K073369

510(k) SUMMARY

FEB 27

Submitter

Keith Dunn
Hu-Friedy Mfg. Co., Inc.
3232 N. Rockwell St.
Chicago, IL 60618
Tel. 773-975-3975 Ext. 3605 Fax 773-868-3558

Date Prepared 11/16/2007

Device Name

Trade name	EI DownPak Barrier Sleeves
Common name	Endodontic Obturator Cover
Classification name	872.3850 Gutta Percha, accessory

Legally marketed Devices to which equivalence is claimed:

TIDI Products (SaniTherm) Disposable Thermometer Sheaths	K983406

Description of the device

The EI® brand DownPak Barrier Sleeves are similar to the TIDI Product (SaniTherm) Disposable Thermometer Sheaths listed above.

The EI DownPak Barrier sleeve and the predicate TIDI Products Disposable Thermometer Sheaths are intended for use by medical professionals in the oral cavity as infection control devices. The EI DownPak Barrier Sleeve will be use to cover the EI DownPak Endodontic Obturator Handpiece which is used for root canal therapy. The CDC Guidelines for Infection Control in Dental Healt Care Settings (Vol. 52, No. RR-17, pg 20, December 19, 2003) references the use of disposable barrier protection. The EI DownPak Barrier sleeves will be used in combination with the cleaning instructions for the EI DownPak

Obturator handpiece which recommends wiping the surface of the handpiece with a soft cloth dampened with pH neutral surface disinfection solution or mild detergent (not containing phenols).

Hu-Friedy will purchase the barrier sleeves from TIDI Products, formerly Banta Healthcare Products, as an own brand private label device. The EI DownPak Barrier Sleeves are identical to the TIDI Products Disposable Sheaths in shape, material, and design. All of the technical specifications are identical to the marketed TIDI Products device. EI has 510k (K070246) approval to market the DownPak device in the US. The EI DownPak barrier sleeves are compatible with the EI DownPak handpiece.

The EI DownPak barrier sleeves are identical to the TIDI Products Disposable Thermometer Sheaths. All of TIDI Products probe cover products (i.e. thermometer sheath, instrument sheaths, and dental camera covers) are manufactured to ASTM E1104-98. The material construction meets the requirements for poly products, referenced in Part 177 21 CFR (specifically 177.1340 and 177.1520). These sheaths have been tested and certified to be in compliance for sensitization, cytoxicity, and irritation as specified in ISO 10993 1. Finally, these sheaths have been tested and certified to be in compliance for viral penetration in accordance with ASTM F1671.

The decision to private label EI DownPak Barrier Sleeves was made after successfully completing a field validation study #604 where clinicians evaluated the barrier sleeve for fit, ease of use, readability of the DownPak display through the barrier sleeve, activation of the controls (on/off and vibration button), disposal of the barrier sleeve, resistance to tearing, and tactile sensitivity.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 27 2008

Mr. Keith Dunn
Director, Regulatory Affairs & Quality Systems
Hu-Friedy Manufacturing Company, Incorporated
3232 North Rockwell Street
Chicago, Illinois 60618

Re: K073369
Trade/Device Name: EI DownPak Barrier Sleeves
Regulation Number: 872.3850
Regulation Name: Gutta Percha
Regulatory Class: I
Product Code: EKM
Dated: November 28, 2007
Received: November 30, 2007

Dear Mr. Dunn:

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.

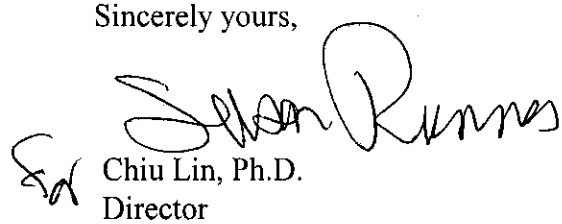
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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); 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.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K073369

Device Name: EI DownPak Barrier Sleeves

Indications for Use:
This product is intended for use by dental professionals only. This device is an accessory to the EI DownPak Endodontic Obturator Handpiece which is used in the oral cavity for root canal therapy. The barrier sleeve will be used to cover the hand piece thereby reducing the risk of cross infection while in use.

Prescription Use _____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation

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

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