



U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER: (kml)

FOLDER: K983406 - 153 pages

COMPANY: BANTA HEALTHCARE GROUP, LTD. (BANTHEALGROU)

PRODUCT: THERMOMETER, ELECTRONIC, CLINICAL (FLL)

SUMMARY: Product: SANITHERM ORAL DISPOSABLE THERMOMETER SHEATHS FOR MERCURY THERMOMETER,

DATE REQUESTED: Aug 2, 2016

DATE PRINTED: Aug 2, 2016

Note: Printed



BANTA Healthcare Products

570 ENTERPRISE
 NEENAH, WI 54956
 920/751-4300 Fax: 920/751-4370
 800/215-5484

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.

570 ENTERPRISE
NEENAH, WI 54958
920/751-4300 Fax: 920/751-4370
800/215-5484

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 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.

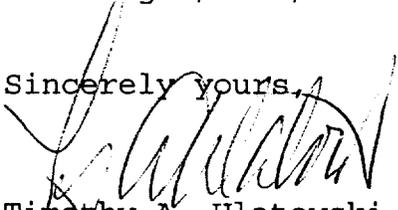
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

Page 2 - Mr. Peppard

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

S70 ENTERPRISE
NEENAH, WI 54956
920/751-4300 Fax: 920/751-4370
800/215-5464

INTENDED USE:

Page 1 of 1

510(k) Number (if known): K 983406

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
Patricia Curran
(Division Sign-Off) (Optional Format 1-2-96)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K983406

SUBSTANTIAL EQUIVALENCE:



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
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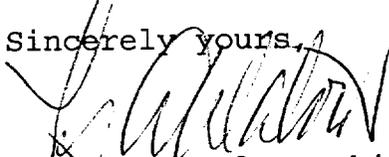
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Page 2 - Mr. Peppard

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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

2

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

INTENDED USE:

Page 1 of 1

510(k) Number (if known): K 983406

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(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
Patricia Ciscenti
(Division Sign-Off) (Optional Format 1-2-96)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K983406

SUBSTANTIAL EQUIVALENCE:



From: Reviewer(s) - Name(s) Jen NAKALAMA

Subject: 510(k) Number K983406

To: The Record - It is my recommendation that the subject 510(k) Notification:

- Refused to accept.
- Requires additional information (other than refuse to accept).
- Accepted for review _____.
- Is substantially equivalent to marketed devices.
- NOT substantially equivalent to marketed devices.

De Novo Classification Candidate? YES NO

Other (e.g., exempt by regulation, not a device, duplicate, etc.)

- Is this device subject to Postmarket Surveillance? YES NO
- Is this device subject to the Tracking Regulation? YES NO
- Was clinical data necessary to support the review of this 510(k)? YES NO
- Is this a prescription device? YES NO
- Was this 510(k) reviewed by a Third Party? YES NO
- Special 510(k)? YES NO
- Abbreviated 510(k)? YES NO

This 510(k) contains:

Truthful and Accurate Statement Requested Enclosed
(required for originals received 3-14-95 and after)

A 510(k) summary OR A 510(k) statement

The required certification and summary for class III devices

The indication for use form (required for originals received 1-1-96 and after)

Material of Biological Origin YES NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

No Confidentiality Confidentiality for 90 days Continued Confidentiality exceeding 90 days

Predicate Product Code with class:

Additional Product Code(s) with panel (optional):

EO FULL 540.2910 CLASS II

Review: Paloma Arcante (Branch Chief) AMDB (Branch Code) 10/16/98 (Date)

Final Review: [Signature] (Division Director) 10/19/98 (Date)

K993466 "SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

REVIEWER: JN NAKAYAMA DIVISION/BRANCH: DDICD/GHDB

TRADE NAME: SANU-THERM COMMON NAME: THERMOMETER SHEATH

PRODUCT TO WHICH COMPARED: K871465 (510(k) NUMBER IF KNOWN)

YES (NO)

1. IS PRODUCT A DEVICE?

✓

- IF NO STOP

2. DEVICE SUBJECT TO 510(k)?

✓

- IF NO STOP

3. SAME INDICATION STATEMENT?

✓

- IF YES GO TO 5

4. DO DIFFERENCES ALTER THE EFFECT OR RAISE NEW ISSUES OF SAFETY OR EFFECTIVENESS?

- IF YES STOP - NE

5. SAME TECHNOLOGICAL CHARACTERISTICS?

✓

- IF YES GO TO 7

6. COULD THE NEW CHARACTERISTICS AFFECT SAFETY OR EFFECTIVENESS?

- IF YES GO TO 8

7. DESCRIPTIVE CHARACTERISTICS PRECISE ENOUGH?

✓

- IF NO GO TO 10 - IF YES STOP - SE

8. NEW TYPES OF SAFETY OR EFFECTIVENESS QUESTIONS?

- IF YES STOP - NE

9. ACCEPTED SCIENTIFIC METHODS EXIST?

- IF NO STOP - NE

10. PERFORMANCE DATA AVAILABLE?

- IF NO REQUEST DATA

11. DATA DEMONSTRATE EQUIVALENCE?

SE

NOTE: IN ADDITION TO COMPLETING PAGE TWO, "YES" RESPONSES TO QUESTIONS 4, 6, 8, AND 11, AND EVERY "NO" RESPONSE REQUIRES AN EXPLANATION ON PAGE THREE AND/OR FOUR

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, Maryland 20850

Premarket Notification [510(k)] Review

Date: October 15, 1998

To: The Record

Office: HFZ-480
Division: DDIGD/GHDB

From: Von Nakayama, Scientific Reviewer

Document No: K983406
Company Name: Banta Healthcare
Device Name: SaniTherm® Thermometer Sheaths

Contact Person: Richard Peppard, QA/RA Manager
(920) 751-4300

Product(s) to Which Compared:
Abco Dealers Thermometer Sheath (K871465)

Indications for Use:
For use as a barrier that is used as an accessory to
oral or rectal, digital or mercury thermometers.

