510(k) SUMMARY

K971606

DENTSPLY

NAME & ADDRESS: **DENTSPLY International**
570 West College Avenue
P.O. Box 872
York, PA 17405-0872
(717) 845-7511
~~Fax (717) 854-2343~~
P. J. Lehn Telefax (717) 849-4343

CONTACT: P. Jeffery Lehn JUN - 3 1997

DATE PREPARED: April 29, 1977

TRADE OR PROPRIETARY NAME: STERILE FLEXOFILE® FILES AND INSTRUMENTS

COMMON OR USUAL NAME: Files and Reamers

CLASSIFICATION NAME: Dental hand instruments 872.4565

LEGALLY MARKETED DEVICE: Presterilized FlexoFile® Files and Reamers K943584

DEVICE DESCRIPTION: FlexoFile® files and instruments are manufactured for DENTSPLY Caulk by DENTSPLY Maillefer®. They are pre-1976 medical devices and are exempt from premarket notification. However, this 510(k) submission is necessary because DENTSPLY Caulk plans to market these devices as Sterile and to revise the labeling to reflect this change. There are no changes to the composition, manufacturing process, or sterilization process.

STERILE FLEXOFILE® FILES AND INSTRUMENTS are precision instruments twisted from a single shaft of stainless steel for maximum fracture resistance. They feature preinserted silicone stops for convenience and safety. They reduce the chance of apical transportation and breakage from binding in the canal. They feature non-slip plastic handles for a firmer grip, as well as ISO color coding for easy identification.

After sterilization, these files and instruments presented the same resistance in torsion and shear stress as non-sterilized instruments. No significant change in color or mechanical behavior of the plastic handles was evident following gamma irradiation.

INTENDED USE: STERILE FLEXOFILE® FILES AND INSTRUMENTS are used to file and shape root canals and to remove necrotic tissue as a means to create a funnel-shaped cavity.

TECHNOLOGICAL CHARACTERISTICS: As noted above, there are no changes in the composition, manufacturing or sterilization of these files and instruments.

These files and instruments were subjected to sterilization by gamma irradiation from a Cobalt 60 source. The validation method used was AAMI Method 1.

The device package is a compartmentalized container with six (6) individually separated cells. The package includes a heat-sealed non-tearing perforated thermal adhesive strip. This strip allows for a single cell to be opened per file as required by the dentist, while all other file cells remain sealed and sterile.

We believe that the fact that the new device is identical to the predicate device, along with the sterilization data presented, supports the safety and effectiveness of STERILE FLEXOFILE® FILES AND INSTRUMENTS for the intended uses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 3 1997

Mr. P. Jeffrey Lehn
Director, Corporate Compliance and Regulatory Affairs
Denstsply International
570 West College Avenue
York, Pennsylvania 17405-0872

Re: K971606
Trade Name: Sterile Flexofile Files and Instruments
Regulatory Class: I
Product Code: EFA
Dated: April 29, 1997
Received: May 1, 1997

Dear Mr. Lehn:

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

PREMARKET NOTIFICATION

INDICATIONS FOR USE STATEMENT

(As Required by 21 CFR 801.109)

510(K) Number: K971606

Device Name: STERILE FLEXOFILE® FILES AND INSTRUMENTS

Indications for Use:

Used to file and shape root canals and to remove necrotic tissue as a means to create a funnel-shaped cavity.

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K971606

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ____