JAN 8 1999

K983574

510(k) SUMMARY
StarDental® LUBE FREE LOW SPEED MOTOR ATTACHMENTS

Company:

StarDental®, Division of DentalEZ®
Owner/operator number 2520265

Contact Person:

William Guscott
Product Development Engineer
StarDental®, Division of DentalEZ®
1816 Colonial Village Lane
Lancaster, PA 17601
Phone: (717) 291-1161
Fax: (717) 291-9742

Device Trade Name:

StarDental® TITAN® Series Motor Attachments

Common or Usual Name:

Low Speed Motor Attachments

Predicate Devices:

Star, Midwest, KAVO, W&H, NSK and Champion Dental low speed motor attachments.

Description/Intended Use:

Dental attachments and accessories to be used by the dental clinician during routine dental procedures. The attachments affix to a low speed dental motor.

Substantial Equivalence:

The Low Speed Attachments as submitted are substantially equivalent to other attachments currently being marketed by Star, Midwest, KAVO, W&H, NSK and Champion Dental. Materials used to manufacture the components are similar. Means of operation are identical, compressed air powers a variable speed rotary vane motor to provide power to the attachments through a geared drive train for various dental procedures. The differentiation between the predicate devices and the submitted is the redesign of standard lubricated bearings to non-lubricated bearings and bushings.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 8 1999

Mr. William Guscott
Product Development Engineer
StarDental®, Division of DentalEZ®
1816 Colonial Village Lane
Lancaster, Pennsylvania 17601

Re: K983574
Trade Name: StarDental® TITAN® 3 Lubefree Motor Attachments
Regulatory Class: I
Product Code: EGS
Dated: September 29, 1998
Received: October 13, 1998

Dear Mr. Guscott:

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 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). 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 Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS 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" (21CFR 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/dsma/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

Statement of Intended Use

Low speed dental attachments are used intraorally by trained dental professionals for drilling and preparation of dental cavities for restoration, such as fillings. Furthermore, the intended use extends to disking, cavity and crown preps, polishing, post and pin drilling and pin setting. The intended use is identical to that of the predicate low speed motor attachments.

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K983574

Prescription Use ✓
(Per 21 CFR 801.109)