March 28, 2018

DentalEZ, Inc.
Kay Engle
Regulatory Affairs/QA Supervisor
1816 Colonial Village Lane
Lancaster, Pennsylvania 17601

Re: K173465
Trade/Device Name: Concentrix MX-AC High-Speed Handpiece
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece And Accessories
Regulatory Class: Class I
Product Code: EFB
Dated: February 26, 2018
Received: February 27, 2018

Dear Kay Engle:

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.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Andrew I. Steen -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K173465

Device Name
Concentrix MX-AC High-Speed Handpiece

Indications for Use *(Describe)*
The Concentrix MX-AC High-Speed Handpiece is used by trained dental professionals for a variety of procedures including but not limited to caries and amalgam removal, restorative work and crown preparations.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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| DentalEZ, Inc., StarDental Division | 510(K) Summary<br>Concentrix MX-AC High Speed Handpiece | 510(k) Summary K173465 |
|---|---|---|

## I. SUBMITTER

DentalEZ Inc., StarDental Division
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Kay Engle, Regulatory Affairs/QA Supervisor
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Rob Young, Senior Director of Engineering
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March 26, 2018

## II. DEVICE

Name of the Device: Concentrix MX-AC High-Speed Handpiece
Common or Usual Name: High-Speed Handpiece Air-Powered
Classification Name: Dental Handpieces and Accessories
Regulation Number: 21 C.F.R. § 872.4200
Regulatory Class: I
Product Code: EFB

## III. PREDICATE DEVICE

Primary Predicate: Concentrix High-Speed Handpiece Series - Concentrix MX, Concentrix PX Concentrix FX and Concentrix SX (K113301) as manufactured by StarDental
Reference Device: Lube Free Autochuck Turbine with Vortex Air Seal for Use with StarDental 430 Series Lube Free High Speed Dental Handpieces (K982593)

## IV. DEVICE DESCRIPTION:

The Concentrix MX-AC High-Speed Handpiece is a pneumatically driven, non-fiber optic, 2/3 line fixed backend handpiece that is capable of reaching rotational speeds of 302,000 rpms at a recommended air pressure of 32 PSI.
The handpiece is constructed of stainless steel, including the internal air and water tubes which provide drive air to the turbine assembly and cooling water to the work site. The stainless steel and aluminum air driven turbine assembly provides spin to the bur and incorporates steel lubricated bearings and a push button autochuck.
The burs used with the Concentrix MX-AC High Speed Handpiece are ISO 1797-1, type 2 burs. Only burs with hardened, tempered steel shanks or carbide shanks should be used.

## V. INDICATIONS FOR USE

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

## VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE:

The Concentrix MX-AC High-Speed Handpiece and the predicate device have the same technological characteristics:

- Intended use
- Method of operation
- Use of the same base materials
- Lubrication requirements
- Autoclavable

The following technological differences exist between the Concentrix MX-AC High-Speed Handpiece and the predicate:

- Autochuck turbine
- Free run speed
- End cap assembly

The proposed Concentrix MX-AC High-Speed Handpiece has the same technological similarities and differences as noted above for the primary predicate. The reference predicate uses a push button autochuck feature which is incorporated into the proposed device.

The difference between the proposed devices and the primary predicate device is the type of chucking mechanism used in the turbine assembly and the end cap assembly. These differences do not affect the performance of the device.

The following table summarizes the comparison of the proposed Concentrix MX-AC High-Speed Handpiece to the primary predicate and reference predicate for indications for use and technological characteristics.

| **Device** | **Proposed device: Concentrix MX-AC High-Speed Handpiece (K173465)** | **Primary Predicate: Concentrix High Speed Handpiece Series – Concentrix MX, Concentrix PX, Concentrix FX and Concentrix SX (K113301)** | **Reference Device: Lube Free Autochuck Turbine with Vortex Air Seal for Use with StarDental 430 Series Lube Free High Speed Dental Handpieces (K982593)** |
|---|---|---|---|
| Indications for Use | The Concentrix MX-AC High-Speed Handpiece is used by trained dental professionals for a variety of procedures including but not limited to caries | The Concentrix High-Speed Handpieces are used by trained dental professionals for a variety of procedures including but not limited to caries | High-speed dental handpieces are used intraorally by trained dental professionals for drilling and preparation of dental caries for |

