January 8, 2026

Shenzhen Med-link Electronics Tech Co., Ltd.
Summer Xia
Regulatory Affairs Specialist
Zone A of 1st and 2nd Floor, and 3rd Floor, Building A, No. 7, Tongsheng Industrial Park Road
Shanghenglang Community,
Shenzhen, 518109
China

Re: K251160
Trade/Device Name: Sterile temperature probe (Model: W0001ES, W0028ES, W0101FS-A, W0101FS-P, W0099LS, W0099FS, W0099PS)
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: December 12, 2025
Received: December 12, 2025

Dear Summer Xia:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Colleen J. Lawrimore -S

Colleen Lawrimore, Ph.D.
For David Wolloscheck, Ph.D.
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K251160

Device Name
Sterile temperature probe (Model: W0001ES, W0028ES, W0101FS-A, W0101FS-P, W0099LS, W0099FS, W0099PS)

Indications for Use *(Describe)*
The sterile temperature probe is used with Mindray BeneVision N17 patient monitor to monitor body or skin surface temperature. The device is for use by qualified healthcare personnel.
The probe is offered in the following three configurations:
- Body cavity temperature probe for monitoring of the core temperature in adult and pediatric patients by insertion into the esophageal; and for monitoring of the body temperature in adult and pediatric patients by insertion into the rectal or nasopharyngeal cavity.
- Skin contact temperature probe for monitoring of skin temperature to an adult and pediatric patient's skin surface.
- Ear cavity temperature probe for monitoring of body temperature by insertion of the foam into pediatric or adult's auditory canal.
For pediatric population, the subpopulations are children and adolescents.

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 - K251160

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92.
Type of submission: Traditional
The assigned 510(k) number: K251160

1. Submitter information

Manufacturer Name: Shenzhen Med-link Electronics Tech Co., Ltd.
Address: Zone A of 1st and 2nd Floor, and 3rd Floor, Building A, No. 7, Tongsheng Industrial Park Road, Shanghenglang Community, Dalang Street, Longhua District, 518109 Shenzhen, PEOPLE'S REPUBLIC OF CHINA
Tel: 86-755-61568825
Fax: 86-755-61120055
Establishment Registration Number: 3006636961

2. Correspondent information

Summer Xia (Regulatory Affairs Specialist)
Shenzhen Med-link Electronics Tech Co., Ltd.
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3. Data of Preparation

8st, January, 2026

4. Identification of the subject device

Device Common Name: Temperature Probe
Trade/Device name: Sterile Temperature Probe (Model: W0001ES, W0028ES, W0101FS-A, W0101FS-P, W0099LS, W0099FS, W0099PS)
Classification name: Clinical Electronic Thermometer
Regulation number: 21 CFR 880.2910
Device Class: Class II
Product Code: FLL
Review Panel: General Hospital

5. Identification of the Predicate Device

No.	Device Name	Common Name	Manufacture	Classification and Code	Classification regulation	510(k) number
1	DeRoyal Temperature Monitoring Probe	Temperature Monitoring Probe	DeRoyal Industries, Inc.	Class II, FLL	21 CFR 880.2910	K200631

6. Indications for Use of the Subject Device

The sterile temperature probe is used with Mindray BeneVision N17 patient monitor to monitor body or skin surface temperature.
The device is for use by qualified healthcare personnel.
The probe is offered in the following three configurations:
- Body cavity temperature probe for monitoring of the core temperature in adult and pediatric patients by insertion into the esophageal; and for monitoring of the body temperature in adult and pediatric patients by insertion into the rectal or nasopharyngeal cavity.
- Skin contact temperature probe for monitoring of skin temperature to an adult and pediatric patient's skin surface.
- Ear cavity temperature probe for monitoring of body temperature by insertion of the foam into pediatric or adult’s auditory canal.

For pediatric population, the subpopulations are children and adolescents.

7. Device Description

The sterile temperature probe is a compatible sensor for use with Mindary BeneVision N17 patient monitor, as an accessory of the legally marketed patient monitor on the US market, the sterile temperature probe is indicated for continuous monitoring of body temperature in hospital settings. It mainly consists of plug, cable, and probe at patient side. When in use, the probe should be connected to the compatible device, and the temperature change of the patient's measured part is sensed through the built-in NTC thermistor at the probe end and the patient's body temperature is measured. The subject devices are used with Mindray BeneVision N17 patient monitor, which was cleared under K182075.
The temperature probes are packed individually into a paper plastic pouch in sterile condition and are single use only.

