May 12, 2020

Fiab SpA
Francesco Batistini
Regulatory Affairs Manager
Via Costoli, 4
Vicchio, Firenze 50039
Italy

Re: K192210
Trade/Device Name: ESOTEST MULTI 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

Dear Francesco Batistini:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated October 10, 2019. Specifically, FDA is updating this SE Letter to correct the Indications For Use statement for your device as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Tina Kiang, OHT3: Office of Gastrorenal, ObGyn, General Hospital and Urology Devices, 301-796-7030, tina.kiang@fda.hhs.gov

Sincerely,

Sapana Patel -S

for Tina Kiang, Ph.D.
Director
Division of Drug Delivery and General Hospital and Human Factors
Office of Gastrorenal, ObGyn, General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

October 10, 2019

FIAB SpA
Francesco Batistini
Regulatory Affairs Manager
Via Costoli, 4
Vicchio, Firenze, 50039 Italy

Re: K192210
Trade/Device Name: ESOTEST MULTI 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: August 7, 2019
Received: August 14, 2019

Dear Mr. Francesco Batistini:

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,

Geeta K.
Pamidimukkala -S

for Alan Stevens
Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices,
and Human Factors
OHT3: Office of Gastrorenal, ObGyn,
General Hospital and Urology 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192210

Device Name
ESOTEST MULTI

Indications for Use *(Describe)*
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.

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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ESOTEST MULTI Esophageal Temperature Probe and Temperature Monitoring System with Visualization

510(k) Summary

Submitter: Fiab SpA
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50039 Vicchio
Florence, Italy

Application Correspondent: Mr. Francesco Batistini,
Title: Official Correspondent
Phone: (39) 055 849 79 43
Fax: (39) 055 849 79 87
E-mail: regulatory@fiab.it

Preparation Date: September 24, 2019

Trade Name: ESOTEST MULTI
Esophageal Temperature Probe and Temperature Monitoring System

Common or Usual Name: Thermometer, Electronic, Clinical

Regulation Name: Clinical Electronic Thermometer

Regulation Number: 21 CFR 880.2910

Product Codes: FLL, IKD

Device Class: Class II

Predicate Device: K180047 – ESOTEST MULTI Esophageal Temperature Probe and Temperature Monitoring System

Device Indications for Use:

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.

Device Description:

The device is composed of the following cleared (K180047) system components:

- Monitor ESOTEST MULTI MONITOR
- Esophageal probe ESOTEST MULTI PROBE
- Patient cable ESOTEST MULTI PATIENT CABLE

The Adapter cable ESOTEST MULTI ADAPTER CABLE has been added to the system.

The ESOTEST MULTI MONITOR is a device for measuring the esophageal temperature through a sterile, single-use probe. This component, called ESOTEST MULTI PROBE, contains up to seven independent thermal sensors, each one consisting in T-type thermocouple soldered to a spherical steel electrode. The ESOTEST MULTI PATIENT CABLE connects the main unit of the monitor to the temperature probe and continuously converts to digital signals the analog voltages generated by the thermocouples. ESOTEST MULTI MONITOR is able to keep track of the esophageal temperature during clinical procedures which involve heating or cooling processes, with an accuracy of 0.3°C and a response time of 1s. The detected temperatures are visualized as numerical values, colored bars and scrolling plots. An integrated alarm system allows the operator to set 2 independent alarm thresholds, called "upper alarm threshold" and "lower alarm threshold". If any of the measured temperatures gets hotter than the upper threshold or colder than the lower threshold, ESOTEST MULTI MONITOR immediately emits sound and visual effects aimed at getting the attention of the operator. The measured temperatures and the alarm conditions can be stored in the internal memory of the device and examined at a later time on the monitor itself or on an external personal computer (after exporting the corresponding data to an USB mass storage device). By connecting the ESOTEST MULTI to a mapping system through the optional component ESOTEST MULTI ADAPTER CABLE, the probe sensors can be visualized inside a 3D model of the patient's body for optimal placement.

