AUG - 1 2003

K031851

510(K) SUMMARY

December 30, 2002

A. Submitter's Name and Address

Bethel, Inc.
320 S. Vine Avenue
Tyler Texas, 75702
Telephone (903) 593-0543
Facsimile (903) 533-9561

B. Contact Person

Dr. Eric Wade
320 S. Vine Avenue
Tyler Texas, 75702
Telephone (903) 372-1838
Facsimile (903) 533-9561

C. Establishment Registration Number of Submitter

Submitter has not established a registration number

D. Device Name

Proprietary Name: DentaSeptic HPC
Common Name: Dental handpiece control barrier

E. Device Description

The DentaSeptic HPC device is a disposable plastic cover that is made of high density polyethylene (HDPE), that fits over the ends of various high speed and low speed dental handpieces used in the dental/ clinical setting. The cover allows for the attachment and/or protrusion, where applicable, of those parts of the devices that are inserted into the patient's mouth.

F. Intended Use: (Indications of Use)

The DentaSeptic HPC device is intended as a single use, disposable, transparent, plastic, disposable, non-sterile protective cover to be placed over various high speed and low speed dental handpieces used in the dental/ clinical setting. The cover acts as a physical barrier that assists in providing surface protection for the handpieces, reducing cross contamination of equipment, augmenting existing infection control techniques and making clean up and disinfection less time consuming.

G. Device Classification

Classification Name: Dental Handpiece and Accessory
FDA Classification: Class II per 21 CFR 872.4200
Classification Panel: 76
Classification Product Code: EFB

H. Contract Manufacturing Facility

Manufacturing Address:
D&L Tooling & Plastics
950 S. Loop 456
Jacksonville, Texas 75766
Telephone: (903) 586-8357
Facsimile: (800) 227-4829

Mailing Address:
D&L Tooling & Plastics
P.O. Box 1149
Jacksonville, Texas 75766
Telephone: (903) 586-8357
Facsimile: (800) 227-4829

I. Action Taken to Comply with Section 514 of the Act.

None required under Section 514

J. Reasons for 510(k) Submission

This submission precedes an initial product introduction

K. Predicate Devices

Filmtech, Inc.'s Brixton Infection Control Barrier
510(k) Document Control Number -- K963664

Dentsply International, Inc.'s Disposa-Shield Infection Control Barrier
510(k) Document Control Number -- K900093

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 1 2003

Dr. Eric Wade
Bethel, Incorporated
320 South Vine Avenue
Tyler, Texas 75702

Re: K031851
Trade/Device Name: DentaSeptic HPC
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EFB
Dated: June 01, 2003
Received: June 16, 2003

Dear Dr. Wade:

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 (301) 594-4613. 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" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html

Sincerely yours,

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INTENDED USE: (INDICATIONS FOR USE)

Intended Use.

The DentaSeptic HPC device is intended as a single use, disposable, transparent, plastic, disposable, non-sterile protective cover to be placed over various high speed and low speed dental handpieces used in the dental/ clinical setting. The cover acts as a physical barrier that assists in providing surface protection for the handpieces, reducing cross contamination of equipment, augmenting existing infection control techniques and making clean up and disinfection less time consuming.

Kevin Mulley for MSR

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

510(k) Number: K031851