8. Comparison table for subject device and predicate device

Item	Subject Device	Predicate Device	Comparison
Device name	Sterile temperature probe	Temperature Monitoring Probe	/
Trade name	/	DeRoyal Temperature Monitoring Probe	/
510(K) number	K251160	K200631	/
510(K) Owner	Shenzhen Med-link Electronics Tech Co., LTD.	DeRoyal Industries, Inc	/
Indications for Use	The sterile temperature probe is used with Mindray BeneVision N17 patient monitor to monitor body or skin surface temperature. The device is for use by qualified healthcare personnel. The probe is offered in the following three configurations: - Body cavity temperature probe for monitoring of the core temperature in adult and pediatric patients by insertion into the esophageal; and for monitoring of the body temperature in adult and pediatric patients by insertion into the rectal or nasopharyngeal cavity. - Skin contact temperature probe for monitoring of skin temperature to an adult and pediatric patient's skin surface - Ear cavity temperature probe for monitoring of body temperature by insertion of the foam into pediatric or adult's auditory canal. For pediatric population, the subpopulations are children and adolescents.	The DeRoyal Temperature Monitoring Probe is used for routine monitoring of the patient's core body or skin surface temperature. The probe is offered in the following three configurations: - General Purpose Temperature Probe for routine monitoring of the core in adult and pediatric patients by insertion into the nasopharyngeal, esophageal, or rectal cavities; - Adult Skin Temperature sensor for routine monitoring of skin temperature by application of the probe's adhesive cover to an adult patient's skin surface. - Tympanic Temperature Probe for routine monitoring of the core body temperature in adult and pediatric patients by insertion of the ear piece into the aural canal. The device is single use and for use by licensed healthcare practitioners only. The probes are designed to interface with DeRoyal- branded cables for connection with YSI 400 or 700 series compatible monitors, including the following patient monitors and equivalent models:Mindray Passport, Philips IntelliVue, Siemens/Draeger Infinity, and GE Datex-Ohmeda	Note 1

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<tr><th>Item</th><th>Subject Device</th><th>Predicate Device</th><th>Comparison</th></tr>
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<tr><td>Patient population</td><td><table><tr><th>Type</th><th>Device Model</th><th>Patient population</th></tr><tr><td>Skin surface</td><td>W0001ES, W0028ES</td><td>Adult, children and adolescents</td></tr><tr><td rowspan="2">Ear cavity</td><td>W0101FS-A</td><td>Adult</td></tr><tr><td>W0101FS-P</td><td>Children and adolescents</td></tr><tr><td>Body cavity</td><td>W0099LS, W0099FS, W0099PS</td><td>Adult, children and adolescents</td></tr></table></td><td><table><tr><th>Type</th><th>Device Model</th><th>Patient population</th></tr><tr><td>Adult Skin Sensor</td><td>Not provided</td><td>Adult</td></tr><tr><td>Tympanic Probe</td><td>Not provided</td><td>Adult and pediatric</td></tr><tr><td>General Purpose</td><td>Not provided</td><td>Adult and pediatric</td></tr></table></td><td>Note 2</td></tr>
<tr><td>Intended User</td><td>Healthcare professional</td><td>Licensed healthcare practitioners</td><td>SE</td></tr>
<tr><td>Use Environment</td><td>Hospital settings</td><td>Hospital</td><td>SE</td></tr>
<tr><td>Prescription use
or Over-The-Counter Use</td><td>Prescription use</td><td>Prescription use</td><td>SE</td></tr>
<tr><td>Measuring Site</td><td><table><tr><th>Type</th><th>Device Model</th><th>Measuring Site</th></tr><tr><td>Skin surface</td><td>W0001ES, W0028ES</td><td>Skin surface</td></tr><tr><td>Ear cavity</td><td>W0101FS-A, W0101FS-P</td><td>Auditory canal</td></tr><tr><td>Body cavity</td><td>W0099LS, W0099FS, W0099PS</td><td>Esophageal, rectal, nasopharyngeal cavities</td></tr></table></td><td><table><tr><th>Type</th><th>Device Model</th><th>Measuring Site</th></tr><tr><td>Adult Skin Sensor</td><td>Not provided</td><td>Skin surface</td></tr><tr><td>Tympanic Probe</td><td>Not provided</td><td>Auditory Canal</td></tr><tr><td>General Purpose</td><td>Not provided</td><td>Nasopharyngeal, esophageal, rectal cavities</td></tr></table></td><td>SE</td></tr>
<tr><td>Mode of Operation</td><td>Direct Mode</td><td>Direct Mode</td><td>SE</td></tr>
</table>

