K123361

FEB 27 2013

Section 05

510(k) Summary

This document was prepared on 2012/11/07 and reviewed on 2013/02/21

1. Submitter

Fiab SpA
Via Costoli, 4
50039 Vicchio
Florence - Italy
Tel : (39) 055 849 79 216
Fax: (39) 055 849 79 87
Contact: Silvia Calabrò, Official Correspondent
Email: silvia@fiab.it; regulatory@fiab.it

2. Device name and classification

ESOTEST Esophageal Temperature Probe and Temperature Monitoring System.
Regulation description: Clinical electronic thermometer,
Product code: FLL,
Regulation number: 880.2910,
Device class: II,
There were no prior submissions addressed to FDA related to device in object of present submission.

3. Predicates

Lawfully marketed device to which is claimed equivalence:

S-Cath - Esophageal Temperature Probe and Temperature Monitoring System, K112376

4. Device description

ESOTEST *Esophageal Temperature Probe and Temperature Monitoring System* consists of following main parts (on parenthesis is reported FIAB model and reference):

- Monitor (ESOTEST PLUS 7717, 30110),
- Interconnect Cable (F5406/TER),
- Esophageal Probe (26155S/US).

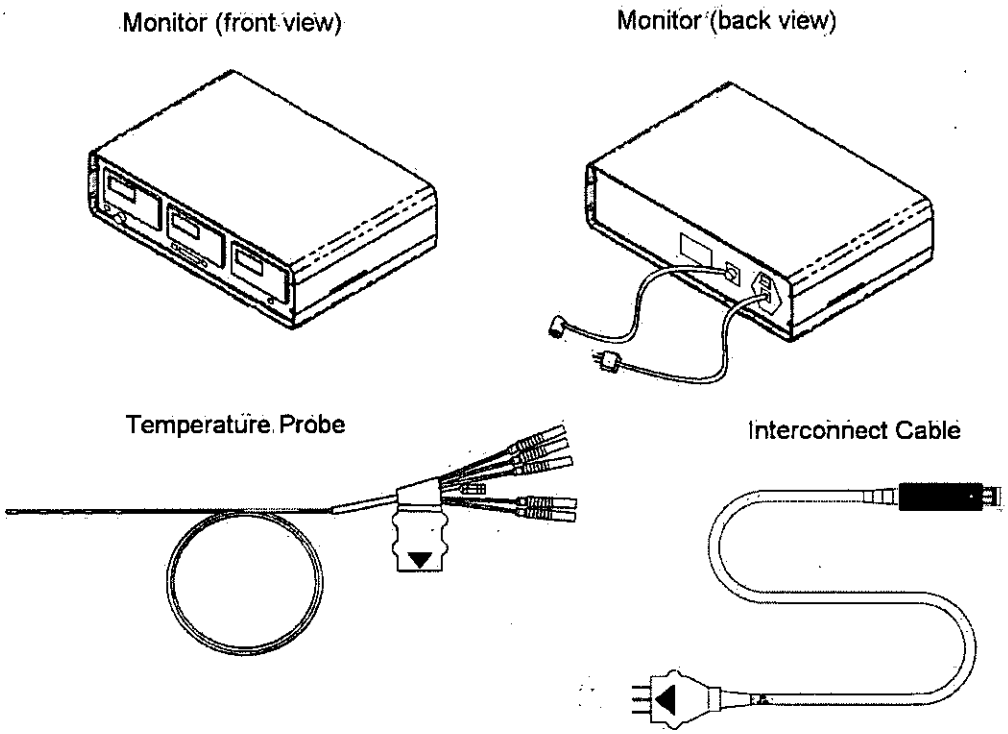

Fig.1: ESOTEST parts.

Monitor shows, on 3 separate led displays, the temperature detected by 3 thermocouple sensors placed in the esophageal probe. The incorporated alarm system allows the operator to set a threshold of adequate temperature. A buzzer and a flashing led signal the exceeding the temperatures of the threshold value alarm.
Esophageal probe is a Ø7Fr lead intended to continuous detection of esophageal temperature at three different points of esophagus. Temperature is get by 3 thermocouple sensors. Esophageal probe is connected to the monitor by interconnect cable.

5. Indications for use

ESOTEST Probe is intended for continuous esophageal temperature monitoring.
ESOTEST Monitor is intended for display continuous temperature measurement (°C) from 3 sensors temperature probe.

6. Comparison to predicate

ESOTEST *Esophageal Temperature Probe and Temperature Monitoring System* have the same intended use as the predicate and do not imply new technological characteristics.
Bench testing contained in this submission demonstrate that any differences in their technological characteristics and performance specifications do not raise any new questions of safety or effectiveness.
Thus FIAB ESOTEST is substantially equivalent to the predicate device S-Cath.

