August 11, 2021

Sensatronic GmbH
% Stephen Gorski
President
Imagenix, Inc.
S65 W35739 Piper Road
Eagle, Wisconsin 53119

Re: K203643
Trade/Device Name: Sensatronic Reusable Temperature Probes
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical electronic thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: July 9, 2021
Received: July 12, 2021

Dear Stephen Gorski:

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,

Payal Patel
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: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*

K213643

Device Name
Sensatronic Reusable Temperature Probes

Indications for Use *(Describe)*
Sensatronic Reusable Temperature Probes are intended to be used for monitoring temperature. The temperature probes are designed for use with GE Healthcare monitoring systems, Schiller and other monitors compatible with YSI 400 Series temperature probes.

The probes are indicated for use by qualified medical personnel only.

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 in accordance with 21 CFR 807.92

(a) (1) **Submitted by:**

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Germany
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j.schwarz(at)sensatronic.com

**Contact Person:** Mr. Jens Schwarz

**Position/Title:** General Manager

**Date of Preparation:** July 9, 2021

(2) **Trade Name:** Sensatronic Reusable Temperature Probes

**Common/Classification Name:** Thermometer, Electronic, Clinical

**Product Code(s):** 21 CFR §880.2910; FLL

**Class:** Class II

(3) **Predicate Device(s):** Substantial Equivalence to:

| K Number | Model | Manufacturer |
|---|---|---|
| K050837 | Reusable Temperature Probes (M1024254 Skin Temperature probe, reusable; M1024247, GP Temperature Probe, Adult, reusable; M1024251 GP Temperature Probe, Pediatric, reusable) | GE Healthcare |

**Reason for Submission:** New Device(s)

(4) **Description of Device:**

Sensatronic Reusable Temperature Probes(s) are designed and constructed for for compatibility with monitoring systems the using YSI 400 series temperature measurements specification.

Sensatronic Reusable Temperature Probes are constructed with the following features:

- Sealed phone plug design suitable for immersion cleaning and disinfection and steam sterilization
- Two internal conductors for connection to the thermistor
- Internal Kevlar fibers for strength and pull resistance

- Biocompatible outer jacket of thermoplastic rubber (TPR)
- The general purpose esophageal/rectal probes are available in three sizes/diameters: 4 mm, 3.2 mm, 2.3 mm, in a 275 cm standard probe length (the -275 denotes the length in centimeters, other lengths available as shown below)
- The probes for skin application are available in three disk sizes/diameters: 16 mm, 10 mm, and 6 mm
- The probes are offered with straight and right-angle ¼ inch (6.35 mm) phono plug type connectors, as well as connectors for Schiller monitoring systems. The following configurations are offered:

| Temperature Probe Types | Model | Suffix (Connector) | Compatibility Series | Cable length | Diameter of Cable/(Tip) |
|---|---|---|---|---|---|
| General Purpose Rectal/ Esophageal Probe, Large | AR-275 | -PA | GE Healthcare (YSI ¼ in. phono plug) | 275 cm | 4.0 mm (4.5 mm tip) |
| | AR-275 | -PRA | | | |
| | AR-200 | -S2 | Schiller | 200 cm | |
| | AR-300 | -S1 | | 300 cm | |
| | AR-500 | -S1 | | 500 cm | |
| General Purpose Rectal/ Esophageal Probe, Medium | PR-275 | -PA | GE Healthcare (YSI ¼ in. phono plug) | 275 cm | 3.2 mm (3.7mm tip) |
| | PR-275 | -PRA | | | |
| | PR-200 | -S2 | Schiller | 200 cm | |
| | PR-300 | -S1 | | 300 cm | |
| | PR-500 | -S1 | | 500 cm | |
| General Purpose Rectal/Esophageal Probe, Small * | NR-275 | -PA | GE Healthcare (YSI ¼ in. phono plug) | 275 cm | 3.2/2.3 mm (2.7mm tip) |
| | NR-275 | -PRA | | | |
| Skin Temperature Probe, Large | SAR-275 | -PA | GE Healthcare (YSI ¼ in. phono plug) | 275 cm | 4.0 mm (16mm disk) |
| | SAR-275 | -PRA | | | |
| | SAR-200 | -S2 | Schiller | 200 cm | |
| | SAR-300 | -S1 | | 300 cm | |
| | SAR-500 | -S1 | | 500 cm | |
| Skin Temperature Probe, Medium | SPR-275 | -PA | GE Healthcare (YSI ¼ in. phono plug) | 275 cm | 3.0 mm (10mm disk) |
| | SPR-275 | -PRA | | | |
| | SPR-300 | -S1 | Schiller | 300 cm | |
| | SPR-500 | -S1 | | 500 cm | |
| Skin Temperature Probe, Small * | SNR-275 | -PA | GE Healthcare (YSI ¼ in. phono plug) | 275 cm | 3.2/2.3 mm (6mm disk) |
| | SNR-275 | -PRA | | | |
| | SNR-300 | -S1 | Schiller | 300 cm | |