Technological Characteristics and Substantial Equivalence:

Element of comparison	**Subject Device: FIAB - ESOTEST MULTI Esophageal Temperature Probe and Temperature Monitoring System with Visualization**	**Predicate Device: K180047 FIAB - ESOTEST MULTI Esophageal Temperature Probe and Temperature Monitoring System**	**Comments**
Thermometer type	Esophageal		Same
Product Code	FLL IKD	FLL	Product code IKD refers to the ESOTEST MULTI ADAPTER CABLE accessory, see the components comparison below
Regulation	880.2910 Clinical Electronic Thermometer 890.1175 Cable, Electrode	880.2910 Clinical Electronic Thermometer	Regulation 890.1175 refers to the ESOTEST MULTI ADAPTER CABLE accessory, see the components comparison below

Element of comparison	Subject Device: FIAB - ESOTEST MULTI Esophageal Temperature Probe and Temperature Monitoring System with Visualization	Predicate Device: K180047 FIAB - ESOTEST MULTI Esophageal Temperature Probe and Temperature Monitoring System	Comments
Indications for use	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.	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.	Same, with the addition of a remark about the lack of an exhaustive evaluation regarding the employment of the ESOTEST MULTI system during specific clinical procedures. The remark applies both to the subject and to the predicate device, as the performance of the system is not affected by the addition of the ESOTEST MULTI adapter cable.
Components	Temperature probe, Patient cable, Monitor. The package of the monitor includes an external power supply and an equipotential cable. Optional component: ESOTEST MULTI ADAPTER CABLE.	Temperature probe, Patient cable, Monitor. The package of the monitor includes an external power supply and an equipotential cable	Same, with the addition of the ESOTEST MULTI ADAPTER CABLE, an optional component sold separately. The technology is the same adopted for the commercially available adapter cables typically used to connect diagnostic catheters to mapping systems.
Temperature measurement range [°C]	0 - 75		Same

Element of comparison	Subject Device: FIAB - ESOTEST MULTI Esophageal Temperature Probe and Temperature Monitoring System with Visualization	Predicate Device: K180047 FIAB - ESOTEST MULTI Esophageal Temperature Probe and Temperature Monitoring System	Comments
Number of temperature sensors	5 or 7		Same
Temperature sensor type	T-type thermocouple (accuracy ±0.3°C)		Same
Measurement presentation/User Interface	LCD monitor Touch screen monitor		Same
Alarm temperature range [°C]	37-41 upper threshold (T_{max}) 12-24 lower threshold (T_{min})		Same
Alarm signal	Visual (flashing red circles on the LCD display) Audible (intermittent sound)		Same
Power requirements	100 - 240 Vac		Same
Monitor classification	I, CF, defib protected		Same
Dimensions [cm]	Monitor: 34(width) x25(height) x6.5 (depth) Patient cable (length): 290 Temperature probe (length and diameter): 83; 7Fr body, 11Fr sensors		Same
Introduction	Esophageal (nose/throat)		Same
Signal processing and display	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.		Same
Software version	Esotest Multi Software Ver. 1.05 (Cod. 91000105)		Same
Patient contacting materials	Polyurethane and Stainless Steel (SST) AISI 304		Same
Operating conditions	+10°C to +40°C Non condensed relative humidity: 30% to 75%		Same
Accuracy	0.3°C within rated output range (ISO 80601-2-56:2009 requirements for clinical thermometers)		Same
Precision and repeatability [°C]	0.1		Same
Response time ([1])	Both heating and cooling response time are approximately 1 second		Same
Requirements for probe sterilization	Compliance to standard ISO 10993-7 Compliance to ANSI/AAMI ST72:2011 and FDA guidelines. Pyrogenicity test as outlined in USP<151>. Shelf life procedure and protocol performed according to standard ISO 11607		Same

(1) Response time is defined as the mean value of the measured time intervals associated to temperature increase (tr) or to temperature decrease (tf) necessary to cover the 63.3% of the total temperature excursion.