I. Purpose

This premarket notification seeks clearance for a sheath that is used with digital and mercury-in-glass thermometers.

II. Device Intended Use and Description:

1.0 Intended Use - The sheath is intended to be a sanitary cover for a thermometer.

2.0 Description - The thermometer sheath is made of polyethylene and ethyl methyl acrylate co-polymers. The rectal use sheaths also include a layer of lubricating jelly made from glyceryl polymethacrylate and propylene glycol. The sponsor stated that these materials are identical to those of the identified comparison devices and provided materials identification data and biocompatibility test summaries to support the safety of these materials.

The sheath is a single use, disposable cover for a thermometer. There are several models of both the oral and rectal versions, packaged in multi-box cases containing 250 to 11,000 sheaths. Directions for Use are printed on the box.

Summary Description

Life-supporting or life-sustaining:	No
Implant:	No
Sterile:	No
Single Use:	No
Prescription use:	No
Home use or portable:	Yes
Drug or biologic component:	No
Kit:	No
Software driven:	No
Electrically operated:	No

Summary of safety and effectiveness: Yes

- 2.1 Sterilization - The devices are non-sterile.
- 2.2 Pyrogenicity - N/A.
- 2.3 Packaging - Cardboard box, labeled on four sides.

III. Correspondence

On October 13, 1998 I spoke to Richard Peppard, QA/RA Manager who provided the additional information about the sheaths: Both the oral and rectal versions of the sheath are made of identical materials, but have designs appropriate for each thermometer type. The labeling will be revised to caution the user that the digital sheaths may not fit all digital thermometers. Further, the indications for use, and the summary of safety and effectiveness have been revised to remove the claim that the sheaths prevent the transmission of pathogens. Mr. Peppard faxed me the additional information on October 14, and mailed the original to the Document Mail Center.

IV. Substantial Equivalence

The sponsor provided specifications and materials data to support the claim that the SaniTherm® Disposable Thermometer Sheath is substantially equivalent to legally marketed sheaths for digital electronic thermometers. These sheaths do not raise any new questions or issues in terms of intended use, technological characteristics, and safety and effectiveness from legally marketed thermometer sheaths.

V. Other Issues Related to the Review

Thermometer sheaths designed for mercury-in-glass thermometers are accessories to an exempt, Class II device; sheaths designed for digital thermometers are accessories to a non-exempt, Class II device.

VI. Recommendation

Substantially Equivalent. Based upon the information provided in

8

the submission and a telephone discussion with the sponsor, I believe that the Banta Healthcare Products SaniTherm® Disposable Thermometer Sheaths are substantially equivalent to legally marketed sheaths that are accessories to:

80 FLL Thermometer, Electronic, Clinical - Class II

Classification should be based on:

880.2910 Clinical Electronic Thermometer


Von Nakayama

BANTA Healthcare Products

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

Quality Assurance – Regulatory Affairs

FAX TO: Mr. Von Nakayama

COMPANY: Food and Drug Administration

FAX NUMBER: 301-480-3002

NUMBER OF PAGES (including this cover sheet) 15

FROM: Richard Peppard

FAX NUMBER: 920-751-4367

DIRECT TELEPHONE NO.: 920-751-4322

DATE: October 14, 1998

TIME: 8:51 AM

Message: Additional Information Supplement to 510(k) K983406

Dear Mr. Nakayama,

Attached please find the following additional information pertaining to the above 510(k) submission. Should you have any questions regarding this added information, please call me at 800-215-5464 ext. 4322.

- **Section B** – The schematic drawing supplied (code B-35) is specific to a Digital Sheath. A second drawing of a Mercury Sheath (code B-91) is being submitted to demonstrate the similarity of Mercury and Digital Sheath designs with the exception of size/shape.
- **Section C** – The table in this section provides examples of Product Components/Specifications for Mercury and Digital Sheaths. These charts represent completed sheath codes for both Digital and Mercury products. They also demonstrate the similarities of Mercury and Digital sheath components and finished products. The listing in Section D provides similar information on completed sheath codes of each type and again provides a comparison of components used. (Digital codes are found on pages 10-12 in section D).

- **Section G** – This Table provides a listing of Banta Finished Product Codes, Private Label Customer Codes, General Description of the product, Cutting and Sealing Dies used in the process, Drawings Numbers and Banta Manufacturing Specification Numbers. Again, these demonstrate the similarities of the Mercury and Digital sheaths.

The page marked 1 of 9 is specific to Mercury Sheaths. A second page specific to Digital sheaths is being submitted as additional information. This is marked as sheet 1 of 6. These comparisons also demonstrate similarity of the sheaths and manufacturing processes

- **Intended Use Statement** (page 16 of 22) – The following has been deleted and a revised statement included. "They help prevent the transmission of pathogens from one patient to another."
- **Substantial Equivalence Statement** (page 17 of 22) – An addendum has been supplied to support equivalence of Mercury and Digital sheaths.
- An addition has been made to the **Proposed Labeling Section** (page 19 of 22) - Examples of Banta Healthcare – Sanitherm - labeling initially submitted were specific to Mercury Sheaths. Additional samples of two proposed Digital Sheath product code labels have been provided. The dispensing label cartons also diagram the instructions for use.
- An addition has also been made to the **Predicate Labeling Section** (page 20 of 22) - This addition indicates that the ABC Dealer labeling defines Mercury Sheaths and the Medline Industries, Inc. labeling defines Digital Sheaths.
- **Summary of Safety and Effectiveness** (pages 21 –22) – The following statements have been added to number six (6) – Device Description: Digital Thermometer Sheaths may not be suitable for use with all clinical thermometers. Example – Clinical thermometers which employ rigid plastic sheaths.

The Substantial Equivalence statement - number ten (10) – has also been changed to indicate the equivalence of Mercury and Digital Sheaths as previously described.

Thank you again for your assistance in reviewing this submission and for your patience in helping me to fully understand the portions of the submission that required additional information.