Feature	**Device under submisison FIAB - ESOTEST**	**Predicate S-Cath**
Thermometer type	esophageal	esophageal
Intended Uses	continuous temperature monitoring of patient's esophagus	continuous patient temperature monitoring, designed for insertion into esophagus
Labelling	Package label: includes product identification, lot number. Instructions for use: established. Temperature probe: labelled for single use	Package label: includes product identification, lot number. Instructions for use: established. Temperature probe: labelled for single use
Components	temperature probe interconnect cable monitor	temperature probe interconnect cable monitor
Temperature measurement range [°C]	25-45	25-45
Number of temperature sensors	3	12
Temperature sensor type	high accuracy thermocouple T type (accuracy ±0,3°C)	NTC thermistor (accuracy ±0,2°C)
Measurement presentation	3 led display	LCD monitor
Display specification	5 digit, 7-segment, 14 mm LED	n.a.
Alarm temperature range [°C]	36-41	0-90
Alarm signal	visual (flashing red led) audible (intermittent buzzer)	visual and audible
Control interface	UP and DOWN on/off volume knob	touch screen monitor
Power requirements	100-120/230 Vac	100-240 Vac

Feature	Device under submisison FIAB - ESOTEST	Predicate S-Cath
Monitor classification	I, CF, defib protected	I,BF, defib protected
Dimensions [cm]	monitor: 36,7x24,9x11,0 interconnect cable (length): 250 temperature probe (length and diameter): 95; ∅7Fr	monitor: 26x20x8,2 interconnect cable (length): 305 temperature probe (length and diameter): 77,5; ∅10Fr
Introduction	esophageal (nose/throat)	esophageal
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 3 sensors per probe measurements and user-selected alarm limit are displayed on LED Displays.	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 displayed LCD Display includes user-selected alarm limits.
Materials (patient contacting)	Polyurethane and Stainless Steel (SST) AISI 304	Flexible Polyether and Rigid Polyamide (PEBAX)
Ambient temperature environment	no special ambient temperature range is specified for the device	no special ambient temperature range is specified for the device
Accuracy [°C]	within rated output range in normal use is not greater than 0,3°C (ISO 80601-2-56:2009 requirements for clinical thermometers)	within rated output range in normal use is not greater than 0,3°C (ISO 80601-2-56:2009 requirements for clinical thermometers)
Precision and repeatibility [°C]	0,1	0,1
Response time	Both heating transient response time and cooling transient response time are approximately 1"; time is for probe plunged from reference bath to a water bath with a 2°C differential.	Heating transient response time is 7" and cooling transient response time is approximately 4.5" (time is for probe plunged from reference bath to a water bath with a 2°C differential)
Other capabilities	Device fully complies with UL and IEC (electrical, EMC): UL60601-1:2006 IEC60601-1-2: 2007 UL listing: FIAB SPA: Medical equipment PIDF (UL File # E324758)	Device fully complies with IEC (electrical, EMC): IEC60601-1:1998+A1+A2; IEC60601-1-2:2007

Tab.1: Comparison table.

7. Non-clinical performance data

In order to support Substantial Equivalence and performance characteristics of ESOTEST, non-clinical test were performed; the detailed description is reported on Section 18.

Following it is reported a brief description of the tests, including purpose, measurement protocols and layouts, and the acceptance criteria for each parameter under test; the materials and the instruments used; the measurements results; the values of the parameters attributed to the devices as confirmed by the compliance to the specified criteria.

Performance characteristics that are evaluated were obtained from FDA guidance: "Guidance on the content of premarket notification [510(K)] submission for clinical electronic thermometers" [March 1993] and performed according to FIAB internal protocol developed by following the guidelines of the technical standards:

- ISO 80601-2-56:2009 - Medical electrical equipment. Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement
- NIST Technical Note 1297: 1994 Edition - Guidelines for Evaluating and Expressing the Uncertainty of NIST Measurement Results.

Performance characteristics that were evaluated are in the following table:

Characteristic	***ESOTEST requirement***	***Reference***
Accuracy of the device	±0,3℃	ISO 80601-2-56 – 201 .101.2 Laboratory accuracy
Precision in condition of repeatability	0,1℃	NIST TN 1296 – Appendix D
Response Time	1s	ISO 80601-2-56 – 201.101.3 Time response for a continuous clinical thermometer

Thermometric chain of the devices under test

The esophageal temperature measurement process is realized through a thermometric chain resulting by 3 elements: ESOTEST Probe, interconnect cable for the connection of probe to the monitor and the ESOTEST Monitor itself. Since the ESOTEST system has 3 independent thermometers and independent connection to the sensor in the probe for each device there are 3 independent thermometric chain that work at the same time.

