 10993-1	Same
Software	Compliance to IEC 62304	Compliance to IEC 62304	Same
Electrical safety	Compliance to IEC 60601-1	Compliance to IEC 60601-1	Same
EMC	Compliance to IEC 60601-1-2	Compliance to IEC 60601-1-2	Same
Performance bench testing	Compliance to ISO 80601-2-56	Compliance to ISO 80601-2-56	Same

Substantial Equivalence Discussion:

Esophageal temperature monitoring using standard temperature sensor technology (thermocouple or thermistor) is the technological principle for both the subject and predicate devices.

The subject device has the same intended use as the predicate device, which is legally marketed. The subject device (CIRCA S-CATH M Esophageal Temperature Probe and Temperature Monitoring System) and the predicate device (ESOTEST MULTI Esophageal Temperature Probe and Temperature Monitoring System, K192210) are similar in the following areas:

- Indications for use
- Components

- Temperature monitoring technology and monitor display
- Probe diameter and rout of administration
- Accuracy, precision and repeatibility

Both systems have been evaluated to FDA recognized consensus standards in the areas of biocompatibility, sterilization, software, electrical safety, EMC, and performance for clinical electronic thermometers.

Due to the difference in shape of the subject device compared to the predicate device, Circa is using a reference device (S-Cath Esophageal Temperature Probe and Temperature Monitoring System (K112376)) to address the safety and effectiveness of the new technological characteristic when compared to the predicate device.

The s-curve shape of the subject device has been reviewed and cleared in a similar device, S-Cath Esophageal Temperature Probe and Temperature Monitoring System (K112376). The S-Cath Esophageal Temperature Probe and Temperature Monitoring System is intended for continuous temperature monitoring and is designed for placement in the esophagus. The Probe evaluated the impact the s-curve shape had on performance time, accuracy, precision, and repeatibility. Performance testing was conducted per Standard 80601-2-56 / First Edition 2009-10-01 *Medical electrical equipment – Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement*. Results for the reference device and its predicate device showed that the s-curve shape provided a faster response time.

Because more sensors are placed along the s-curve shape of the device to cover the geometry, the distance between each sensor is closer for the subject device than for the predicate device. The number of sensors are much like that for the reference device. Therefore, the s-curve shape is as safe and effective and does not raise different questions of safety and effectiveness.

VI. NON-CLINICAL PERFORMANCE DATA

No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for this device. Performance, labeling, electrical, biocompatibility, and sterilization testing of the subject device was conducted based on the risk analysis and on the requirements of recognized standards and FDA guidance documents.

The device was subjected to the following non-clinical testing to demonstrate that it performs as intended to the predicate device:

TEST NAME	ENDPOINT	RESULT SUMMARY
In vitro cytotoxicity, sensitization, and intracutaneous reactvity	Verifying the compliance of the esophageal probe to the requirements of ISO 10993-1 for the considered type and duration of contact.	Results of tests demonstrate that the sample can be considered non cytotoxic, not sensitizing, and meets the requirements of intracutatneous reactivity.

TEST NAME	ENDPOINT	RESULT SUMMARY
Sterility	Verifying the compliance of the esophageal probe to the requirements of sterilization according to standard ANSI/AAMI/ISO 11135.	Results of EO sterilization validation and tests demonstrate the device meets a Sterility Assurance Level (SAL) of 10^{-6}.
Software system tests	Verifying the correct implementation of the software requirements according to standard IEC 62304.	Following completion of all software lifecycle activities, the software device does not have any unresolved anomalies (bugs or defects).
All the applicable safety tests prescribed by the IEC 60601-1 standard	Verifying the compliance of the system to the IEC 60601-1 standard.	The system passed all the applicable tests.
All the applicable immunity and emission tests prescribed by the IEC 60601-1-2 standard	Verifying the compliance of the system to the IEC 60601-1-2 standard.	The system passed all the applicable tests
Accuracy and response time test	Verifying the compliance of the system to the ISO 80601-2-56 standard.	The system accuracy and response time meets the requirements of the standard
Mapping cable validation	Verifying the compliance of the mapping cable to the ANSI/AAMI EC53:2013 standard.	The cable manufacturing process guarantees the compliance to the standard
Performance test in the working environment	Verifying the immunity of the system to the most common disturbances sources in the working environment, verifying the compatibility with 3D cardiac mapping systems.	The system is not affected by the noise sources in the working environment. The system is compatible with the following 3D cardiac mapping systems: EnSite NavX and CARTO 3
Performance test *in vivo* (animal) setting	Evaluate precision and accuracy of the electrode position detected by the 3D cardiac mapping system by measuring the distances between electrodes and control catheter tip on fluoroscopy and 3D cardiac mapping system.	Data confirmed S-CATH M probe is visible on 3D cardiac mapping system with a determined precision and accuracy of 2.0 ± 1.2mm on CARTO 3 and 7.4 ± 5.3mm on EnSite NavX.

VII. CONCLUSIONS

Based on the performance testing, comparison and analysis in the submission, the subject device is substantially equivalent to the ESOTEST MULTI Esophageal Temperature Probe and Temperature Monitoring System (K192210).