Element of comparison	Subject Device: FIAB - ESOTEST MULTI Esophageal Temperature Probe and Temperature Monitoring System with Visualization	Predicate Device: K180047 FIAB - ESOTEST MULTI Esophageal Temperature Probe and Temperature Monitoring System	Comments
Biocompatibility of the patient contacting part	Compliance to ISO 10993-1		Same
Software	Compliance to EN 62304		Same
Electrical safety	Compliance to IEC 60601-1		Same
EMC	Compliance to EN 60601-1-2		Same
Performance bench testing	Compliance to ISO 80601-2-56:2009		Same

Substantial Equivalence Discussion:

As shown in the table above, there is no significant difference in terms of design, materials, use or performance between the subject device and the predicate device. The indications for use of the subject device is same as the predicate device.
In fact, the adapter cable is an optional component intended exclusively to provide visualization of the location of the temperature probe. Such feature does not change the intended use of ESOTEST MULTI as a clinical thermometer for the detection of the esophageal temperature. Extensive non-clinical testing proves that the addition of the adapter cable to the system does not raise any new questions of safety or effectiveness.

The ESOTEST MULTI ADAPTER CABLE works in the identical way as a diagnostic cable for the purpose of electrode visualization. The ESOTEST MULTI ADAPTER CABLE is similar to the commercially available adapter cables typically used to connect diagnostic catheters to mapping systems, such as the St Jude Medical Supreme Diagnostic Cable, Model 401986.

Non-Clinical Testing Summary:

To ensure that the introduction of the adapter cable does not compromise in any way the safety and the performance of ESOTEST MULTI, the tests required by the IEC 60601-1 and IEC 60601-1-2 standards have been carried out with the adapter cable connected to the system. In addition, the performance of ESOTEST MULTI when connected to a mapping system and the sensors visualization feature have been verified during several clinical procedures. Such tests demonstrated that the presence of the adapter cable does not interfere with the temperature measurement and that the probe sensors are correctly visualized by the mapping system. All the non-clinical tests that have been performed on the ESOTEST MULTI system are listed in the table below.

Test name	Endpoint	Result summary
EO and ECH residual testing	The residual levels must be below the limit values prescribed by the ISO 10993-7 standard	EO < 0.1 mg/disp ECH < 1 mg/disp

Test name	Endpoint	Result summary
LAL test	After the sterilization, the endotoxin concentration must be below the limit prescribed by the ANSI/AAMI ST72:2011 standard and FDA guidelines.	Endotoxin concentration <5
Pyrogen test	The material used for the contact part must be pyrogen free	According to USP, the tested product meets the requirement for the absence of pyrogens
Shelf life test	Validation of the declared shelf-life of the packaged probe (4 years) according to the standard ISO 11607	Results of tests demonstrate that the packaging system ensures sterility of device for a claimed period of 4 years
In vitro cytotoxicity test, sensitization test, intracutaneous reactivity test, acute systemic toxicity test	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 not cytotoxic, not sensitizing, meets the requirements of intracutaenous reactivity and meets the requirement for the absence of pyorogens
Software system tests	Verifying the correct implementation of the software requirements according to standard EN 62304	The residual anomalies found do not impact on the safety or on the performance of the device
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/emissions tests prescribed by the IEC 60601-1-2 standard	Verifying the compliance of the system to the EN 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 80601-2-56:2009 standard	The system accuracy and response time meets the requirements of the standard
Adapter cable validation	Verifying the compliance of the ESOTEST MULTI ADAPTER CABLE to the ANSI/AAMI EC53:1995 standard	The cable manufacturing process guarantees the compliance to ANSI/AAMI EC53:1995 standard
Performance test in the working environment	Verifying the immunity of the system to the most common disturbance sources in the working environment, verifying the compatibility with mapping systems	The system is not affected by the noise sources in the working environment. The system is compatible with the following mapping systems: EnSite Precision and Carto 3

Conclusion:

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 (K180047).