

510(K) SUMMARY
Premarket Notification [510(K)] Summary
(per 21 CFR 807.92)

JUL 18 2011

Company Name

Medivance, Inc.
321 South Taylor Avenue, Suite 200
Louisville, Colorado 80027

Contact Person: Lynne Aronson
Director, Regulatory Affairs and Quality Assurance
Telephone: 303-926-1917
Facsimile: 303-926-1924

Device Name

Proprietary Name: Nasogastric Tube Temperature Sensor
Common Name: esophageal temperature probe
Classification Name: esophageal stethoscope with electrical conductors;
electronic clinical thermometer

Predicate Devices

The Medivance Nasogastric Tube (NGT) Temperature Sensor is substantially equivalent in intended use, design, technological characteristics, and system features and functions to the following predicate devices in commercial distribution:

| <u>Device Name</u> | <u>Manufacturer</u> | <u>510(k)</u> |
|---|---------------------|---------------|
| Level 1 Esophageal Temperature Probe | Smiths | K935603 |
| Therma-Temp Esophageal Stethoscope with Temperature Sensor, and Steri-Temp Esophageal Temperature Probe | Cincinnati Sub-Zero | K072621 |

Indications for Use

The NGT Temperature Sensor is indicated for continuous measurement of patient core (esophageal) temperature in patients using Bard® or Argyle® 16 Fr or 18 Fr nasogastric sump tubes or other 16 Fr or 18 FR nasogastric tubes with a vent lumen of sufficient diameter to allow easy movement of the sensor within the lumen.

Description of the Device

The Medivance Nasogastric Tube (NGT) Temperature Sensor is a sterile, single use, disposable YSI400 series thermistor temperature probe that is designed for placement in the vent lumen of a 16 or 18 Fr Bard Nasogastric Sump or Argyle Salem Sump® nasogastric tube (or other 16 Fr or 18 FR nasogastric tubes with a vent lumen of sufficient diameter to allow easy movement of the sensor within the lumen) for measurement of esophageal temperature.

Substantial Equivalence Summary

The Medivance NGT Temperature Sensor and the predicate Smiths Level 1 and Cincinnati Sub-Zero esophageal temperature sensors are substantially equivalent with respect to the following:

| | |
|----------------------------|--|
| Indications for Use: | Continuous core patient temperature measurement (esophageal) |
| Technical Characteristics: | YSI 400 series thermistor |
| Accuracy Specifications: | $\pm 0.2^{\circ}\text{C}$ within the physiologic temperature range |
| Labeling: | Sterile, Single Use Only |
| Compliance with Standards: | Applicable sections of BS EN 12470-4 and/or ISO 80601-2-56 |

Test Summary

Testing demonstrated that the Medivance NGT Temperature Sensor performance meets the applicable requirements of BS EN 12470-4 (Clinical thermometers-Part 4: Performance of electrical thermometers for continuous measurement) and ISO 80601-2-56 (Medical electrical equipment – Particular requirements for basic and safety and essential performance of clinical thermometers for body temperature measurement).

Biocompatibility testing in accordance with ISO 10993-1 demonstrated that the Medivance NGT Temperature Sensor patient contact materials are non-cytotoxic, non-irritating and non-sensitizing.

Conclusions

The Medivance NGT Temperature Sensor has the same intended use and technological characteristic as the commercially-available predicate devices. The performance testing has demonstrated that the Medivance NGT Temperature Sensor meets the applicable requirements of BS EN 12470-4 and ISO 80601-2-56, and therefore provides substantially equivalent performance and safety as the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Ms. Lynne Aronson
Director, Regulatory Affairs and Quality Assurance
Medivance, Inc.
321 South Taylor Avenue, Suite 200
LOUISVILLE CO 80027

JUL 18 2011

Re: K110956
Trade/Device Name: Nasogastric Tube Temperature Probe
Regulation Number: 21 CFR§ 880.2910
Regulation Name: Clinical electronic thermometer
Regulatory Class: II
Product Code: FLL
Dated: July 11, 2011
Received: July 12, 2011

Dear Ms. Aronson:

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.

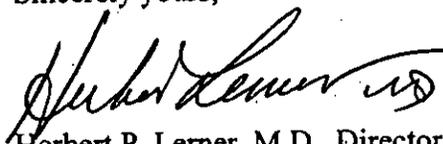
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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" (21 CFR 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,



Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE (FDA FORM)

510(k): K110956

Device: Nasogastric Tube Temperature Probe

Indications for Use:

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Prescription Use X
Use _____

OR

Over-the-Counter

(Per 21 CFR 801.109)

(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 Reproductive, Gastro-Renal, and
Urological Devices
510(k) Number K110956

(Optional Format 1-2-96)