BANTA Healthcare Products

570 ENTERPRISE
NEENAH, WI 54956
920/751-4300 Fax: 920/751-4370
800/215-5464

K983406

OCT 19 1998

SUMMARY OF SAFETY AND EFFECTIVENESS:

September 21, 1998

1. Company Information:
Banta Healthcare Products
570 Enterprise
Neenah, WI 54956
Registration #: 2182318
Phone: (920) 751-4300
Fax: (920) 751-4370
Contact Name: Richard Peppard
Contact Title: QA/RA Manager

2.

DEVICE NAME:	Thermometer Sheaths
PROPRIETARY NAME:	SaniTherm Thermometer Sheaths, Oral and Rectal, Digital and Mercury
COMMON NAME:	Thermometer Sheaths
CLASS:	II
PRO CODE:	FLL and FLK
PERFORMANCE STANDARDS:	None

3. Manufacturing Site Information:
Banta Healthcare Products
570 Enterprise
Neenah, WI 54956
Registration #: 2182318
Phone: (920) 751-4300
Fax: (920) 751-4370
Contact Name: Richard Peppard
Contact Title: QA/RA Manager

4. Y2K:
This product is not affected by Y2K.

5. Latex Content:
This product and its packaging are latex-free.

6. Device Description:
SaniTherm Disposable Thermometer Sheaths are plastic coverings used for either oral or rectal, mercury or digital thermometers. Digital Thermometer Sheaths may not be suitable for use with all clinical thermometers. Example – Clinical thermometers which employ rigid plastic sheaths.

7. Sterilization Information:
This product is not sold sterile.

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8. Product Specifications
Banta Thermometer Sheaths are made from ethylene methyl acrylate copolymer film.

9. Intended Use/Indications for Use
These devices are indicated for use as a barrier that is used as an accessory to oral or rectal, digital or mercury thermometers. These sheaths are non-sterile and are intended for single patient use only.

10. Substantial Equivalence
These devices are substantially equivalent to other similar devices currently on the market. (Abco Dealers, K871465 and Medline Industries, Inc., K772365). Banta Digital and Mercury Thermometer Sheaths are identical in respect to materials, construction and manufacturing process. Size may be vary to accommodate differences in Digital and Mercury Thermometers.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 19 1998

Mr. Richard Peppard
QA/RA Manager
BANTA Healthcare Products
570 Enterprise
Neenah, Wisconsin 54956

Re: K983406
Trade Name: SaniTherm® Disposable Thermometer Sheaths
Regulatory Class: II
Product Code: FLL
Dated: September 21, 1998
Received: September 28, 1998

Dear Mr. Peppard:

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 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

BANIA Healthcare Products

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INTENDED USE:

510(k) Number (if known): K983406

Device Name: Thermometer Sheaths

Indications for Use:

These devices are indicated for use as a barrier that is used as an accessory to oral or rectal, digital or mercury thermometers. These sheaths are non-sterile and are intended for single patient use only.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ___
(Per 21 CFR 801.109)

OR Over-The-Counter Use ✓

(Division Sign-Off)
Division of Dental, Infection Control, and General Hospital Devices
510(k) Number K983406

(Optional Format 1-2-96)

SUBSTANTIAL EQUIVALENCE: