K101054

Romidan Ltd.

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Document No.: 05.00

Section 5.: "510(k) Summary"

SEP 3 · 2010

RomiApex™ A-15, Electronic Apex Locator

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)

Section's content

5.1 Owner &Submitter's Details: [807.92(a)(1)]

Owner & Submitter Name:	Romidan LTD
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Name of Contact Person:	Mr. Eitan Margalit
Establishment Registration No.:	3003518307
Date prepared:	**July 1st, 2010**

US Agent:

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5.2 Candidate Device Details: [807.92(a)(2)]

Trade Name:	RomiApex™ A15 – Electronic Apex Locator
Common Name:	Apex Locator
Classification Name:	Locator, Root Apex
Product Code:	LQY – Locator, ROOT APEX
Review Panel:	Dental
Device Class:	Unclassified

5.3 Predicate Device Identification: [807.92(a)(3)]

Devices to which substantial equivalence is claimed:

Table 5.3: Predicate Device Identification

Predicate Medical Device Name	Applicant Name	510(k) Number(*)
BINGO-1020	DENT CORP, Research & Development	K992233

(*) See "510(k) Premarket Notification Database Search for more details.

Additional Substantial Equivalence Information is provided in the attached Substantial Equivalence Comparison Table. (see Para 807.92(a)(6)).

5.4 Device Description: [807.92(a)(4)]

- The RomiApex™ A-15 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 RomiApex™ A-15 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.
- The measurements in RomiAPEX™ A-15 are performed utilizing AC signals at two frequencies – 500 Hz and 8 kHz. The frequencies are alternated rather then mixed, as it is done in other apex locators, thus canceling the need for signal filtering and eliminating the noise caused by non-ideal filters.
- The device consists of a main body incorporating the LCD display, a lip Clip, a file clip a cable and a touch prob.
- The device is powered by one 1.5 AAA Alkaline battery.

5.5 Intended Use : [807.92(a)(5)]

RomiAPEX™ A-15 is indicated for patients who need to undergo root canal treatment, which requires precise determination of position of the dental file in the canal relatively to the root apex.

5.6 Substantial Equivalence Comparison Table: [807.92(a)(6)]

Table 5.6: Substantial Equivalence Comparison

Line No.	Device Characteristics	Predicate Device	Candidate Device
		Bingo-1020	**RomiApex™ A-15**
1.	Device definition	Electronic apex locator	Same as in Bingo-1020
2.	Intended Use	Precise apex localization during root canal treatment.	Same as in Bingo-1020
3.	Indications for use	Bingo-1020 is a modern device for precise apex localization during root channel treatment. Bingo-1020 is distinguished by increasing precision at 0.1mm on wet/dry, large graphic display where current position of endo file is reflected and other essential information is displayed.	RomiAPEX™ A-15 is indicated for patients who need to undergo root canal treatment, which requires precise determination of position of the dental file in the canal relatively to the root apex.
4.	Where to be used (clinics, home etc.)	This product must only be used in hospital environments, clinics or dental offices by qualified dental personnel.	Same as in Bingo-1020
5.	Device category	Active, invasive	Same as in Bingo-1020
6.	Power Source	2.4V NiMH rechargeable batteries	1.5V alkaline primary battery
7.	External charger	Input: 230V/50-60Hz Output: 6Vdc @ 200mA	External charger is not required
8.	Current Consumption	Maximum – 30 mA DC.	Maximum – 13 mA DC.
9.	Method of calculating location of root canal apex	RMS functions of the measured signals at two frequencies are used to calculate the test scores which are compared to statistically predefined thresholds.	Same as in Bingo-1020
10.	Display	Custom monochrome LCD Display	Custom color LCD Display

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Line No.	Device Characteristics	Predicate Device **Bingo-1020**	Candidate Device **RomiApex™ A-15**
11.	Buttons	Three push buttons: 1. On / Off 2. Sound control 3. Demo MODE (training mode)	Two push buttons: 1. Same as in Bingo-1020 2. Same as in Bingo-1020 3. "Demo MODE" (for training) is not an offered feature in RomiApex™ A-15.
12.	Sound indication	Piezzo transducer with sound level control (high, medium, low, mute).	Same as in Bingo-1020
13.	Adjustment before measurement	Not required	Same as in Bingo-1020
14.	Calibration	Not required	Same as in Bingo-1020
15a.	Measuring signal amplitude	Nominal – doesn't exceed 25 mV AC.	Same as in Bingo-1020
15.b		The maximum voltage applied to the patient doesn't exceed 300 mV DC.	Same as in Bingo-1020
16.	Frequencies used for measurements	500 Hz and 8 kHz	Same as in Bingo-1020
17.	Weight	430 Gr	100 Gr
18.	Dimensions	W160 x H95 x T35 mm	W55 x H92 x T16mm
19.	Files to be used with the device	Any kind of standard dental files may be used	Same as in Bingo-1020
20a.	Safety features	The same connector on the device is used both for measuring cable connection and for battery charging. This safety feature prevents simultaneous connection of the device to the patient and to the mains via external charger.	No external charger should be connected to the device. And due that such safety feature is not needed in RomiApex™ A-15 at all.
20b.	Safety features (Continue)	The type of connector used – Mini DIN	A new type of connector is used – Micro USB. This type of connector was specially designed to provide particularly high mechanical strength and is guaranteed by the manufacturer for 10,000 mating cycles.
21.	Automatic on/off switch	Automatic turn-off after 5 min. of the idle state.	**Same as in Bingo-1020**

End of Table 5.6

5.7 Conclusions: [807.92(b)(3)]

- Romidan's RomiApex™ A-15, subject of this submission, constitutes a safe, reliable, and effective medical device, meeting all the declared requirements of its intended use. Device presents no adverse health effects or safety risks to patients when use as intended.

- The RomiApex™ A-15 has the same intended use and fundamental scientific technology as its predicate device – Bingo 1020 (K992233)

- The RomiApex™ A-15 was evaluated against it's predicate, and was found to be Substantial Equivalent.

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

Mr. Eitan Margalit
General Manager
Romidan, Limited
5 Simcha Holzberg Street
Kiryat Ono
Israel 55022

SEP 3 2010

Re: K101054
Trade/Device Name: RomiApex™ A-15, (an Apex Locator)
Regulation Number: Unclassified
Regulation Name: None
Regulatory Class: None
Product Code: LQY
Dated: August 26, 2010
Received: August 30, 2010

Dear Mr. Margalit:

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,

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

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Section 4.: Indication for Use Statement

510(k) Number (if known): _____

Device Name: **RomiApex™ A-15, (an Apex Locator)**

Indications for Use:

- RomiAPEX™ A-15 is indicated for patients who need to undergo root canal treatment, which requires precise determination of position of the dental file in the canal relatively to the root apex.

Prescription Use __√___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 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)
)ivision of Anesthesiology, General Hospital
ıfection Control, Dental Devices

510(k) Number: K101054

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