* NOTE: The distal 50cm of the probe cable is stepped to the smaller diameter 2.3mm cable

**Probe Connector Suffix Guide:**

| Connector Suffix | Connector/Contact Description |
|---|---|
| -PA | 6.35 mm phono plug, 2 conductor, straight |
| -PRA | 6.35 mm phono plug, 2 conductor, right angle |
| -S1 | Siemens monitor, 5 pin, straight |
| -S2 | Siemens monitor, 8 pin, straight |

Table 1: Probe Configurations offered

## (5) Intended use:

The intended use for the Sensatronic Reusable Temperature Probes is the same as the predicate Temperature Probes: monitoring of temperature.

### Indications for Use:

Sensatronic Reusable Temperature Probes are intended to be used for monitoring temperature. The temperature probes are designed for use with GE Healthcare monitoring systems, Schiller and other monitors compatible with YSI 400 Series temperature probes.

The probes are indicated for use by qualified medical personnel only.

Prescription use only.

## (6) Technological Characteristics:

The Sensatronic Reusable Temperature Probes utilize the same technological principles as the predicate devices to measure temperature: both incorporate thermistor temperature sensors in the probes which utilize the YSI 400 resistance specification, and are offered in both rectal/esophageal and skin-applied models. Refer to the following comparison table:

Comparison of Technological Features to Predicate Devices:

| Product/Feature | Sensatronic Reusable Temperature Probes | GE Healthcare Reusable Temperature Probes | Remark |
|---|---|---|---|
| Manufacturer | Sensatronic GmbH | GE Healthcare | |
| Model Number(s) | AR-275 -PA; AR-275-PRA; AR-200-S2; AR-300-S1; AR-500-S1;<br>PR-275 -PA; PR-275-PRA; PR-200-S2; PR-300-S1; PR-500-S1;<br>NR-275-PA; NR-275-PRA;<br>SAR-275-PA; SAR-275-PRA; SAR-200-S2; SAR-300-S1; SAR-500-S1;<br>SPR-275-PA; SPR-275-PRA; SPR-300-S1; SPR-500-S1<br>SNR-275-PA; SNR-275-PRA; SNR-300-S1 | M1024254 (Skin probe)<br>M1024247 (GP Probe)<br>M1024251 (GP Probe)<br>GP is general purpose esophageal/rectal | Product range for both devices includes both general purpose and Skin probes |
| 510(k) Number | K203643 | **K050837** | |
| Application/Intended use: | Measurement and monitoring of patient temperature | Measurement and monitoring of patient temperature | Same |

| Product/Feature | Sensatronic Reusable Temperature Probes | GE Healthcare Reusable Temperature Probes | Remark |
|---|---|---|---|
| Application Site(s) | Rectal/esophageal; Skin | Rectal/esophageal; Skin | Same application sites |
| Reusable | ✓ YES | ✓ YES | Same |
| Steam Sterilization | ✓ YES | ✓ YES | Same |
| Operating principle(s) | Single thermistor sensor, with NTC (negative temperature coefficient) specification meeting YSI 400 series compatibility | Single thermistor sensor, with NTC (negative temperature coefficient) specification meeting YSI 400 series compatibility | Same thermistor characteristics, both meet YSI 400 series compatibility |
| Accuracy | ± 0.1 °C (25 °C – 45 °C) | ± 0.1°C (0°C to 50°C) | Equivalent in the physiological range |
| Measurement Range | 0°C to 50°C | 0°C to 50°C | Same |
| Probe Construction – Rectal/Esophageal | | | |
| Cable and Tip Material | Biocompatible Thermoplastic Elastomer | Biocompatible Plastic (type not specified) | Equivalent Function |
| Tip Profile | Cylindrical, with formed rounded tip | Cylindrical, with formed rounded tip | Same |
| Esophageal/Rectal Probe Tip dimensions | Type A: 4.5 mm;<br>Type P: 3.7 mm;<br>Type N: 2.7 mm | 4mm;<br>3mm; | Sensatronic tip has 3 available diameters, GE has 2; minor differences in dimensions |
| Probe Construction – Skin | | | |
| Tip (Disk) Material | Stainless steel, Biocompatible Plastic | Stainless steel, Plastic (type not specified) | Equivalent function |
| Tip (Disk) dimensions | Type A: 16 mm;<br>Type P: 10 mm;<br>Type N: 6 mm | 10 mm; | Sensatronic disk offers 3 available diameters, GE offers 1 |
| Cable and Connector | | | |
| Cable overall length | 2.75 meters standard length; 2, 3, and 5 meters in specific models | 3 meters (all models) | Equivalent functionality, some difference in length |
| Connector(s) | Straight Phone Plug; Right Angle Phono Plug; Manufacture specified types (incl. Schiller); YSI 400 series function | Straight Phone Plug); YSI 400 series function | Equivalent electrical function; GE Healthcare offers straight Phono plug style; Sensatronic Probes are offered in additional connector styles; all have YSI 400 series function |
| Cleaning, Disinfection, and Sterilization Methods | | | |