Respectfully yours,



Richard C. Peppard
QA/RA Manager
Banta Healthcare Products, Inc.

BANTA Healthcare Products

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

INTENDED USE:

Page 1 of 1

510(k) Number (if known): K

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 _____

(Optional Format 1-2-96)

SUBSTANTIAL EQUIVALENCE:

14

BANTA Healthcare Products

570 ENTERPRISE
NEENAH, WI 54956
920/751-4300 Fax: 920/751-4370
800/215-5484

SUBSTANTIAL EQUIVALENCE:

Banta Mercury and Digital Thermometer Sheaths are substantially equivalent to these thermometer sheaths:

K772385 **Medline Thermometer Sheaths**
Medline Industries, Inc.
One Medline Place
Mundelein, IL 60060

K871465 **Abco Dealers Thermometer Sheaths**
6601 West Mill Road
P.O. Box 23090
Milwaukee, WI 53223

Banta Digital Thermometer Sheaths are identical to Banta Mercury Thermometer Sheaths in respect to materials, construction and manufacturing process. Size may vary to accommodate differences in Digital and Mercury Thermometers.

BANTA Healthcare Products

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

PROPOSED LABELING:

- Banta Healthcare Products - Sanitherm Digital Thermometer Sheath
- Banta Healthcare Products - Sanitherm Mercury Thermometer Sheath

*Proposed
Labeling
6 Pages*

*(Proposed Labeling)
SHIPPING CONTAINER
MASTER LABEL*

SaniTherm®

Oral Disposable Thermometer Sheaths

FOR DIGITAL THERMOMETER

**QUANTITY: 50 BOXES/CASE
100/BOX**

REORDER NO: 20633

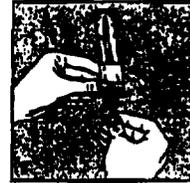
MANUFACTURED BY:

BANTA Healthcare Products

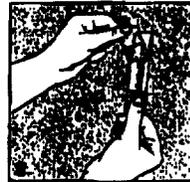
**570 Enterprise Drive
Neenah, Wisconsin 54958**

INNER - dispensing
CARTON for code
20633.

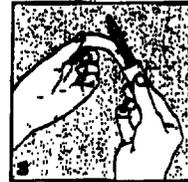
SaniTherm® System II™
Oral Disposable
Thermometer Sheaths



DIRECTIONS: Hold SaniTherm sheath at the arrows. Insert thermometer by sliding it between the white tab and the arrows, to its extremity.



Hold thermometer and the arrow tab. Peel back the blue protective cover.



Peel away the paper backing. Thermometer is protected and ready for normal use.

MANUFACTURED BY:

BANTA Healthcare Products

NEENAH, WI 54956 - RIALTO, CA 92376

Oral Disposable
Thermometer Sheaths

SaniTherm®
System II™

Oral Disposable Thermometer Sheaths
SaniTherm® System II™

P/N 9819

SaniTherm® System II™
Oral Disposable Thermometer Sheaths

For Mercury Thermometer REORDER: 20521
 For Digital Thermometer REORDER: 20633

18

*Shipping Container
Master Label
for "Bulk" orders.*

SaniTherm[®]

Oral Disposable Thermometer Sheaths

FOR DIGITAL THERMOMETER

**QUANTITY: 10 BOXES/CASE
500/BOX**

REORDER NO: 20634

MANUFACTURED BY:

BANTA Healthcare Products

570 Enterprise Drive
Neenah, Wisconsin 54956

CARTON FOR "Bulk orders"

For Mercury Thermometer
REORDER: 20524

For Digital Thermometer
REORDER: 20634

**SaniTherm®
System II™**

**SaniTherm®
System II™**

Oral Disposable Thermometer Sheaths

Oral
Disposable
Thermometer
Sheaths



KPB# 00695-207
P/N 9820

**SaniTherm®
System II™**

Oral Disposable
Thermometer Sheaths

INNER DISPENSING

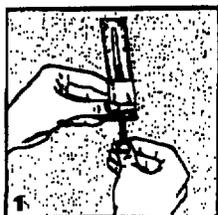
CARTON FOR "BULK ORDER"

Continued

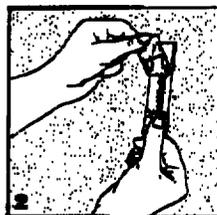
*Oral Disposable
Thermometer Sheaths*

SaniTherm[®] System II[™]

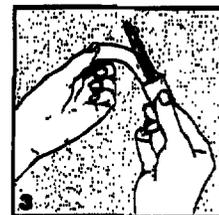
SaniTherm[®] System II[™] - It Works



DIRECTIONS: Hold SaniTherm sheath at the arrows. Insert thermometer by sliding it between the white tab and the arrows, to its extremity.

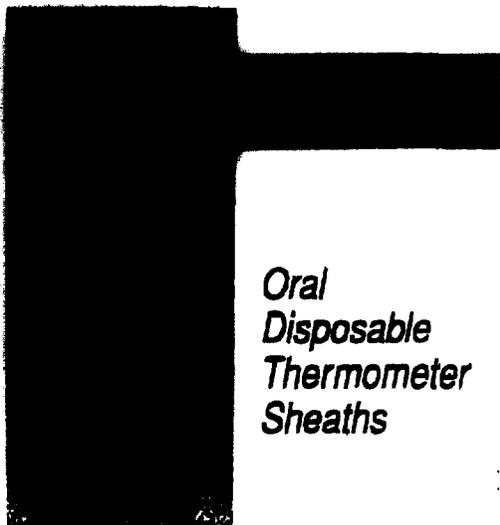


Hold thermometer and the arrow tab. Peel back the blue protective cover.



Peel away the paper backing. Thermometer is protected and ready for normal use.