| Device | **Proposed device: Concentrix MX-AC High-Speed Handpiece (K173465)** | **Primary Predicate: Concentrix High Speed Handpiece Series – Concentrix MX, Concentrix PX, Concentrix FX and Concentrix SX (K113301)** | **Reference Device: Lube Free Autochuck Turbine with Vortex Air Seal for Use with StarDental 430 Series Lube Free High Speed Dental Handpieces (K982593)** |
|---|---|---|---|
| | and amalgam removal, restorative work and crown preparations | and amalgam removal, restorative work and crown preparations | restoration, such as fillings. Autochuck turbines are used in place of a bur tool to facilitate bur changing. |
| Product Code | EFB | EFB | EFB |
| Operational Mode | Air driven | Air driven | Air driven |
| Type of chuck | Autochuck | Manual chuck:MX | Autochuck |
| Operating Pressure | 32 PSI | 32 PSI | Dependent on the handpiece |
| Coupling Type | ISO 9168, Type 1 | MX: ISO 9168, Type 1 | N/A |
| Bur Dimension | ISO 1797-1, Type 2 | ISO 1797-1, Type 2 | ISO 1797-1, Type 2 |
| Material composition | Stainless steel | Stainless steel | Stainless steel |
| Components | High speed pneumatic driven Handpiece.<br>Lubricated steel bearing autochuck turbine assembly<br>Pushbutton end cap | High speed pneumatic driven Handpiece.<br>Lubricated steel bearing, manual chuck turbine assembly<br>Single piece threaded end cap | Lube free ceramic autochuck turbine assembly<br>Pushbutton end cap |
| Biocompatibility | Stainless steel<br>Steel bearings<br>Biocompatibility tests were conducted in accordance with the requirements of ISO 10993-10 and ISO 10993-12. Test results indicate the device is non-cytotoxic, non-sensitizing and non-irritating. | Stainless steel<br>Steel bearings | Stainless steel<br>Ceramic bearings |

| Device | **Proposed device: Concentrix MX-AC High-Speed Handpiece (K173465)** | **Primary Predicate: Concentrix High Speed Handpiece Series – Concentrix MX, Concentrix PX, Concentrix FX and Concentrix SX (K113301)** | **Reference Device: Lube Free Autochuck Turbine with Vortex Air Seal for Use with StarDental 430 Series Lube Free High Speed Dental Handpieces (K982593)** |
|---|---|---|---|
| Sterilization | Sterilization validation in accordance with ANSI/AAMI ST79:2010 & A4:2013, AAMI/ANSI/ISO 14937:2009 and ANSI/AAMI ST81:2004 (R2010) | Sterilization validation in accordance with ANSI/AAMI ST79:2010 & A4:2013, AAMI/ANSI/ISO 14937:2009 and ANSI/AAMI ST81:2004 (R2010) | Sterilization validation report references AAMI TIR No. 12-1994 |
| Performance | Variable 302,000 rpm +/- 10% | Variable 385,000 rpm +/- 10% | Variable 430,000 rpm, +/- 10% |
| Risk analysis | ISO14971:2012 Medical devices – Application of risk management to medical devices | ISO14971:2000 Medical devices – Application of risk management to medical devices | Risk Analysis at time of submission unknown. Current risk analysis per ISO 14971:2012 – Application of risk management to medical devices |

**VII. PERFORMANCE DATA**

The following tests were conducted to evaluate the functional performance and safety the Concentrix MX-AC High-Speed Handpiece:

- ISO 14457:2012 Dentistry – Handpieces and Motors
- ISO 60601-1:2005 Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance

The test results confirm that the Concentrix MX-AC High-Speed Handpiece conforms to the requirements of ISO 14457:2012 and ISO 60601-1:2009 and is substantially equivalent for use as a high-speed handpiece.

Biocompatibility testing was conducted in accordance with Good Laboratory Practices regulations (FDA, 21 CFR, Part 58- Good Laboratory Practice for Nonclinical Laboratory Studies). ISO 10993-10 "Biological Evaluation of Medical Devices, Part 10: Tests for Irritation and Skin Sensitization" and ISO 10993-12 "Biological Evaluation of Medical Devices, Part 12: Sample Preparation and Reference Materials" and the FDA Guidance Document "Use of International Stnadard ISO 10993-1, "Biological evaluation of medical devices – Part 11: Evaluation and testing within a risk management process", issued on June 16, 2016. Testing completed on this device includes:

- Cytotoxicity per ISO 10993-5
- Sensitization per ISO 10993-10
- Irritation per ISO 10993-10

Sterilization validation for the sterilization of the handpiece which incorporate the turbine assembly was performed in accordance to ANSI/AAMI ST79:2010 & A4:2013, AAMI/ANSI/ISO 14937:2009 and ANSI/AAMI ST81:2004 (R2010).

Cleaning and disinfection validation was conducted per the FDA Guidance Document for "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling" issued on March 17, 2015.

A risk analysis for the Concentrix MX-AC High- Speed Handpiece was developed using ISO14971:2012.

## VIII. CONCLUSION

Based upon the comparison of technological characteristics, demonstrated through bench testing and intended use, the Concentrix MX-AC High- Speed Handpiece is substantially equivalent to the predicate devices.