Item	Subject Device	Predicate Device	Comparison
Nature of Body Contact	Body cavity: Mucosal Membrane Skin surface: Intact Skin Ear cavity: Intact Skin	General Purpose: Mucosal Membrane Adult Skin Sensor: Intact Skin Tympanic Probe: Intact Skin	SE
Duration of Contact	Body cavity: Limited (< 24 hours) Skin surface: Limited (< 24 hours) Ear cavity: Limited (< 24 hours)	General Purpose: Limited (< 24 hours) Adult Skin Sensor:Prolonged (≥24 hours) Tympanic Probe: Prolonged (≥24 hours)	Note 3
Reference Body Site	Body cavity:Esophageal, rectal or nasopharyngeal cavities Skin surface: Skin Surface Ear cavity: Auditory canal	General Purpose: Esophageal, rectal or nasopharyngeal cavities Adult Skin Sensor: Skin Surface Tympanic Probe: Aural canal	SE
Principle of operation	Resistance of thermistor based on the metal conductor increases with temperature decrease, and the linear changes to the characteristics of the temperature measurement	Thermistor resistance based on the metal conductor increase with temperature decrease, and the linear changes to the characteristics of the temperature measurement	SE
Design/ Construction	① Body cavity: Wire set with a connector at the proximal end and a thermistor on the patient end. The wire set is enclosed in a tube that may be inserted into the application site. ② Skin surface: Wire set with a connector at the proximal end and a thermistor on the patient end. An adhesive probe cover applies the device to the patients' skin. ③Ear cavity: Wire set with a connector at the proximal end and a thermistor on the patient end. A foam earplug is used to insert into the patient's auditory canal	① General Purpose: Wire set with a thermistor chip at the distal end and a blue connector at the proximal end. The wire set is enclosed in a tube that may be inserted into the application site. ② Adult Skin Sensor: Wire set with a thermistor chip at the distal end and a blue connector at the proximal end. An adhesive probe cover applies the device to the patients' skin ③Tympanic Probe: Wire set with a thermistor chip at the distal end and a blue connector at the proximal end. A foam ear plug is used to insert the device into the patient's aural canal	SE

Item	Subject Device	Predicate Device	Comparison
Material	① Body cavity: PVC connector and PVC tube cable Thermistor: Ceramic ② Skin surface: Cover: double faced adhesive and foam Wire:Tinned copper with PVC insulation Thermistor: Ceramic Connector: PVC Strain Relief: PVC Cap: Epoxy ③Ear cavity: Ear Plug: Foam Wire: Tinned copper with PVC insulation Thermistor: Ceramic Connector: PVC Strain Relief: PVC Cap: Epoxy	① General Purpose: Tube: PVC Wire: Copper with PVC insulation Thermistor: Ceramic Connector: PVC-molded brass Strain Relief: PVC Cap: UV-cured adhesive ② Adult Skin Sensor: Cover: Adhesive foam Wire: Copper with PVC insulation Thermistor: Ceramic Connector: PVC-molded brass Strain Relief: PVC Cap: UV-cured adhesive ③Tympanic Probe: Ear Plug: Foam and/or cotton ball Wire: Copper with PVC insulation Thermistor: Ceramic Connector: PVC-molded brass Strain Relief: PVC Cap: UV-cured adhesive	Note 4
Power supply	Via patient monitor	Via patient monitor	SE
Thermistor	2.252 KΩ@25℃	/	Note 5

Item	Subject Device	Predicate Device	Comparison
Length	Body cavity: 600mm, 750mm Skin surface: 800mm Ear cavity: 800mm	Length: Body cavity: \ Skin contact: \ Tympanic Probe: \	Note 6
Rated Output Range	25℃~45℃	25°C to 45°C	SE
Accuracy	±0.1℃	±0.2°C	Note 7
Operating condition	5℃ ~ 40℃, 0～95%RH, 86kPa ~ 106kPa	25°C ~ 45°C	Note 8
Storage Condition	-10°C to +40°C, -10°C to +40°C, 86kPa ~ 106kPa	-25°C to +55°C	Note 9
Disposable or Reusable	Disposable	Disposable	SE
Sterile or Non-sterile	Sterile	General purpose temperature probe: Sterile Adult skin temperature sensor: Sterile Tympanic configuration is non-sterile	Note 10
Sterilization method	Sterilized with Ethylene Oxide	General Purpose: Sterilized with Ethylene Oxide Adult Skin Sensor: Sterilized with Ethylene Oxide Tympanic Probe: No	Note 11
Biocompatibility	Cytotoxicity complied with ISO 10993-5 Sensitization complied with ISO 10993-10 Irritation complied with ISO 10993-23	Cytotoxicity complied with ISO 10993-5 Sensitization complied with ISO 10993-10 Irritation complied with ISO 10993-10	SE
Basic Safety	IEC 60601-1	IEC 60601-1	SE
Performance	ISO 80601-2-56	ISO 80601-2-56	SE
EMC	IEC 60601-1-2	IEC 60601-1-2	SE
Clinical Testing	Not applicable	Not applicable	SE

