Section 5: 510(k) Summary

JAN 23 2012

Company:

DentalEZ Inc., StarDental Division
Owner/operator number 2520265

Contact Person:

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Proprietary/Trade Name:

Concentrix High-Speed Handpiece Series – Concentrix MX, Concentrix PX, Concentrix FX and Concentrix SX

Classification:

Handpiece, Air-powered, Dental (21 C.F.R. § 872.4200, Product code EFB)

Predicate Device:

Star Dental 430 Series High Speed Handpiece (K960719)

The Concentrix High-Speed Handpieces have the same intended uses, methods of operation and technology as the previously cleared predicate devices.

Device Description:

The Concentrix High-Speed Handpieces are pneumatically driven, hand-held devices used by trained dental professionals to perform a variety of dental procedures.

The Concentrix MX is a non-fiber optic, 2/3 line fixed backend handpiece with a steel bearing manual chucking turbine. The Concentrix PX is a non-fiber optic, 2/3 line fixed backend handpiece with a steel bearing, push button autochuck

turbine. The Concentrix FX is a non-fiber optic, 3/4 line fixed backend handpiece with a steel bearing, push button autochuck turbine. The Concentrix SX is a fiber optic, swivel handpiece with a steel bearing, push button autochuck turbine.

Intended Use:

The Concentrix High-Speed Handpieces are used by trained dental professionals for a variety of procedures including but not limited to caries and amalgam removal, restorative work and crown preparations.

Technological Characteristics:

The Concentrix High-Speed Handpieces are pneumatically driven, hand-held devices which have the same technological characteristics as the predicate devices. Three of the handpieces (MX, PX, FX) are non-fiber optic with a fixed backend which does not allow the handpiece to swivel when attached to tubing. The fourth handpiece (SX) contains fiber optics and is designed to accommodate a type 3 swivel connector.

All of the Concentrix handpieces incorporate steel bearing turbines which require lubrication. The recommended lubricant is Dentalube II, which is manufactured by StarDental (K070869). The Concentrix MX is the only handpiece in the series that uses an existing manual type chucking mechanism. The Concentrix PX, FX and SX versions all use an existing push-button type chucking mechanism.

Technological Characteristics	**Predicate Device Comparison conclusion**
Indication for use	Identical
Target population	Identical
Design	Similar
Materials	Similar
Performance	Similar
Sterility	Identical
Biocompatibility	Identical
Mechanical safety	Identical
Chemical safety	Identical
Energy used and/or delivered	Identical
Compatibility with environment and other devices	Identical
Where used	Identical
Standards met	Similar
Electrical Safety	Not applicable

Substantial Equivalence:

The determination of substantial equivalence is based on the premise that the proposed device and the predicate devices have the same intended use and technology and are similar in design.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Jim Watkins
Engineering/Quality Manager
DentalEZ, Inc.
StarDental Divison
1816 Colonial Village Lane
Lancaster, PA 17601

JAN 2 3 2012

Re: K113301
Trade/Device Names: Concentrix High-Speed Handpiece Series – Concentrix MX, Concentrix PX, Concentrix FX, and Concentrix SX
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EFB
Dated: November 4, 2011
Received: November 8, 2011

Dear Mr. Watkins:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K113301

Device Name: Concentrix High-Speed Handpiece Series – Concentrix MX, Concentrix PX, Concentrix FX and Concentrix SX

Indications for Use:

The Concentrix High-Speed Handpieces are used by trained dental professionals for a variety of procedures including but not limited to caries and amalgam removal, restorative work and crown preparations.

CAUTION: Federal law restricts this device to sale by or on the order of a dentist.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

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

510(k) Number: K113301