| Product/Feature | Sensatronic Reusable Temperature Probes | GE Healthcare Reusable Temperature Probes | Remark |
|---|---|---|---|
| Cleaning & Disinfection Method(s) | Manual wipe with cleaning agents or machine washing; immersion in disinfectant | Manual wipe with cleaning agents or machine wash; immersion in disinfectant | Equivalent function: both support manual cleaning, machine wash and disinfectant immersion |
| Sterilization Method(s) | Steam autoclave at 132°C/4 minutes (max 100 cycles) | 1) Plasma (Sterrad);<br>2) Steam autoclave for 20 minutes at 121°C/250°F (max 100 cycles), or<br>3) Steam autoclave 18 minutes at 134°C/273°F (max 30 cycles) | Equivalent function: Sensatronic specifies current industry practices for autoclave temperature of 132°C with 100 cycles durability; predicate lists 30 cycles durability; Sensatronic does not specify plasma (Sterrad) method |
| Physical and Environmental Specifications | | | |
| Operating Conditions | 0°C…+50°C<br>10…100 % r. h | 0°C – +50°C | Equivalent Operating Range |

As summarized above, the Sensatronic Reusable Temperature Probes utilize equivalent technological characteristics and specifications as the listed predicate devices.

(b) (1) **Non-Clinical Tests Submitted:**

Sensatronic Reusable Temperature Probes were laboratory tested to current applicable standards for medical device electrical safety and electromagnetic compatibility as well as particular standards for clinical thermometers. The following standards were utilized in compliance testing:

- Electrical safety testing per IEC 60601-1
- Electromagnetic compatibility testing per IEC 60601-1-2
- Usability evaluation per IEC 60601-1-6 and IEC 62366 for professional use
- Particular requirements for clinical thermometers per ISO 80601-2-56 including accuracy.
- Environmental storage testing per IEC 60068-2-78 and IEC 60068-2-1
- Cable pull testing per ANSI/AAMI/ EC53 (used as reference standard only)

The probes met acceptance criteria for compliance to the standards.

The probes were evaluated to the requirements of the following guidance:

- Guidance on the Content of Premarket Notification [510(k)] Submissions for Clinical Electronic Thermometers, March 1993

The probes met the requirements of guidance.

Risk management, risk and hazard analysis of the probes was performed to the following standard:

- Application of risk management to medical devices per ISO 14971

The probes met risk management criteria for acceptability of residual risks.

Probe patient contact materials were evaluated for biocompatibility. The tests were performed to the following standards and included the listed tests:

- Biocompatibility testing per ISO-10993-1, ISO-10993-5 and ISO-10993-10
- Cytotoxicity test
- Irritation testing
- Sensitization testing

The probe materials met the acceptance criteria for biocompatibility.

The probes were evaluated for the efficacy of the specified manual and machine reprocessing methods and cleaning and disinfection agents for:

- Efficacy of cleaning/bioburden removal per methods of ISO 15583-5, AAMI TIR30, FDA Guidance for Reprocessing Medical Devices in Health Care Settings
- Efficacy of disinfection methods (bioburden)

The probes met acceptance criteria for cleaning and disinfection.

The probes were evaluated for the efficacy of steam sterilization:

- Efficacy of steam sterilization (gravity, forced vacuum) per methods of ISO 17665-1 and ISO 11737-2.

The probes met the acceptance criteria for steam sterilization.

The probes were evaluated for reuse life durability for per the reprocessing methods specified in device labeling:

- Manual cleaning/disinfection: up to 300 cycles
- Machine washing/disinfection: up to 300 cycles
- Steam sterilization: up to 100 cycles

The probes met acceptance criteria for durability and performance after testing.

In summary, the probes met acceptance criteria for conformance to the applicable standards, performance accuracy, biocompatibility, cleaning and disinfection, steam sterilization, and durability. Residual risks met criteria for acceptability for the intended use.

## (2) Clinical Tests Submitted:

(none)

## (3) Conclusions from Tests:

As described in (b)(1) and (b)(2) above, the Sensatronic Reusable Temperature Probes are equivalent to the predicate temperature probes as supported by compliance, laboratory, and biocompatibility testing.

The results of all tests demonstrate that the Sensatronic Reusable Temperature Probes meet specified requirements for device compatibility and substantial equivalence to the referenced predicate devices.