SaniTherm[®] System II[™]



*Oral
Disposable
Thermometer
Sheaths*

MANUFACTURED BY:

BANTA Healthcare Products

570 Enterprise Drive
Neenah, Wisconsin 54956

21

BANTA Healthcare Products

570 ENTERPRISE
NEENAH, WI 54958
920/751-4300 Fax: 920/751-4370
800/215-5464

PREDICATE LABELING:

- **Abco Dealers - Standard Thermometer Sheaths, Mercury, Oral, Disposable**

Abco Dealers
6601 West Mill Road
P.O. Box 23090
Milwaukee, WI 53223

- **Medline - Digital Rectal Thermometer Sheaths**

Medline Industries, Inc.
One Medline Place
Mundelein, IL 60060

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BANTA Healthcare Products

570 ENTERPRISE
NEENAH, WI 54958
920/751-4300 Fax: 920/751-4370
800/215-5484

SUMMARY OF SAFETY AND EFFECTIVENESS:

September 21, 1998

*Add
To
Summary of
Safety &
Effectiveness
Tab.*

- 1. **Company Information:**
Banta Healthcare Products
570 Enterprise
Neenah, WI 54958
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 54958
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.

JS

BANTA Healthcare Products

570 ENTERPRISE
NEENAH, WI 54956
920/751-4300 Fax: 920/751-4370
800/215-5484

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 vary to accommodate differences in Digital and Mercury Thermometers.

Internal Administrative Form

	YES	NO
1. Did the firm request expedited review?		✓
2. Did we grant expedited review?		✓
3. Have you verified that the Document is labeled Class III for GMP purposes?		✓
4. If, not, has POS been notified?		✓
5. Is the product a device?		✓
6. Is the device exempt from 510(k) by regulation or policy?	✓	✓
7. Is the device subject to review by CDRH?	✓	✓
8. Are you aware that this device has been the subject of a previous NSE decision?		✓
9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?		✓
10. Are you aware of the submitter being the subject of an integrity investigation?		✓
11. If, yes, consult the ODE Integrity Officer.		✓
12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #191-2 and Federal Register 90N0332, September 10, 1991.		✓

25

Screening Checklist

For all Premarket Notification 510(k) Submissions

Device Name: Savethern Oral Disposable Thermometer K 983406
 Submitter (Company): Banta Healthcare Products, Inc.

Items which should be included (circle missing & needed information)	SPECIAL		ABBREVIATED		TRADITIONAL		✓ IF ITEM IS NEEDED AND IS MISSING
	YES	NO	YES	NO	YES	NO	
		GO TO #24		GO TO #24	✓		
1. Cover Letter clearly identifies Submission as: a) "Special 510(k): Device Modification" b) "Abbreviated 510(k)" c) Traditional 510(k)		■		■	✓		

2. "SPECIALS" - ONLY FOR MODIFICATIONS TO MANUFACTURER'S OWN CLASS II, III OR RESERVED CLASS I DEVICE

a) Name & 510(k) number of legally marketed (unmodified) predicate device					
b) STATEMENT - INTENDED USE AND INDICATIONS FOR USE OF MODIFIED DEVICE AS DESCRIBED IN ITS LABELING HAVE NOT CHANGED*		■		■	
c) STATEMENT - FUNDAMENTAL SCIENTIFIC TECHNOLOGY OF THE MODIFIED DEVICE HAS NOT CHANGED*		■		■	
d) Design Control Activities Summary		■		■	
i) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis		■		■	
ii) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied		■		■	
iii) A declaration of conformity with design controls. The declaration of conformity should include:		■		■	
1) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met		■		■	
2) A statement signed by the individual responsible, that manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.		■		■	

	SPECIALS		ABBREVIATED		TRADITIONAL		✓ IF ITEM IS NEEDED AND IS MISSING
	YES	NO	YES	NO	YES	NO	
3. ABBREVIATED 510(K): SPECIAL CONTROLS/CONFORMANCE TO RECOGNIZED STANDARDS							
a) For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type							
b) If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.							
c) For a submission, which relies on a recognized standard, a declaration of conformity to the standard. The declaration should include the following:							
i) An identification of the applicable recognized consensus standards that were met							
ii) A specification, for each consensus standard, that all requirements were met, except for inapplicable requirements or deviations noted below							
iii) An identification, for each consensus standard, of any way(s) in which the standard may have been adapted for application to the device under review, e.g., an identification of an alternative series of tests that were performed							
iv) An identification, for each consensus standard, of any requirements that were not applicable to the device							
v) A specification of any deviations from each applicable standard that were applied							
vi) A specification of the differences that may exist, if any, between the tested device and the device to be marketed and a justification of the test results in these areas of difference							
vii) Name/address of test laboratory/certification body involved in determining the conformance of the device with applicable consensus standards and a reference to any accreditations for those organizations							
d) Data/information to address issues not covered by guidance documents, special controls, and/or recognized standards							

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

September 28, 1998

BANTA HEALTHCARE PRODUCTS, INC.
570 ENTERPRISE DR.
NEENAH, WI 54957
ATTN: RICHARD PEPPARD

510(k) Number: K983406
Received: 28-SEP-1998
Product: SANITHERM ORAL
DISPOSABLE
THERMOMETER SHEATHS
FOR MERCURY

The Center for Devices and Radiological Health (CDRH), Office of Device Evaluation (ODE), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

On January 1, 1996, FDA began requiring that all 510(k) submitters provide on a separate page and clearly marked "Indication For Use" the indication for use of their device. If you have not included this information on a separate page in your submission, please complete the attached and amend your 510(k) as soon as possible. Also if you have not included your 510(k) Summary or 510(k) Statement, or your Truthful and Accurate Statement, please do so as soon as possible. There may be other regulations or requirements affecting your device such as Postmarket Surveillance (Section 522(a)(1) of the Act) and the Device Tracking regulation (21 CFR Part 821). Please contact the Division of Small Manufacturers Assistance (DSMA) at the telephone or web site below for more information.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the Document Mail Center will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations, we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official. Any telefaxed material must be followed by a hard copy to the Document Mail Center (HFZ-401).

