OCT 0 8 2010

K101177

510(k) Summary of Safety & Effectiveness

Pursuant to CFR 807.92, the following 510(k) Summary is provided:

1. (a)	**Submitter Address:**	George J. Hattub MedicSense, USA 291 Hillside Avenue Somerset, MA 02726 www.medicsense.com
1. (b)	***Manufacturer Address:***	MedicNRG, Ltd. PO Box 338, MP Jordan Valley Kibbutz Afikim, Israel 15148
	Mfg. Phone:	972-4-675-4217
	Contact Person:	Michal Zach, QA Manager
	Date:	June 12, 2010
2.	***Device & Classification Name:***	Locator, Root, Apex, Class 2, Product Code LQY, unclassified ApexNRG Rider(Apex Locator)
3.	***Predicate Device:***	MedicNRG ApexDAL Apex Locator (K080113)
4.	***Description:***	The ApexNRG Rider is a dental apex locator which has the ability to measure the depth of the root canal by electronic means.
5.	***Intended Use:***	The ApexNRG Rider is intended for the measurement of the length of the root canal for purposes of performing root canals and related dental procedures, for use by a trained professional in general dentistry.
6.	***Comparison of Technological Characteristics:***	With respect to technology and intended use, the Modified MedicNRG-Rider (Apex Locator) is substantially equivalent to its predicate device which is the MedicNRG DAL Apex Locator. The primary difference is that the modified device can be used in conjunction with a dental handpiece or as a separate, external unit. Like its predicate device (K080113) it utilizes a multi-frequency response signal using DSP technology with a fast algorithm reducing the delay between calculation and display of measurement. The signals are generated as a response to multi-frequency signals having a 6.5 and 1.3 kHz repetition rate. The following table delineates the differences between the predicate device and the ApexNRG Rider

Device Characteristic	**Modified Device** ApexNRG Rider	**Predicate Device** Apex DAL Electronic Apex Locator	**Comment**
Intended Use	To measure the length of the root canal for the purpose of performing root canals and related dental procedures for use by a trained professional in general dentistry	To measure the length of the root canal for the purpose of performing root canals and related dental procedures for use by a trained professional in general dentistry	same
Power Source	Single CR2450 V	AA 1.5 V	different
Electric Current	Less than 10 µA	Less than 10 µA	same
Method of calculating location of root canal apex	Comparison of a multi-frequency response signal using DSP technology with a different algorithm reducing the delay between calculation and display of measurement. The signals are generated as a response to multi-frequency signals having a 6.5 and 1.3 kHz repetition rate. The frequencies used for comparison 6.5 kHz - 1.3 kHz Square Wave with 3 cycles used for measurement.	Comparison of a multi-frequency response signal using DSP technology with a different algorithm reducing the delay between calculation and display of measurement. The signals are generated as a response to multi-frequency signals having a 6.5 and 1.3 kHz repetition rate. The frequencies used for comparison 6.5 kHz - 1.3 kHz Square Wave with 3 cycles used for measurement.	same

Frequencies used for comparison	6.5 kHz - 1.3 kHz Square Wave	6.5 kHz - 1.3 kHz Square Wave	same
Number of cycles used for measurement	3	3	same
Display	6 LED- Distance provided every 0.25 mm from 0.5 mm to the apex.	8 LED- Distance provided every 0.25 mm from 0.5 mm to the apex.	Same
Adjustment before measurement	Not required	Not required	Same
Measuring Voltage	Up to 15 mV	Up to 15 mV	Same
Weight	26 grams	50 grams	Same
Dimensions	L:67 x W: 34 x H: 19 mm	L: 87 x W: 60 x H: 18 mm	Same

Based upon the testing results, MedicNRG believes this difference does not raise additional safety of efficacy concerns.

7. Testing

The determination of substantial equivalence is based on an assessment of non-clinical performance data. This testing consisted EMC and Electrical Testing as well as Software Validation. The results of this testing supported a determination of substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Medicnrg, Limited
C/O Mr. George Hattub
Medicsense, USA
291 Hillside Avenue
Somerset, Massachusetts 02726

OCT 0 8 2010

Re: K101177
Trade/Device Name: ApexNRG Rider (Apex Locator)
Regulation Number: None
Regulation Name: None
Regulatory Class: Unclassified
Product Code: LQY
Dated: August 24, 2010
Received: August 30, 2010

Dear Mr. Hattub:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: ApexNRG Rider (Apex Locator)

Indications For Use: The ApexNRG Rider is indicated for the measurement of the length of the root canals and related dental procedures, for use by a trained professional in general dentistry.

Prescription Use _X_ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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