Tests performed

Accuracy: ESOTEST's accuracy was verified comparing temperature measurements performed by each of three thermometers present in the device with temperature measured by a reference thermometer. A reference thermometric chain, consisting in a reference probe (Pt100) and a reference thermometer, both calibrated, was used as

comparison instrument in order to evaluate the difference between the values of the same temperature, measured by the two chains. Explored temperature range is 25-45°C.
The measurements was performed in order to verify that thermometric chain realized with ESOTEST System (connecting cable, connectors and internal wiring employed for the assembly of ESOTEST System), ensure the accuracy requirements of the reference standard, as well as the predicate device's performances (±0,3°C).
For the tests were used 3 ESOTEST Monitor with 3 Probes, a thermostatic bath and a reference thermometer with probe. Based on a considerable number of measurements, the results were that for each tested thermometer (3 thermometers for each monitor for a total of 9 tested thermometers) none of the difference between reference and measured temperature exceed the device's accuracy. Then it was possible to conclude that the device ESOTEST Monitor with his ESOTEST Probe and their connecting cable is characterized by an accuracy of ±0,3°C in the whole measurement range 25-45°C.

Repeatibility: The purpose of this test is to measure, in condition of repeatability, the precision of the thermometric chain previously described and verify that it do not exceeds the displays resolution (0,1°C). For the tests were used 5 ESOTEST Monitor with Probe a thermostatic bath and a reference thermometer with probe. Under repeatibility conditions were performed 14 measurements for each thermometer (for a total of 15 independent thermometers) and results obtained confirmed that precision is in the specified limit (0,1°C).

Response time: the purpose of this test is measure rise and fall times of the values displayed by ESOTEST Monitor in reply to temperature variations sensed by ESOTEST Probe, and verify that these response times do not exceed the limits established (1,6s). For the test were used 6 ESOTEST Monitor and probe, 1 thermostatic bath, 1 adiabatic bottle, 2 reference thermometers, 1 video camera. Following procedure was followed: a bath is at a certain temperature (T) and the other one is maintained at a greater temperature (T+2°C). For the rise time: after thermal stabilization in the thermostatic baths at lower temperature probe was plunged in the thermostatic bath at upper temperature. Rise time is obtained measuring elapsed time from plunging of probe in the upper bath to the achievement of final temperature. For the fall time it was repeated same procedure from upper to lower bath. Rise and fall times were evaluated through a statistically significant and independent number of measurements (18 for each evaluation). Results confirmed that rise and fall times are in the expected range.

8. Conclusion

The following data have been considered from devices comparison (*ESOTEST Esophageal Temperature Probe and Temperature Monitoring System* vs *S-Cath - Esophageal Temperature Probe and Temperature Monitoring System*) and from performance testing, in order to demonstrate Substantial Equivalence:

- the same intended use and site application (temperature monitoring of patient's esophagus);
- the same components of monitoring system (probe, interconnect cable, monitor);
- similarity of technical/physical features (in terms of procedure of use);
- the same temperature measurement range (25-45 °C);
- the same accuracy of measurement (±0,3°C in the whole measurement range);
- the same precision and repeatibility (0.1°C);
- a faster response time (1" for both heating and cooling transient response time).

According to these data we can finally conclude that the temperature measurement system composed of ESOTEST Monitor, ESOTEST Probe and their connecting cable, is substantially equivalent to the predicate device in terms of performances, usage characteristics, safety of use.
The differences with the predicate device do not affect substantial equivalence of performances and do not raise any new safety concern.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 27, 2013

Ms. Silvia Calabrò
FIAB SpA
Official Correspondent
Via P. Costoli, 4
50039 Vicchio
Florence Italy

Re: K123361
Trade/Device Name: Esophageal Temperature Probe and Temperature Monitoring System
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic thermometer
Regulatory Class: II
Product Code: FLL
Dated: January 10, 2013
Received: January 18, 2013

Dear Ms. Calabrò:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 04

Indications for Use

510(k) Number (if known): - K123361

Device Name:

ESOTEST Esophageal Temperature Probe and Temperature Monitoring System

Indications For Use:

ESOTEST Probe
Esotest probe is intended for continuous esophageal temperature monitornig.

ESOTEST Monitor
Esotest monitor is intended for display continuous temperature measurement (°C) from 3 sensors temperature probe.

Prescription Use __X____ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

Kathleen E. Fitzgerald

Digitally signed by Kathleen E. Fitzgerald
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=0010093027, cn=Kathleen E. Fitzgerald
Date: 2013.02.26 11:40:17 -05'00'

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