You should be familiar with the manual entitled, "Premarket Notification 510(k) Regulatory Requirements for Medical Devices" available from DSMA. If you have other procedural or policy questions, or want information on how to check on the status of your submission (after 90 days from the receipt date), please contact DSMA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address <http://www.fda.gov/cdrh/dsmamain.html> or me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Staff

510(K) Submission

Sani-Therm[®] Thermometer Sheaths Oral and Rectal Non-Sterile

Submitted By:
Banta Healthcare
570 Enterprise
Neenah, WI 54956
920/751-4300
800/215-5464
Fax: 920/751-4370

30
AO
E. Glass
II

h983406

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

RECEIVED
29 SEP 98 13 52
T01/ARQH/OCE/DWC

510(k) NOTIFICATION LETTER:

September 21, 1998

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
1390 Piccard Drive
Rockville, MD 20850

Dear Sir/Madam:

Enclosed please find copies of 510(k) notification for devices we intend to market. These devices are Thermometer Sheaths.

The premarket notification information required by 21 CFR §807.87 is as follows:

- 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.

GA-17

H10 class 4

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

6. **Device Description:**
SaniTherm Disposable Thermometer Sheaths are plastic coverings used for either oral or rectal, mercury or digital thermometers.
7. **Sterilization Information:**
This product is not sold sterile.

We are including the FDA recommended cover sheet for 510(k) submissions. Please direct any questions to the contact listed in section 1.0 above.

Respectfully submitted,



Richard Peppard
QA/RA Manager

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

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Primary Skin Irritation Test (Lubricating Jelly) M
Schwartz and Peck Patch Test (Lubricating Jelly) N
Eye Irritation Test (Lubricating Jelly) O
Vaginal Mucosal Irritation Test (Lubricating Jelly) P
Acute Oral Toxicity Test (Lubricating Jelly) Q

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

510(k) NOTIFICATION LETTER:

September 21, 1998

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
1390 Piccard Drive
Rockville, MD 20850

Dear Sir/Madam:

Enclosed please find copies of 510(k) notification for devices we intend to market. These devices are Thermometer Sheaths.

The premarket notification information required by 21 CFR §807.87 is as follows:

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.

RECEIVED
20 SEP 03 13 55
10A/CDBRH/ODT/10770

34

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

6. **Device Description:**
SaniTherm Disposable Thermometer Sheaths are plastic coverings used for either oral or rectal, mercury or digital thermometers.

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

We are including the FDA recommended cover sheet for 510(k) submissions. Please direct any questions to the contact listed in section 1.0 above.

Respectfully submitted,



9/21/98

Richard Peppard
QA/RA Manager

PREMARKET SUBMISSION COVER SHEET:

Date of Submission: September 21, 1998		FDA Document Number:	
Section A Type of Submission			
<input checked="" type="checkbox"/> 510(k) <input type="checkbox"/> 510(k) Add'l Information	<input type="checkbox"/> IDE <input type="checkbox"/> IDE Amendment <input type="checkbox"/> IDE Supplement <input type="checkbox"/> IDE Report	<input type="checkbox"/> PMA <input type="checkbox"/> PMA Amendment <input type="checkbox"/> PMA Report	<input type="checkbox"/> PMA Supplement - Regular <input type="checkbox"/> PMA Supplement - Special <input type="checkbox"/> PMA Supplement - 30 Day <input type="checkbox"/> PMA Supplement - Panel Track
Section B Reason for Submission -- 510(k)s Only			
<input checked="" type="checkbox"/> New Device <input type="checkbox"/> Other reason (specify):	<input type="checkbox"/> Additional or expanded indications	<input type="checkbox"/> Change in technology, design, materials, or manufacturing process	
Section B2 Reason for Submission -- PMAs Only			
<input type="checkbox"/> New Device <input type="checkbox"/> Withdrawal <input type="checkbox"/> Additional or expanded indications <input type="checkbox"/> Licensing agreement <input type="checkbox"/> Labeling change: <input type="checkbox"/> Indications <input type="checkbox"/> Instructions <input type="checkbox"/> Performance Characteristics <input type="checkbox"/> Shelf life <input type="checkbox"/> Trade name <input type="checkbox"/> Other (specify below) <input type="checkbox"/> Change in ownership <input type="checkbox"/> Change in correspondent <input type="checkbox"/> Other reason (specify)	<input type="checkbox"/> Change in design, component, or specification <input type="checkbox"/> Software <input type="checkbox"/> Color Additive <input type="checkbox"/> Other (specify below) <input type="checkbox"/> Process Change: <input type="checkbox"/> Manufacturer <input type="checkbox"/> Sterilizer <input type="checkbox"/> Packager <input type="checkbox"/> Response to FDA correspondence (specify below) <input type="checkbox"/> Request for applicant hold <input type="checkbox"/> Request for removal of applicant hold <input type="checkbox"/> Request for extension <input type="checkbox"/> Request to remove or add manufacturing site	<input type="checkbox"/> Location change: <input type="checkbox"/> Manufacturer <input type="checkbox"/> Sterilizer <input type="checkbox"/> Packager <input type="checkbox"/> Distributor <input type="checkbox"/> Report Submission: <input type="checkbox"/> Annual or periodic <input type="checkbox"/> Post-approval Study <input type="checkbox"/> Adverse Reaction <input type="checkbox"/> Device defect <input type="checkbox"/> Amendment <i>06/22/98 1351</i>	
Section B3 Reason for Submission -- IDEs Only			
<input type="checkbox"/> New device <input type="checkbox"/> Addition of institution <input type="checkbox"/> Expansion / extension of study <input type="checkbox"/> IRB certification <input type="checkbox"/> Request hearing <input type="checkbox"/> Request waiver <input type="checkbox"/> Termination of study <input type="checkbox"/> Withdrawal of application <input type="checkbox"/> Unanticipated adverse effect <input type="checkbox"/> Emergency use: <input type="checkbox"/> Notification of emergency use <input type="checkbox"/> Additional <input type="checkbox"/> Other reason (specify)	<input type="checkbox"/> Change in: <input type="checkbox"/> Correspondent <input type="checkbox"/> Design <input type="checkbox"/> Informed consent <input type="checkbox"/> Manufacturer <input type="checkbox"/> Protocol- feasibility <input type="checkbox"/> Protocol - other <input type="checkbox"/> Sponsor <input type="checkbox"/> Report submission: <input type="checkbox"/> Current investigator <input type="checkbox"/> Annual progress <input type="checkbox"/> Site waiver limit reached <input type="checkbox"/> Final	<input type="checkbox"/> Response to FDA letter concerning: <input type="checkbox"/> Conditional approval <input type="checkbox"/> Deemed approved <input type="checkbox"/> Deficient final report <input type="checkbox"/> Deficient progress report <input type="checkbox"/> Deficient investigator report <input type="checkbox"/> Disapproval <input type="checkbox"/> Request extension of time to respond to FDA <input type="checkbox"/> Request meeting <input type="checkbox"/> IOL submissions only <input type="checkbox"/> Change in IOL wavier <input type="checkbox"/> Request for protocol waiver	

