March 30, 2018

Good Doctors Co., Ltd.
% Priscilla Chung
Regulatory Affairs Consultant
LK Consulting Group USA, Inc.
690 Roosevelt
Irvine, California 92620

Re: K171867
Trade/Device Name: Dr's Finder NEO
Regulatory Class: Unclassified
Product Code: LQY
Dated: February 23, 2018
Received: February 28, 2018

Dear Priscilla 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.

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)*
K171867

Device Name

Dr's Finder NEO

Indications for Use *(Describe)*

Dr's Finder NEO 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.***

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# 510(k) Summary

(K171867)

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

Date: Mar 29, 2018

**1. 510K Applicant / Submitter:**

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**2. Submission Contact Person**

LK Consulting Group USA, Inc.
690 Roosevelt, Irvine CA 92620
Priscilla Juhee Chung
Phone: 714.202.5789 Fax: 714-409-3357
Email: juhee.c@lkconsultinggroup.com

**3. Device**

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

**4. Predicate Device**

- **Primary Predicate Device:**
  Dr's Finder by Good Doctors Co., Ltd. (K151274)

- **Reference Device:**
  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 NEO is intended for detecting the apex of root canal.

## 9. Substantial Equivalence Discussion:

The Dr's Finder Neo is substantially equivalent to the Dr's Finder (K151274) and MULTIPLE (APEX LOCATOR), MODEL RCM-7 (K090925). The Dr's Finder Neo and the predicate devices have the same intended use, the same principles of operation and similar technological characteristics.
The major difference between the subject device and the Dr's Finder (K151274) is that the subject device does not have Bluetooth function to transfer the data to the mobile App. The major difference between the subject device and the Apex Locator (K090925) is the frequencies used for measurement.
We have performed side by side performance test on the subject device and the reference device (K090925), and the test results show that the subject device would perform as well as the reference device. We evaluated the reference device (K090925) instead of the primary predicate device (K151274) to compare the performance with the leading model in the market. The reference device has been marketed and used longer than the primary predicate device.

| | **Subject Device** | **Primary Predicate Device** | **Reference Device** |
|---|---|---|---|
| 510(K) # | K171867 | K151274 | K090925 |
| Device Name | Dr's Finder neo (AL-DFA20) | Dr's Finder (AL-DF10) | MULTIPLE (APEX LOCATOR), MODEL RCM-7 |
| Manufacturer | Good Doctors Co., Ltd. | Good Doctors Co., Ltd. | J. MRITAMFG. CORP |
| Product Code | LQY | LQY | LQY |
| Design |  |  |  |
| Indications for Use | Dr's Finder Neo is intended for detecting the apex of root canal. | Dr's Finder is intended for detecting the apex of root canal. | RCM-7 is a dental device, Apex Locator.<br>It can be used to detect the apex of root canal. |

| | | | |
|---|---|---|---|
| Method of calculating location of root | Comparison of impedance multi frequencies | Comparison of impedance multi frequencies | Comparison of impedance at multi frequencies |
| Measurement Current | 30 uA, maximum | 30 uA, maximum | 30 uA, maximum |
| Measurement Power | Lithium Polymer DC 4.2V (rechargeable) | Lithium Polymer DC 4.2V (rechargeable) | DC 4.5V LR03 (AAA size X3ea) batteries |
| Power Consumption | 0.46 W | 0.29 W | 0.2 W |
| Frequencies used for comparison | 400 Hz, 5400Hz, and 10400 Hz | 400 Hz, 5400Hz, and 10400 Hz | - |
| Display | OLED | OLED | LCD |
| Accessory | File hook, Lip hook, Probe cord | File hook, Lip hook, Probe cord | File hook, Lip hook, Probe cord |
| Accuracy | ±0.2mm | ±0.2mm | - |
| Dimensions (W x L x H) | 43 x 46 x 16 mm | 55 x 85 x 21mm | 60 x 103 x57mm |
| Weight | 24g | 56g | 110g |
| Bluetooth transfer to mobile app | No | Yes | No |

## 10. Performance Tests (Non-clinical)

- The comparison testing on Dr's Finder NEO and the predicate device (RCM-7, K090925) was performed to compare the measurement performance of locating apex root using extracted tooth and a stainless steel file. Based on the test results, we conclude that the Dr's Finder NEO is substantially equivalent to the reference device.
- The EMC and electrical safety testing was conducted on the Dr's Finder NEO in accordance with the following standards.
  - EN60601-1:2006/A1:2013 Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance
  - EN60601-1-2:2015 Medical electrical equipment. General requirements for basic safety and essential performance. Collateral Standard. Electromagnetic disturbances. Requirements and tests
  - EN 61000-3-2:2014 Electromagnetic compatibility (EMC). Limits. Limits for harmonic current emissions (equipment input current ≤ 16 A per phase)
  - EN 61000-3-3:2013 Electromagnetic compatibility (EMC). Limits. Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current ≤ 16 A per phase and not subject to conditional connection

- EN 55011:2009/A1:2010 Industrial, scientific and medical equipment. Radio-frequency disturbance characteristics. Limits and methods of measurement

- 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: It is implemented by referring to IEC 60601-1:2005+A1:2012 Clause 14 and FDA software validation guidance "General Principles of Software Validation; Final Guidance for Industry and FDA Staff , Document issued on: January 11, 2002".

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 NEO is substantially equivalent to the predicate device as described herein in.