DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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February 22, 2017

MICRO-NX Co., Ltd
% Ms. Priscilla Chung
Regulatory Affairs Consultant
Lk Consulting Group USA, Inc.
800 Roosevelt Ste 417
Irvine, California 92606

Re: K161500
Trade/Device Name: MEG - TORQ
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: Class I
Product Code: EKX
Dated: January 24, 2017
Received: January 25, 2017

Dear Ms. Chung:

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 contact the Division of Industry and Consumer Education 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. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education 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,

Michael J. Ryan -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)*

K161500

Device Name

MEG-TORQ

Indications for Use *(Describe)*

This product is a cordless motor handpiece system intended for tightening and loosening an abutment screw to fix and remove the abutment on a dental implant in prosthodontic treatment.

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.

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510(k) Summary

(K161500)

Date: Feb 14, 2017

1. Applicant / Submitter:

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2. Submission Correspondent:

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3. Device:

Proprietary Name:	MEG-TORQ
Common Name:	Dental Implant Torque Driver
Classification Name:	Handpiece, Direct Drive, AC-powered
Classification:	Class I, 21 CFR 872.4200
Classification Product Code:	EKX

4. Predicate Device:

CORDLESS PROSTHODONTIC SCREWDRIVER WITH TORQUE CALIBRATION SYSTEM, MODEL ISD900 by NAKANISHI Co., Ltd. (K110278)

5. Device Description:

This device is a cordless torque driver used for connecting and disconnecting dental implant abutments used in dentistry. The torque driver function includes adjustment of spinning direction

(forward and reverse), speed and torque. The maximum torque is 35 Ncm. The device consists of a torque driver, a charge adapter and a charge cradle.

6. Indications for Use:

This product is a cordless motor handpiece system intended for tightening and loosening an abutment screw to fix and remove the abutment on a dental implant in prosthodontic treatment.

7. Performance Data(Non-Clinical):

The following properties were tested based on the referenced standards. All the test results support substantial equivalence to the predicate devices.

- Performance test in accordance with ISO 14457:2012 Dentistry - Handpieces and motors
- Sterilization validation testing in accordance with ANSI/AAMI ST79, ISO17665-1, ISO 17665-2, ISO 11138-1, and ISO11138-3
- Electrical safety and EMC test in accordance with IEC 60601-1, IEC 60601-1-6, EN 606011-1-2, EN 61000-3-2, EN 61000-3-3

8. Performance Data(Clinical):

No clinical performance testing was provided in the submission.

9. Substantial Equivalence

MEG-TORQ is substantially equivalent to ISD900 (K110278). The following comparison table is presented to demonstrate substantial equivalence.
The intended use of the subject device is the same as the predicate device. The subject device is also similar to the predicate device in terms of operational modes, type of chuck, patient contacting part, and shank type which confirms to ISO1797-1. The differences between the subject device and the predicate devices are device dimensions, speed in rpm, and torque options. However, the non-clinical performance test results provided in this submission support that the subject device is substantially equivalent to the predicate device. Especially, the maximum speed and torque test was performed to verify that the use of the subject device with the highest rpm does not shear off the abutment screw. The test results showed that this difference does not raise a concern in this regard.

	Submission Device	**Predicate Device**
510(k) Number	K161500	K110278
Device Name	Meg-Torque	CORDLESS PROSTHODONTIC SCREWDRIVER WITH TORQUE CALIBRATION SYSTEM, MODEL ISD900

Common Name	Handpiece, Direct Drive, AC-Powered	Handpiece, Direct Drive, AC-Powered
Manufacturer	MICRO-NX Co., Ltd	NAKANISHI Co., Ltd.
Intended Use	This product is a cordless motor handpiece system intended for tightening and loosening an abutment screw to fix and remove the abutment on a dental implant in prosthodontic treatment.	This product is a cordless motor handpiece system intended for tightening and loosening an abutment screw to fix and remove the abutment on a dental implant in prosthodontic treatment.
Operational modes	Speed control, Torque control, Rotate both forward/reverse operation, Calibration	Speed control, Torque control, Rotate both forward/reverse operation, Calibration
Air/water ports	N/A	N/A
Fiberoptics	N/A	N/A
Dimensions	30×28×200(mm) (Width×Length×Height)	27×29×207(mm) (Width×Length×Height)
Type of chuck	Push Button Chuck	Push Button Chuck
Coupling dimensions	N/A	N/A
Chemical composition of the waterlines	N/A	N/A
The patient-contacting portions of the device	The rotary instrument.	The rotary instrument.
Light intensity	N/A	N/A
Bur extraction force	N/A	N/A
Maximum air/water pressure	N/A	N/A
Speed in rpms	15, 30, 45, 60 rpm	15, 20, 25rpm
Torque	5,15,20,25,30,35Ncm	10-40Ncm in 1 or 5 Ncm increments
Conformance with standards for shanks	Screwdriver shank ø2.35mm ISO1797-1 Type1	Screwdriver shank ø2.35mm ISO1797-1 Type1
Coupling dimensions	N/A	N/A
Hose connections	N/A	N/A

10. Conclusion:

Based on the performance testing results, comparison of technology, and the indications for use, contained in the submission, MICRO-NX Co., Ltd. concludes that the MEG-TORQ is substantially equivalent to the predicate device.