DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

May 13, 2015

Modern Korea Co. Ltd.
c/o Ms. Priscilla Chung
LK Consulting Group USA, Inc.
2651 East Chapman Avenue, Suite 110
Fullerton California, 92831

Re: K141886
Trade/Device Name: MDK Handpieces
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EFB
Dated: April 13, 2015
Received: April 14, 2015

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 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. 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 Erin I. Keith, M.S.
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)*
K141886

Device Name

MDK Handpieces

Indications for Use *(Describe)*

MDK high-speed handpieces are used for the removal of carious material, reducing of hard tooth structure, cavity and crown preparations, removal of fillings, processing and finishing tooth preparations, restorations, and for polishing teeth.
MDK low-speed handpieces used for teeth cutting, cavity and crown preparation, restorations and polishing teeth.
All the devices are designed for use by a trained professional in the field of general dentistry.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary
(k141886)

This summary of 510(K) is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: 05/11/2015

1. 510k Applicant / Submitter

Modern Korea Co., Ltd.
#604, Ilsantechnotown, 138, Ilsan-ro,
Ilsandong-gu, Goyang-si, Gyeonggi-do,
410-722, Republic of Korea
Tel: +82-31-906-5601
Fax: +82-31-906-5600

2. Submission Correspondent

Priscilla Chung
LK Consulting Group USA, Inc.
2651 E Chapman Ave. Ste 110,
Fullerton, CA 92831
Phone: 714-202-5789 Fax: 714-409-3357
Email: juhee.c@lkconsultinggroup.com

3. Device

- Trade Name: MDK Handpieces
- Classification Name: Dental Handpiece and Accessories
- Classification Regulation: Class I, 21 CFR 872.4200
- Product Code: EFB

4. Predicate Device:

- **Primary Predicate Device for MDK High-Speed Handpieces:**
  MASTERtorque LUX 8900 L (K130560) by Kaltenbach & Voigh GMbH
- **Reference Predicate Devices for MDK High-Speed Handpieces:**
  Dental Air-Powered Handpiece, models TIGER 300TTIGER 300K, TIGER 300W, TIGER 300B (K062812) by THUNDER TIGER CORP.
- **Primary Predicate Device for MDK Low-Speed Handpieces:**
  Vigor Series Low speed dental handpieces (K112305) by THUNDER TIGER CORP.

5. Description:

The MDK handpieces are dental hand pieces for use by a trained professional in the field of general

dentistry. They are air-powered handpieces that are reusable and have a fiber optic light system (some models do not have this feature.). The MDK handpieces are supplied with water, air and light through the tube and dental treatment units.

The MDK handpieces offer high-speed handpieces and low-speed handpieces according to rpm. The high-speed handpieces with fiber optic have 11 models and those without fiber optic have 10 models. The low-speed handpieces are divided into 3 types: contra angle handpieces provided with and without a fiber optic light system, and straight handpieces. The contra angle handpieces with fiber optic have 4 models and those without fiber optic have 10 models. The straight handpieces have 2 models.

The MDK handpieces are hand-held, channeled instruments that are powered by compressed air delivered through a hose to an air channel in the handpieces. This impels the turbine in the head of the handpiece to revolve. The bur of the high speed handpieces can rotate up to 400,000 rpm and the bur of the low speed handpieces can rotate up to 100,000 rpm. Dental burs (not part of this 510k) can be inserted into the chuck system of each handpiece (push button, latch, screw, snap-on or tip-lock chuck options).

The low-speed handpieces are used with the air motors (20,000 rpm) made by our company and offer various gear ratio (1:1(constant), 20:1(speed reduction), 30:1(speed reduction), and 1:5(speed increase)). The high-speed handpieces are used with the following compatible couplings made by the third party manufacturers. *

1) Kaltenbach & Voigt GmbH & Co. : KaVo MULTIflex LUX Series
2) Sirona Dental Systems GmbH : Sirona R/F Series
3) W&H Dentalwerk Bumoos GmbH : W&H Series
4) Bien-Air Dental S.A. : BienAir Unifix L Series
5) NSK : NSK Machlite/Phatelus Series

The headpieces are made of titanium and stainless steel, and must be cleaned and sterilized between use by the user.

6. Indications for Use:

MDK high-speed handpieces are used for the removal of carious material, reducing of hard tooth structure, cavity and crown preparations, removal of fillings, processing and finishing tooth preparations, restorations, and for polishing teeth. MDK low-speed handpieces used for teeth cutting, cavity and crown preparation, restorations and polishing teeth.
All the devices are designed for use by a trained professional in the field of general dentistry.

7. Comparison to the Cleared Device

7.1. High-speed handpieces

The subject device is intended for the same use as MASTERtorque LUX 8900 L by Kaltenbach & Voigh GmbH and the Dental Air-Powered Handpiece, models TIGER 300T, TIGER 300K, TIGER300W, TIGER 300B, and TIGER 300N by THUNDER TIGER CORP. The subject device is substantially equivalent to the predicate devices in design, principle of operation, raw materials, performance specifications and sterilization method.
The internal structure or design, and the materials of the subject device might be different from the predicate devices; however, the test results of the biocompatibility test, the sterilization validation, and the performance tests support that the subject device is

substantially equivalent to the predicate devices.

