

K984201

XI. SAFE MEDICAL DEVICES ACT OF 1990 SUMMARY OF SAFETY AND EFFECTIVENESS. October 8, 1998. [Separate Pages]

A. Anders Sundh, Dentronic, Box 733, S-931 27 Skelleftea, Sweden. Phone 46 910 835 70.

I. Classification Names and numbers: Material, tooth shade resin, 76EBF, Class II.

Porcelain powder for clinical use, 76EIH, Class II.

II. Common/Usual Name: Dental restorative material, porcelain powder/blocks

III. Proprietary Names: Denzir™

IV. Establishment Registration Number: Foreign, in process

V. Classification: These are Class II devices, intended to restore carious lesions or structural defects in teeth, described in CFR 872.3690. Like porcelain powder, this device is delivered in final form for use by the dentist, and is ceramic in nature. Porcelain powder is described in CFR 872.6660.

VI. Device Description: Denzir™ is a zirconium dioxide-yttrium oxide ceramic, capable of machining by modern methods. The dentist prepares the tooth surfaces, sends a properly prepared impression of those surfaces to the dental laboratory where it is scanned and an inlay or onlay prepared by modern computerized lathe methods and returned to the dentist. The dentist then finally prepares the tooth surfaces involved and cements (lutes) the inlay or onlay in place with standard dental adhesives (luting) materials. Denzir™ inlays are alternatives to gold, amalgam, porcelain, or composite filling materials, except that their application more closely resembles gold inlays or porcelain inlays, onlays or veneers in that they are actually prepared in a dental laboratory. The material is radio-opaque, for ready visualization.

VII. Substantial Equivalence: The "510(k) "Substantial Equivalence" Decision-Making Process (Detailed) from ODE Guidance Memorandum #86-3 was followed as described below:

1. These products have the same intended use, to restore carious lesions or structural defects in teeth and are used as inlays, and onlays,

2. The technological characteristics for this product are similar to those for the predicate devices and those currently on the market except for differences in methods of use. The technological features, although distinct, have the same intended use as the devices listed as equivalent.

3. Descriptive information provided shows that the materials from which Denzir™ are made are well established as the basis of many different kinds of implants, mainly more demanding than is the mouth. Denzir™ is equivalent in use and properties to devices described in K-973221, K-971869, and K-943168.

4. This product has been tested for biocompatibility by methods accepted in the US. and Europe. The material meets ISO 6872 (1995) and has been CE marked for indicated uses. The luting materials prescribed for use with this material meet currently valid ISO standards for the various product types.

(End of Summary)



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

SEP 29 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Anders Sundh
President
Dentronic AB
Box 733
S-931 27 Skellefteå
Sweden

Re: K984201
Trade Name: Denzir™
Regulatory Class: II
Product Code: EIH
Dated: April 26, 1999
Received: August 16, 1999

Dear Mr. Sundh:

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.

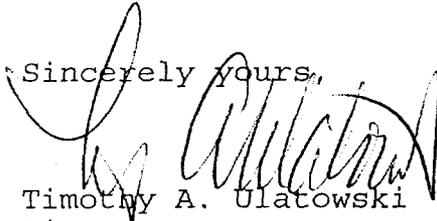
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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 pre-market 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) 594-4690. 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

VIII.1 Indications for Use: [Separate Page]

510(k) Number: NA

Device Name: Denzir™

Indications for use:

Intended to restore carious lesions or structural defects in teeth. It is intended for use in cavities Classes I, II, and V (inlays and onlays) and as a restorative material intended for veneers, crowns and bridges.

(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)



(Division Sign Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number KA4201