				FDA Document Number:	
Section C Product Classification					
Product Code: FLL & FLK		C.F.R. Section: 880.2910 & 880.2920		Device Class: <input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II	
Classification Panel: General Hospital - 80				<input type="checkbox"/> Class III <input type="checkbox"/> Unclassified	
Section D Information on 510 (k) Submissions					
Product codes of devices to which substantial equivalence is claimed:				Summary of, or statement concerning, safety and effectiveness data:	
1	2	3	4	<input checked="" type="checkbox"/> 510(k) summary attached	
5	6	6	8	<input type="checkbox"/> 510(k) statement	
Information codes of devices to which substantial equivalence is claimed:					
510(k) Number		Trade or proprietary or model name		Manufacturer	
1	K871465	1	Thermometer Sheaths	1	Abco Dealers
2	K772365	2	Thermometer Sheaths	2	Medline Industries, Inc.
Section E Product Information - Applicable to All Applications					
Common or usual name of classification name: Thermometer Sheaths					
Trade or proprietary or model name			Model number		
1	SaniTherm Oral Disposable Thermometer Sheaths for Mercury Thermometer			1 Various	
	SaniTherm Oral Disposable Thermometer Sheaths for Digital Thermometer			Various	
	SaniTherm Oral Disposable Thermometer Sheaths – Long			Various	
	SaniTherm Oral Disposable Thermometer Sheaths for Mercury Thermometer - Flat			Various	
	Mercury Oral Thermometer Kits			Various	
2	SaniTherm Rectal Disposable Thermometer Sheaths for Mercury Thermometer			2 Various	
	SaniTherm Rectal Disposable Thermometer Sheaths for Digital Thermometer			Various	
	Mercury Rectal Thermometer Kits			Various	
	Flat Mercury Rectal Thermometer Sheath			Various	
FDA document numbers of all prior related submissions (regardless of outcome):					
1	2	3	4	5	6
None					
Data included in submission: <input checked="" type="checkbox"/> Laboratory testing <input type="checkbox"/> Animal trials <input type="checkbox"/> Human trials					
Indications (from labeling): Supplied non-sterile and intended for single use only Intended for use as a non-sterile barrier used in conjunction with mercury or digital oral or rectal thermometers.					

			FDA Document Number:		
Section F Manufacturing/Packaging/Sterilization					
<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		FDA establishment registration number: 2182318		<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract manufacturer <input type="checkbox"/> Repackager/relabeler	
Company/Institution name: Banta Healthcare Products.					
Division Name (if applicable): N/A				Phone number (include area code): (920) 751-4300	
Street address: 570 Enterprise				FAX number (include area code): (920) 751-4370	
City: Neenah		State/Province: WI		Country: USA	
ZIP/Postal Code: 54956					
Contact Name: Richard Peppard					
Contact Title: QA/RA Manager					
Section G Manufacturing/Packaging/Sterilization					
<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		FDA establishment registration number:		<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract manufacturer <input type="checkbox"/> Repackager/relabeler	
Company/Institution name:					
Division Name (if applicable):				Phone number (include area code):	
Street address:				FAX number (include area code):	
City:		State/Province:		Country:	
ZIP/Postal Code:					
Contact Name:					
Contact Title:					
Section H Manufacturing/Packaging/Sterilization					
<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		FDA establishment registration number:		<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract manufacturer <input type="checkbox"/> Repackager/relabeler	
Company/Institution name:					
Division Name (if applicable):				Phone number (include area code): ()	
Street address:				FAX number (include area code): ()	
City:		State/Province:		Country:	
ZIP/Postal Code:					
Contact Name:					
Contact Title:					

			FDA Document Number:	
Section G			Applicant or Sponsor	
Company/Institution name: Banta Healthcare Products.			FDA establishment registration number: 2182318	
Division Name (if applicable): N/A			Phone number (include area code): (920) 751-4300	
Street address: 570 Enterprise			FAX number (include area code): (920) 751-4370	
City: Neenah	State/Province: WI	Country: USA	ZIP/Postal Code: 54956	
Signature: <i>R Peppard 9/21/98</i>				
Name: Richard Peppard				
Title: QA/RA Manager				
Section H			Submission correspondent (if different from above)	
Company/Institution name:				
Division Name (if applicable):			Phone number (include area code): ()	
Street address:			FAX number (include area code): ()	
City:	State/Province:	Country:	ZIP/Postal Code:	
Contact name:				
Contact title:				

Your voluntary completion of this Premarket Submission Cover Sheet will not affect any FDA decision concerning your submission, but will help FDA's Center for Devices and Radiological Health process your submission more efficiently. The information you provide should apply only to a single accompanying submission. Please do not send cover sheets for any previous submissions. See the instructions for additional information on completing the cover sheet. If you have a question concerning completion of the cover sheet, please contact the division of Small Manufacturers Assistance at (800) 638-2041 or (301) 443-6597.

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

PREMARKET NOTIFICATION TRUTHFUL AND ACCURATE STATEMENT:

I certify that, in my capacities as QA/RA Manager at Banta Healthcare Products, I believe to the best of my knowledge, that all data and information submitted in this premarket notification are truthful and accurate and that no material fact has been omitted.



Signature

Richard Peppard

Typed Name

9/21/58

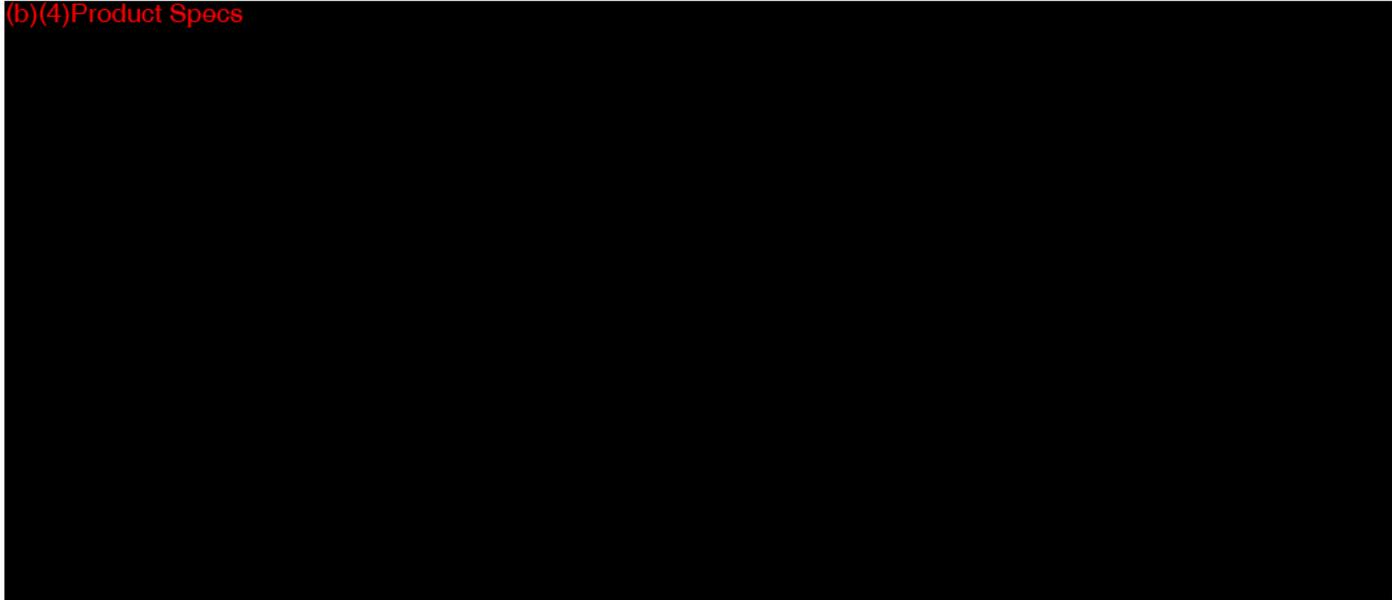
Date

510(k) Number

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

PRODUCT SPECIFICATIONS AND MATERIAL DATA SAFETY SHEETS:

(b)(4)Product Specs



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

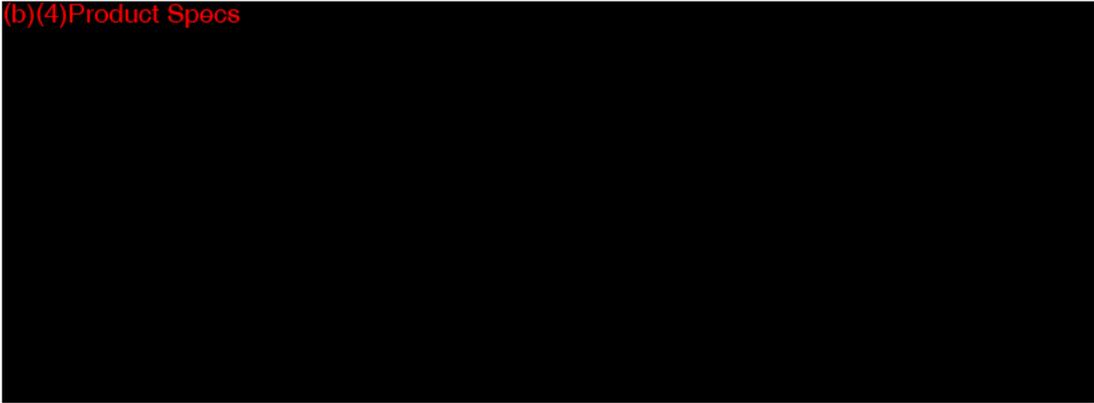
LABORATORY TESTING:

(b) (4)



TEST RESULTS:

(b)(4)Product Specs



57

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

MANUFACTURING CONTROLS:

Banta manufactures these thermometer sheaths in full compliance with QSR and CGMP as well as ISO9001 and EN46001.

The film is melted and cast and the product is heat sealed and covered with more film. Operators during the manufacturing process do not touch this product.

2. MONTHLY MAINTENANCE

On the last Friday of each month, clean the machine and floor thoroughly.