	Subject Device	Primary Predicate Device	Reference Predicate Device
Device Name	MDK handpieces - High-speed handpieces	MASTERtorque LUX 8900 L	Dental Air-Powered Handpiece, models TIGER 300T, TIGER 300K, TIGER 300W, TIGER 300B, TIGER 300N
510K	K141886	K130560	K062812
Manufacturer	MODERN KOREA Co., Ltd.	Kaltenbach & Voigh GMbH	THUNDER TIGER CORP.
Indications for use	MDK high-speed handpieces are used for the removal of carious material, reducing of hard tooth structure, cavity and crown preparations, removal of fillings, processing and finishing tooth preparations, restorations, and for polishing teeth. All the devices are designed for use by a trained professional in the field of general dentistry.	The MASTERtorque LUX 8900 L is intended for the removal of carious material, reducing hard tooth structure, cavity preparation, finishing tooth preparations, restorations, and for polishing teeth. They are designed for use by a trained professional in the field of general dentistry.	THUNDER TIGER Dental Air-Powered Handpiece, models TIGER 300TTIGER 300K, TIGER 300W TIGER 300B. TIGER 300N are intended for removing carious material, reducing hard tooth structure, cavity preparation, finishing tooth preparations and restorations and polishing teeth.
Principle of operation	Through the tubes connected to a dental unit, the air-powered handpiece receives the air for rotation, the cooling water and light for illumination of the operation area.	Through the tubes connected to a dental unit, the air-powered handpiece receives the air for rotation, the cooling water and light for illumination of the operation area.	Through the tubes connected to a dental unit, the air-powered handpiece receives the air for rotation, the cooling water and light for illumination of the operation area.
Air/water ports	Up to four	Up to four	Information not available
Fiber optics	With or without built-in light system	With built-in light system	With or without built-in light system
Type of chuck	Push button	Push button	Identical
Chemical composition of the patient-contacting portions of the device	Stainless steel and titanium	Stainless steel	Titanium
Chemical composition of the water/air	Stainless steel and titanium	German silver and stainless steel	Information not available

lines			
Bur retention force	30N	Up to 24N	35N
Operating pressure	36psi to 43psi	41 psi recommended	Information not available
Rotation Speed	320,000 ~ 400,000rpm	340,000 ~ 400,000rpm	300,000 ~ 350,000 rpm
Accessories	Wrench, Connector (for inserting lubricant)	Wrench, Connector (for inserting lubricant)	Wrench, Connector (for inserting lubricant)
Lubricant	Pana-Spray made by NSK(K052700)	KaVo QUATTROcare (K071288)	Liquid oil type spray can
Sterilization	Steam autoclave method	Steam autoclave method	Steam autoclave method

7.2. Low-speed handpieces

The subject device is intended for the same use as Vigor Series Low speed dental handpieces by THUNDER TIGER CORP. The subject device is substantially equivalent to the predicate device in design, principle of operation, raw materials, performance specifications and sterilization method.
The subject device offers more chuck system models than the predicate device, but the test results of the bur release force test supported that this difference would not raise a question of the risk related to chuck.

	Subject Device	**Primary Predicate Device**
Device Name	MDK handpieces - Low-speed handpieces	Vigor Series Low speed dental handpieces
510K	K141886	K112305
Manufacturer	MODERN KOREA Co., Ltd.	THUNDER TIGER CORP.
Indications for use	MDK low-speed handpieces used for teeth cutting, cavity and crown preparation, restorations and polishing teeth. All the devices are designed for use by a trained professional in the field of general dentistry.	The Vigor Series Low speed dental handpieces & Accessories are powered by either low speed air motor or electric micro-motor for teeth cutting, cavity and crown preparation, restorations and polishing teeth. The Vigor A Low Speed Air Motor is used in conjunction with accessories such as contra-angle, such as The Vigor C Low Speed Contra-Angle handpieces, and straight handpiece, such as The Vigor S Low Speed Straight handpieces. The motor contains chip air and water that help with removing debris from teeth cutting. The Low Speed Contra Angle Dental Handpiece that is intended for removing carious material, cavity and crown preparations, finishing tooth

		preparations, reducing hard tooth structures, restorations and polishing teeth. The Straight Handpiece contains chip air and water that help with removing debris from teeth cutting.
Principle of operation	Through the tubes connected to a dental unit, the air-powered handpiece receives the air for rotation, the cooling water and light for illumination of the operation area.	Through the tubes connected to a dental unit, the air-powered handpiece receives the air for rotation, the cooling water and light for illumination of the operation area.
Air/water ports	Up to 4 holes	Up to 4 holes
Fiber optics	With or without built-in light system	With or without built-in light system
Type of chuck	push button, latch, screw, snap-on or tip-lock chuck options	Push button & latch type
Chemical composition of the patient-contacting portions of the device	Stainless steel and titanium	Stainless steel
Chemical composition of the water/air lines	Stainless steel	Stainless steel
Bur retention force	30N	Information not available
Operating pressure	36psi to 43psi	Information not available
Speed (Motor)	Up to 20,000 rpm	Up to 25,000 rpm
Accessories	Head opener for the latch type, Connector for inserting lubricant, External Spray Tubing with nozzle	Head opener for the latch type, Connector for inserting lubricant, External Spray Tubing with nozzle
Lubricant	Pana-Spray made by NSK(K052700)	Information not available
Sterilization	Steam autoclave method	Steam autoclave method

8. Performance Data

The following bench tests have been performed on the subject device and passed the pre-set criteria.

- Bur release force test
- Reverse analysis report for compatibility with the third party couplings
- Sterilization validation test in accordance with ISO 17665, ISO 11138, ISO 11135, ISO 11607, ISO 17664, and USP 30-NF 25
- Performance test in accordance with ISO 14457
- Biocompatibility test in accordance with ISO 10993-5

- Compatibility test for the third party couplings

The subject device also conformed to the FDA guidance document for Dental Handpieces.

9. Conclusion

Based on the information provided in this 510k submission, we have concluded that our devices are substantially equivalent to the predicate device.