MAR 1 5 2004

K032743

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510(k) Summary of Safety and Effectiveness

The Following 510(k) Summary of Safety and Effectiveness has been prepared pursuant to requirements for 510(k) summaries specified in 21 CFR § 807.92(a).

807.92(a)(1) - Submitter Details:

Submitter name:	MedicNRG Ltd.
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Tel/Fax:	+972-4-6754278
Preparer of application:	MedicNRG Ltd.
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Official Correspondent:	Adi Ickowicz
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e-mail:	adi@medicsense.com
Date:	July 25, 2003

807.92(a)(2) - Device Details:

Trade Name:	Apex NRG - Electronic Apex Locator
Common Name:	Apex Locator
Classification Regulation:	510(k) non exempt
Class:	Unclassified
Product Code:	LQY - LOCATOR, ROOT APEX

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807.92(a)(3) – Predicate Devices:

Medical Device Name	Applicant Name	510(k) Number	Classification
JUSTWO TME-601 Root Apex Locator	Toei Electric Co, POBox 7007 Deerfield, IL 60015	K022020	unclassified
ROOT ZX	J. Morita USA, Inc. 9 Mason Irvine, CA 92618	K921979	unclassified

Additional Substantial Equivalence Information is provided in the attached Substantial Equivalence Comparison Table.

807.92(a)(4) – Device Description:

The Apex NRG is used to measure the distance to the apex during root canal procedures. A low frequency low volt AC signal is applied between the lip electrode and the endodontic file, which is inserted into the root canal. The impedance of the tissues between the electrodes change as the file advances toward the root apex and the measured signals are used to monitor the progress of the file in the tooth.

The Apex NRG operates on the measurement of a weak electrical current flowing between two electrodes. One electrode is a metal hook that rests on the patient's lower lip and the other is the endodontic file that is attached to the file clasp and inserted into the canal. Multi frequencies are used to minimize errors that may be introduced by the entrance of conducting materials such as blood into the canal.

The ratio of the impedance values measured in the canal and lip are calculated to provide a measure of the probe tip relative to the apical foramen.
The device consists of a main body incorporating the display, a lip hook, a file clasp and an apron clasp. The device is powered by one 200mAH CR2032 battery

807.92(a)(5) – Device Intended Use:

Measurement of 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.

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807.92(a)(6) – Substantial Equivalence Comparison Table:

Device Characteristic	Candidate Device	Predicate Devices	
	Apex NRG	ROOT ZX (K921979)	JUSTWO TME-601 Root Apex Locator (K022020)
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.	Measurement of the root canal for the purpose of performing root canals and related dental procedures.	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
Power Source	One CR2032 battery 200mAH	5 AA batteries	4 AAA batteries
Electric Current	Less than 40 µA	Less than 10 µA	Less than 10 µA
Method of calculating location of root canal apex	Comparison of impedance at multi frequencies	Comparison of impedance at two frequencies	Measurement of current at two frequencies
Frequencies used for comparison	6.5 kHz - 1.3 kHz	400 Hz - 8000 Hz	500 Hz - 200 Hz
Number of cycles used for measurement	Multi frequency	2	2
Display	LED	Liquid crystal	Analog
Adjustment before measurement	Unnecessary	Unnecessary	Unnecessary
Measuring Voltage	Up to 15 mV	80 mV	50 mV
Audio location indicator	No	Yes	Yes
Weight	31 g	550 g	280 g
Use with standard dental file	Yes	Yes	Yes
Automatic On/Off switch	Yes	No	Yes

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Clinical Testing:

A clinical study was performed at the Department of Endodontic, School of Dental Medicine Hebrew University; Jerusalem Israel comparing the Apex NRG with two commercially distributed apex locators; the Root ZX™ and the Apit 7™ to radiographic working length. Each patient was evaluated using the Apex NRG, the ROOT ZX and in some cases randomly using the Apit 7™, and the radiographic method. The study included 69 root canals from 30 teeth. The electronic readings were compared to those of the radiographs working length, which were determined by the investigators. The results obtained from the ROOT ZX and the Apex NRG were nearly identical and were similar to those obtained by radiography. The results obtained from the Apit 7™ were in high agreement to both the ROOT ZX and the Apex NRG.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 5 2004

MedicNRG Limited
C/O Mr. Adi Lckowicz
Official Correspondents
Medicsense
P.O. Box 367
Ramat Ha' Sharon,
ISRAEL 47103

Re: K032743
Trade/Device Name: Apex NRG- Electronic Apex Locator
Regulation Number: Unclassified
Regulation Name: None
Regulatory Class: None
Product Code: LQY
Dated: December 1, 2003
Received: January 12, 2004

Dear Mr. Ickowicz :

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.

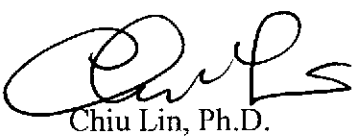
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 594-4613. 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/dsma/dsmamain.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

D. Statement of Indication for Use

510(k) Number (if known): K032743

Device Name: **Apex NRG - Electronic Apex Locator**

Indication For Use:

Measurement of 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.

(PLEASE DO NOT WRITE BELOW THE LINE – CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Kaan Mulop for MSR
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices
510(k) Number: K032743