Note 1: Predicate K200631 skin probe is only applicable to adult while the subject skin surface probe is applicable to adult, children and adolescents; the general purpose and tympanic probe of the predicate device are applicable to adult and pediatric patient, while the body cavity and ear cavity probes of the subject device are applicable to adult and children and adolescents. However, the subject device meets design requirements and complies with requirements of IEC 60601-1, IEC 60601-1-2 and ISO 80601-2-56 standard. This difference therefore does not raise new questions of safety or effectiveness.
The compatible monitor of the subject device is different from the predicate device, but the electrical safety, EMC and performance testing were performed on the subject devices, and the results of testing demonstrate the subject device complies with the requirements of IEC 60601-1, IEC 60601-1-2 and ISO 80601-2-56. Therefore, this difference does not raise new questions of safety or effectiveness.

Note 2: Predicate K200631 skin probe is only applicable to adult while the subject skin surface probe is applicable to adult, children and adolescents; the general purpose and tympanic probe of the predicate device are applicable to adult and pediatric patient, while the body cavity and ear cavity of the subject device are applicable to adult and children and adolescents. However, the subject device meets design requirements and complies with requirements of IEC 60601-1, IEC 60601-1-2 and ISO 80601-2-56 standard. This difference therefore does not raise new questions of safety or effectiveness.

Note 3: The duration of contact for skin surface and ear cavity of subject device is less than predicate device. The subject device complies with ISO 10993-5, ISO 10993-10, ISO 109963-23 and ISO 80601-2-56, so this difference does not raise new questions of safety or effectiveness.

Note 4: There are some differences in the materials used in the subject devices and the predicate devices. Biocompatibility testing was performed on the subject devices. Electrical Safety and EMC testing were performed on the subject devices. These test results demonstrate the subject devices comply with ISO 10993-5, ISO 10993-10 and ISO 10993-23 standard and this difference does not raise new questions of safety or effectiveness.

Note 5: The thermistor information of predicate device is not available. However, the validation test was conducted according to ISO 80601-2-56 standard and the difference does not raise new questions of safety or effectiveness.

Note 6: The length information of predicate device is not available. However, the validation test was conducted according to ISO 80601-2-56 standard and the difference does not raise new questions of safety or effectiveness.

Note 7: Although the measurement accuracy of the subject devices is different from the predicate device, but the subject devices comply with the requirements of ISO 80601-2-56 standard. Therefore, this difference does not raise new questions of safety or effectiveness.
Note 8 and 9: The operating and storage conditions of the subject device are different from the predicate device. Validation testing was conducted according to ISO 80601-2-56 standard

and the difference does not raise new questions of safety or effectiveness.

Note 10 and 11: The ear cavity probe of the subject device is sterile whereas the tympanic probe of the predicate device is non-sterile. The sterilization method for subject device was validated according to the requirements of ISO 11135. Biocompatibility testing was performed on the subject device, and the results of the testing demonstrate the subject device complies with the requirements of ISO 10993-5, ISO 10993-10 and ISO 109963-23. Electrical safety and EMC testing were also performed on the subject devices and the results of the testing demonstrate the subject device complies with the requirement of IEC 60601-1, IEC 60601-1-2 and ISO 80601-2-56. This difference does not raise new questions of safety or effectiveness.

9. Non- Clinical Testing

The following testing was conducted to demonstrate substantial equivalence.

Biocompatibility evaluation

The biocompatibility evaluation for the subject devices were conducted in accordance with the FDA Guidance for Industry and Food and Drug Administration Staff: Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process". The biocompatibility testing included the following tests:

- ISO10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
  - Cytotoxicity
- ISO 10993-10:2021 Biological evaluation of medical devices - Part 10: Tests for skin sensitization
  - Sensitization
- ISO10993-23:2021 Biological evaluation of medical devices - Part 23: Tests for irritation
  - Irritation
  - Oral and rectal Irritation (Body cavity temperature probe only)

The sterile temperature probe is considered surface/mucosal contacting for a duration of not to exceed 24 hours.

Performance Testing

Non-clinical testing has been conducted to verify that the subject devices meet all design specifications which supports the conclusion that it is Substantially Equivalent (SE) to the predicate device. The testing results demonstrate that the subject device complies with the following standards:

- IEC 60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION

Medical electrical equipment - Part 1: General requirements for basic safety and essential

performance

● IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION

Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

● ISO 80601-2-56 Second edition 2017-03

Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement. [Including: Amendment 1 (2018)].

● ASTM D4169-22 Standard Practice for Performance Testing of Shipping Containers and Systems

10. Clinical Testing

No clinical testing was needed to demonstrate substantial equivalence with the predicate device.

11. Conclusion

Based on above comparison and analysis, the Med-link Sterile Temperature Probes are substantially equivalent to the predicate device.