

K 98 2593

OCT 22 1998 Lube Free Autochuck Turbine with Vortex Air Seal for use with StarDental 430 Series Lube Free High Speed Dental Handpiece

510(k) Summary

Company:

**StarDental, Division of DentalEZ Group
Owner/operator number 2520265**

Contact Person:

**Keith C. Peithmar, Director of Marketing
StarDental, Division of DentalEZ Group
1816 Colonial Village Lane
Lancaster, PA 17601
Phone: (717) 291-1161
Fax: (717) 291-9742**

Device Trade Name:

Lube Free Autochuck Turbine with Vortex Air Seal for use with StarDental 430 Series Lube Free High Speed Dental Handpiece

Common or Usual Name Dental Handpiece and Accessories

Predicate Device: StarDental 430 Series High Speed Handpiece

Intended Use/Description:

High-speed dental handpieces are used intraorally by trained dental professionals for drilling and preparation of dental caries for restoration, such as fillings. The intended use is identical to that of the predicate StarDental 430 Series Lube Free High Speed Handpiece. Autochuck turbines are used in place of a bur tool to facilitate bur changing. The intended use of the StarDental Autochuck Turbine with Vortex Air Seal is to both provide the convenience of tool-free bur changing and to eliminate the necessity of lubrication of the turbine after use and before sterilization.

Substantial Equivalence:

The determination of substantial equivalence is based on the fact that the proposed StarDental device and the predicate StarDental device utilize substantially equivalent intended use, technology, design, manufacturing, and materials and so will be substantially equivalent in clinical performance.



OCT 22 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Keith C. Peithman
Director of Marketing
StarDental, Division of DentaleZ Group
1816 Colonial Village Lane
Lancaster, Pennsylvania 17601

Re: K982593
Trade Name: Lube Free Autochuck Turbine with Vortex Air
Seal for Use with StarDental 430 Series Lube Free High
Speed Dental Handpiece
Regulatory Class: I
Product Code: EFB
Dated: July 21, 1998
Received: July 24, 1998

Dear Mr. Peithman:

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.

Page 2 - Mr. Peithman

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

Statement of Indications of Use

High-speed dental handpieces are used intraorally by trained dental professionals for drilling and preparation of dental caries for restoration, such as fillings. The intended use is identical to that of the predicate 430 Series Lube Free High Speed Handpiece.

Autochuck turbines are used in place of a bur tool to facilitate bur changing.

The intended use of the Star Autochuck Turbine with Vortex Air Seal is to both provide the convenience of tool-free bur changing and to eliminate the necessity of lubrication of the turbine after use and before sterilization.

*Prescription Use
per 21CFR 801.109*

Gerald Shipper

(Division Sign-Off)

Division of Dental, Infection Control,
and General Hospital Devices

510(k) Number K982593