K071133

SEP 21 2007

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 Gordon Valley Kibbutz Afikim, Israel 15148
	Mfg. Phone:	972-4-675-4217
	Contact Person:	Michal Zach, QA Manager
	Date:	April 11, 2007
2.	***Device & Classification Name:***	Locator, Root, Apex, Class 2, Product Code LQY, unclassified ApexNRG XFR (Apex Locator)
3.	***Predicate Device:***	MedicNRG XFG Electronic Apex Locator (K063843) & MedicNRG Electronic Apex Locator (K032743)
4.	***Description:***	The ApexNRG Blue is a dental apex locator which has the ability to measure the depth of the root canal by electronic means. It has Blue-Tooth Capability.
5.	***Intended Use:***	The ApexNRG-Blue 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-Blue (Apex Locator) is substantially equivalent to its predicate devices which are the MedicNRG XFR Electronic Apex Locator & MedicNRG Electronic Apex Locator. The primary difference is that the modified device provides Blue-Tooth Capability. Based upon the testing results, MedicNRG believes these differences do not raise additional safety of efficacy concerns.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 1 2007

MedicNRG, Limited
C/O Mr. George J. Hattub
Senior Staff Consultant
MedicSense, USA
291 Hillside Avenue
Somerset, Massachusetts 02726

Re: K071133
Trade/Device Name: ApexNRG-Blue (Apex Locator)
Regulation Number: Unclassified
Regulation Name: Unclassified
Regulatory Class: II
Product Code: LQY
Dated: September 9, 2007
Received: September 17, 2007

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.

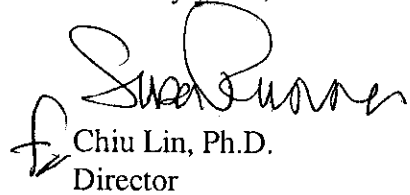
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
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): K071133

Device Name: ApexNRG-Blue (Apex Locator)

Indications For Use: The ApexNRG-Blue 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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