3. REFERENCES

3.1. Q0006: Maintenance Form

REASON FOR DOCUMENT REVISION

REV # DATE

CHANGE AND REASON

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

INTENDED USE:

Page 1 of 1

510(k) Number (if known): K

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. They help prevent the transmission of pathogens from one patient to another. 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 _____

(Optional Format 1-2-96)

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

SUBSTANTIAL EQUIVALENCE:

Banta Thermometer Sheaths are substantially equivalent to these thermometer sheaths:

- | | |
|---------|---|
| K772365 | Medline Thermometer Sheaths
Medline Industries, Inc.
One Medline Place
Mundelein, IL 60060 |
| K871465 | Abco Dealers Thermometer Sheaths
6601 West Mill Road
P.O. Box 23090
Milwaukee, WI 53223 |

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

COMPARISON TABLE:

FEATURE	PREDICATE	NEW DEVICE
Product Name	Medline Thermometer Sheaths Abco Dealers Thermometer Sheaths	SaniTherm Thermometer Sheaths
Intended Use	To provide a covering that helps prevent the transition of pathogens from one patient to another.	To provide a covering that helps prevent the transition of pathogens from one patient to another.
Sterile	No	No
Materials Used	Ethylene Methyl Acrylate Copolymer Glyceryl Polymethacrylate and Propylene Glycol Lubricating Jelly	Ethylene Methyl Acrylate Copolymer Glyceryl Polymethacrylate and Propylene Glycol Lubricating Jelly
Amount of gel used per rectal sheath	Approximately 0.25 grams	Approximately 0.25 grams

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

PROPOSED LABELING:

SaniTherm®

Rectal Disposable Thermometer Sheaths

FOR MERCURY THERMOMETER

QUANTITY: 100 BOXES/CASE
50/BOX

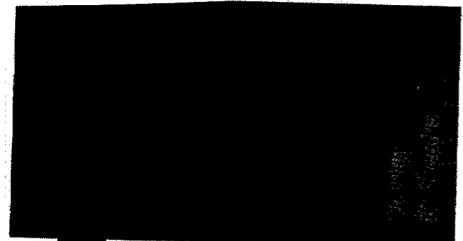
REORDER NO: 20712

MANUFACTURED BY:

BANTA Healthcare Products

570 Enterprise Drive
Neenah, Wisconsin 54956

SaniTherm®
System II™
Rectal Disposable
Thermometer
Sheaths



SaniTherm®
System II™
Rectal Disposable
Thermometer
Sheaths

SaniTherm® System II™

Rectal Disposable Thermometer Sheaths

MANUFACTURED BY:

BANTA Healthcare Products

570 Enterprise Drive, Neenah, Wisconsin 54956

SaniTherm®

Oral Disposable Thermometer Sheaths

FOR MERCURY THERMOMETER

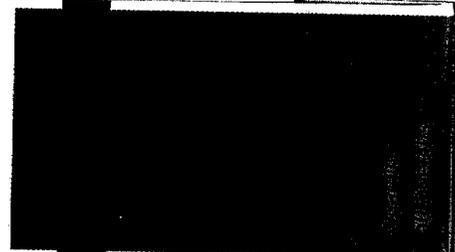
QUANTITY: 100 BOXES/CASE
50/BOX

REORDER NO: 20523

MANUFACTURED BY:

BANTA Healthcare Products

SaniTherm®
System II™
Oral Disposable
Thermometer
Sheaths



SaniTherm® System II™

Oral Disposable Thermometer Sheaths

MANUFACTURED BY:

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SaniTherm®
System II™
Oral Disposable
Thermometer
Sheaths

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NEENAH, WI 54956
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800/215-5464

PREDICATE LABELING:

standard

**thermometer sheaths
oral, disposable**

FOR MERCURY THERMOMETER

QUANTITY: (5000) 100/Bx-50 Bxs/Case
REORDER NO.: **078100**

standard

MFD. FOR ABCO DEALERS, INC.
Milwaukee, Wisconsin 53218-1238

standard

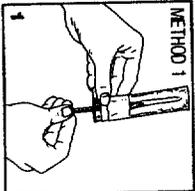
**thermometer sheaths
oral, disposable**

REORDER NO.: **078100**

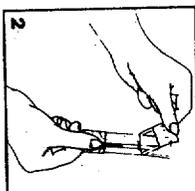


DIRECTIONS:

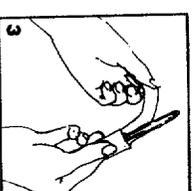
METHOD 1



Hold Standard sheath at red arrows. Insert thermometer by sliding it between the white tab and red arrows, to its extremity.



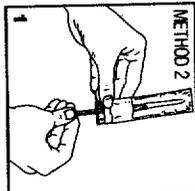
Hold thermometer and sheath at red arrow tab. Peel back the blue protective cover.



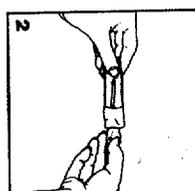
Peel away the paper backing. Thermometer is protected and ready for normal use.

OR:

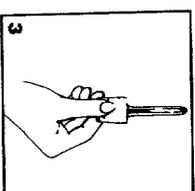
METHOD 2



Hold Standard sheath at red arrows. Insert thermometer by sliding it between the white tab and red arrows, to its extremity.



Hold thermometer and sheath at both ends. Do not hold the blue protective cover. Twist hands in opposite directions.



Pull thermometer and sheath from outer cover. Thermometer is protected by the Standard sheath, and ready for normal use.

145



Master Carton Must Be Opened

Digital Rectal Thermometer Sheaths

Reorder: MDS9608

Lot:



(01)50080196713873

Maste Carton Must Be

Digital Rectal Ther

Reorder: MDS960

Made in USA for: Medline Indust
60060 USA 1-847-949-3150 RE98



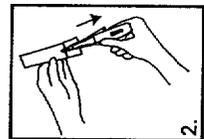
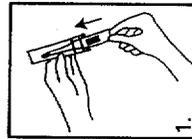
(01)5008019



Disposable Digital Rectal Thermometer Sheaths

1. Insert thermometer by sliding it between clear tab and arrows.
2. Holding thermometer upright, push sheath covering down until sheath separates from backing. Remove the backing. Sheath should remain behind, securely fitted to the thermometer.

Thermometer is protected and ready for normal use.



- Convenient... Use once and discard
- Sanitary... Covered thermometer probe reduces chance of cross-contamination

Digital Rectal Thermometer Sheaths



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

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.

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. They help to prevent the transmission of pathogens from one patient to another. 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)