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

February 4, 2016

Good Doctors Co., Ltd.
c/o Ms. Priscilla Chung
Regulatory Affairs Consultant
LK Consulting Group USA, Inc.
2651 East Chapman Ave, Suite 110
Fullerton, California 92831

Re: K151274
Trade/Device Name: Dr's Finder
Regulation Number: Unclassified
Regulation Name: Unclassified
Regulatory Class: Unclassified
Product Code: LQY
Dated: January 4, 2016
Received: January 5, 2016

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,

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)*

K151274

Device Name

Dr's Finder

Indications for Use *(Describe)*

Dr's Finder is intended for detecting the apex of root canal.

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
(K151274)

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

Date: February 3, 2016

1. 510K Applicant / Submitter:

Good Doctors Co., Ltd.
#208, Woolim Lions Valley B-dong,
283 Bupyeong-daero, Bupyeong-gu, Incheon
403-911, Republic of Korea
Tel: +82-32-424-6325
Fax: +82-32-424-6326

2. Submission Contact Person

LK Consulting Group USA, Inc.
2651 E Chapman Ave Ste 110, Fullerton, CA 92831
Priscilla Juhee Chung
Phone: 714.202.5789 Fax: 714-409-3357
Email: juhee.c@lkconsultinggroup.com

3. Device

- Proprietary Name: Dr's Finder
- Common Name: Apex Locator
- Classification: Unclassified (Pre-Amendment)
- Product Code: LQY

4. Predicate Device

- **Primary Predicate Device:**
  NAVI ROOT by S-Denti Co., Ltd. (K083901)

- **Reference Predicate Devices:**
  Multiple (Apex Locator), Model RCM-7 by J. MRITAMFG. CORP (K090925)

5. Description:

The device allows the relative position of a dental file and the apex to be determined electrically. Using a standard dental file inserted into the root canal as an electrode, the

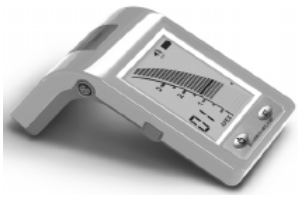
device emits very small electrical currents having frequencies of 400 Hz, 5400Hz, and 10400 Hz. The current between the file and mouth is measured at each of these frequencies, and the readout of the relative proximity to the apex will appear on the meter.

8. Indications for Use

Dr's Finder is intended for detecting the apex of root canal.

9. Substantial Equivalence Discussion:

The Dr's Finder is substantially equivalent to the VAVI ROOT (K083901) and Root ZX mini (K090925). The Dr's Finder and the predicate devices have the same intended use, the same principles of operation and similar technological characteristics. The subject device and primary predicate have slightly different Indications for Use language. However, the difference in language does not change the intended use or substantial equivalence.
The measurement current of the subject device is different from the primary predicate device; however, the reference predicate device has the same measurement current as the subject device. There is also a difference in frequencies used for measurement, however, a side by side performance test was performed on the subject device and the primary predicate device (K090925), and the test results show that the subject device would perform as well as the predicate device.
The materials used in the subject device might be different from the predicate devices as well, however, biocompatibility tests were performed and the results support that the subject device is biocompatible.

	Subject Device	**Primary Predicate Device**	**Reference Predicate Device**
510(K) Number	-	K083901	K090925
Device Name	Dr's Finder (AL-DF10)	NAVI ROOT	MULTIPLE (APEX LOCATOR), MODEL RCM-7
Manufacturer	Good Doctors Co., Ltd.	S-Denti Co., Ltd.	J. MRITAMFG. CORP
Product Code	LQY	LQY	LQY
Design			
Intended Use	Dr's Finder is intended for detecting the apex of root canal.	The NAVI ROOT is intended for measuring the length of the root canal for the purpose of	RCM-7 is a dental device, Apex Locator. It can be used to detect the apex of root canal.

		performing root canals.	
Method of calculating location of root	Comparison of impedance multi frequencies	Comparison of impedance at multi frequencies	Comparison of impedance at multi frequencies
Measurement Current	30 uA, maximum	5 uA±10%	30 uA, maximum
Measurement Power	Lithium Polymer DC 4.2V (rechargeable)	DC 4.5V (AA 1.5V x 3ea)Hz	DC 4.5V LR03 (AAA size X3ea) batteries
Power consumption	0.29 W	150mW	0.2 W
Frequencies used for comparison	400 Hz – 10,400Hz	500 Hz – 5,000 Hz	-
Display	OLED	LCD	LCD
Accessory	File hook, Lip hook, Probe cord	File hook, Lip hook, Probe cord	File hook, Lip hook, Probe cord
Accuracy	±0.2mm	±0.25mm	-
Dimensions (W x L x H)	55 x 85 x 21mm	153 x 138 x 44mm	60 x 103 x57mm
Weight	56g	425g	110g
Calibration	Not required	Not required	Not required

10. Performance Tests (Non-clinical)

- The comparison testing on Dr's Finder and the predicate device (RCM-7, K090925) was performed to compare the measurement performance of locating apex root using extracted tooth. Based on the test results, we conclude that the Dr's Finder is substantially equivalent to the predicate device.
- The EMC and electrical safety testing was conducted on the Dr's Finder in accordance with the following standards.
  - EN 60601-1:2006. + A11:2011
  - EN 60601-1-2:2007
  - EN 61000-3-2:2006/A2:2009
  - EN 61000-3-3:2013
  - EN 55011:2009/A1:2010 GROUP 1, CLASS B
- Biocompatibility testing performed on the File hook and the Lip hook in accordance with the following standards.
  - ISO10993-5: 2009 Cytotoxicity Test
  - ISO10993-10 : 2010 Intracutaneous (Intradermal) Reactivity Test
  - ISO10993-10 : 2010 Sensitization (Maximization Test for delayed hypersensitivity)
- To verify the sterility assurance level (10^{-6}) for steam sterilization procedure of the file hook and the lip hook, the biological indicator (BI) overkill method was used in

accordance to ISO 17665-1 and ISO 17665-2. In addition, dry time under full cycle was validated.

- Software Validation Test

The test results of non-clinical tests performed on the subject device supported that it is substantially equivalent to the predicate devices despite the differences.

11. Conclusions:

Based on the information provided in this premarket notification, Good Doctors Co., Ltd. concludes that the Dr's Finder is substantially equivalent to the predicate device as described herein in.