

K991994

MAY 1 1998

SUMMARY OF SAFETY AND EFFECTIVENESS

1.0 Submitted By:

Peter Zurlo
Manager, Regulatory Affairs
BECTON DICKINSON CONSUMER PRODUCTS
1 Becton Drive
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2.0 Device Name:

B-D Assure Ear Thermometer

3.0 Predicate Device

Thermoscan® Instant Thermometer

4.0 Device Description:

The Becton Dickinson Infrared Thermometer is a device that measures patient body temperature by quantifying the infrared emission from the tympanic membrane.

The tympanic membrane has long been known to be an excellent spot to check body temperature because it shares the blood supply that reaches the hypothalamus, the center of core body temperature regulation.

In clinical application the end of the probe of the infrared thermometer is placed in the outer portion of the auditory canal, where the sensor can get a good view of the tympanic membrane. Placing the probe is very similar to the maneuver used to visualize the ear drum using an otoscope. There is no risk of eardrum injury because the probe is not long enough or small enough to be inserted too deep into the ear canal.

The most advantageous feature of infrared tympanic thermometry is that it takes very little time. Readings can be taken in a few seconds.

5.0 Intended Use:

The B-D Assure Ear Thermometer is designed for home use to measure body temperature from the tympanic membrane.

6.0 Technological Characteristics:

The B-D Assure Ear Thermometer and the predicate device (the Thermoscan® Instant Thermometer) have the same technological characteristics.

See Item 4 above for a description.

7.0 Performance Summary:

The B-D Assure Ear Thermometer has been bench tested and has proven to function in a equivalent manner as the predicate device. Based on the results of the bench testing the B-D Assure Ear Thermometer is considered safe and effective when used as intended.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 1998

Mr. Peter Zurlo
Manager, Regulatory Affairs
BECTON DICKINSON CONSUMER PRODUCTS
1 Becton Drive
Franklin Lakes, New Jersey 17417-1883

Re: K971994
Trade Name: B-D Assure Ear Thermometer
Regulatory Class: II
Product Code: FLL
Dated: January 30, 1998
Received: February 2, 1998

Dear Mr. Zurlo:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially-equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of

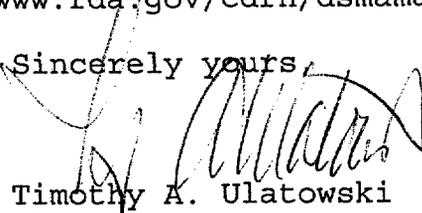
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the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K971994

Device Name: B-D Assure Ear Thermometer

Indications for Use:

The B-D Assure Ear Thermometer is designed for measuring body temperature in a home setting.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Pattina Ciccenti

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

510(k) Number K971994

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use X

(Optional Format 1-2-96)