K111474

NOV - 2 2011

"510(k) Summary"

BINGO PRO, 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 Details: [807.92(a)(1)]

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

Trade Name:	BINGO PRO – 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 Device Name	Name of Manufacturer	Name of Applicant	510(k) Number
Bingo-1020	Forum Engineering Technologies (96) Ltd., (Israel)	DENT CORP, Research & Development (USA)	K992233

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

BINGO PRO is a modern apex locator intended for precise localization of root canal apex.

The measurements in BINGO PRO are performed utilizing AC signals at two frequencies – 500 Hz and 8 kHz. The frequencies are alternated and not mixed, eliminating the need for signal mixing and frequency discrimination electronic circuits. The patented signal measuring method utilized in BINGO PRO is based on measurements of RMS (Root Mean Square) level of the signal.

Advanced 3D user interface implemented in BINGO PRO is based on high resolution TFT color graphic display. "Live" real time presentation of endodontic file movement inside the canal is designed to make dentist's work easier and to increase his confidence. Display indicators are carefully designed to be intuitively understood and to serve for instant troubleshooting during device usage.

BINGO PRO shows the movement of the file inside the canal from the beginning of the measurements to the end, providing uninterrupted feedback to the dentist. ROOT WIZARD file tracking algorithm enables full-scale display of the file movement during the treatment while APICAL ZOOM feature enables high-resolution display of the file advance in pre-apical and apical zones. Large, clearly recognizable graphical and numerical readings in the APICAL ZOOM are designed to enable precise control over the file advance matching the individual technique of the dentist. Visual information is accompanied by optional audio

signals. Numerical values and the numerical scale shown in the APICAL ZOOM do not represent actual distance from the apex in mm; they serve as a convenient reference to judge the file tip position in relation to the apex.

Operation of BINGO PRO is fully automatic, no manual calibrations or adjustments are required. The measured signal is analyzed and automatic adjustments are made if required. The device may operate within different conditions in the root canal: dry or wet. BINGO PRO may only be used with stainless steel or nickel titanium endodontic files.

According to the modern approach, the final distance of the probe tip from the apex should vary in different cases: for example, in non-contaminated root canal the tip should be about 0.5 mm before the minor apical foramen; in case of bacterial contamination the canal should be cleaned to the apex. Such cases may occur in different teeth of the same patient or even in the different canals of the same root. VIRTUAL APEX feature implemented in BINGO PRO enables to mark a predetermined indication position on the display in the APICAL ZOOM area. When VIRTUAL APEX feature is enabled, the dentist gets clear visual and audio feedback that the color bar indicating file tip position has reached the pre-selected point in the apical zone. If the virtual apex is set at the fifth bar, for example, the visual mark appears at 0.5 position. Additionally, special easily recognizable "VIRTUAL APEX" audio signal is activated when the color bar indicator reaches the virtual apex mark. Utilizing the VIRTUAL APEX feature, the dentist may choose to proceed either to the VIRTUAL APEX mark in non-contaminated canals or to the APEX indication in contaminated canals using visual or audio feedback. Numerical value of virtual apex mark does not represent actual distance from the apex in mm.

Built-in Demo mode of BINGO PRO enables easy simulation of all stages of the treatment and is designed to simplify familiarization of the user with the device.

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

BINGO PRO is an electronic device used for precise apex localization and working length determination during root canal treatment. The device enables to obtain correct results in canals with different conditions - dry or wet.

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	**BINGO PRO**
1.	Device definition	Electronic apex locator	The same as in Bingo-1020.
2.	Intended Use	Precise apex localization during root canal treatment.	The same as in Bingo-1020.

Line No.	Device Characteristics	Predicate Device	Candidate Device
		Bingo-1020	**BINGO PRO**
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.	BINGO PRO is an electronic device used for precise apex localization and working length determination during root canal treatment. The device enables to obtain correct results in canals with different conditions - dry or wet.
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.	The same as in Bingo-1020.
5.	Device category	Active, invasive	The same as in Bingo-1020.
6.	Power Source	Low voltage NiMH rechargeable batteries (3.6V)	Low voltage NiMH rechargeable batteries (2.4V)
7.	External charger	Input: 115V/50-60Hz Output: 6V DC @ 200mA	Input: 120V/50-60Hz Output: 6V DC @ 500mA.
8.	Current Consumption	Maximum – 50 mA DC	Maximum – 250 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.	The same as in Bingo-1020.
10.	Display	Custom monochrome LCD	3.5" Color TFT Display
11.	Buttons	Three pushbuttons: 1. On / Off 2. Sound control 3. MODE	The same as in Bingo-1020.
12.	Sound indication	Piezzo transducer with sound level control (high, medium, low, mute).	The same as in Bingo-1020.

Line No.	Device Characteristics	Predicate Device	Candidate Device
		Bingo-1020	**BINGO PRO**
13.	Adjustment before measurement	Not required	The same as in Bingo-1020.
14.	Calibration	Not required	The same as in Bingo-1020.
15.	Measuring signal amplitude	Nominal – doesn't exceed 25 mV AC.	The same as in Bingo-1020.
16.	Frequencies used for measurements	500 Hz and 8 kHz	The same as in Bingo-1020.
17.	Weight	430 Gr	300 Gr
18.	Dimensions	160 x 95 x 35 mm	74 x 120 x 70 mm
19.	Endodontic Files to be used with the device	Bingo-1020 may only be used with stainless steel or nickel titanium endodontic files.	The same as in Bingo-1020.
20.	Type of Connector	The type of connector used – Stereo plug.	The type of connector used – Micro-USB plug.
21.	Automatic Turn-off function	The device turns off automatically after 5 min. of idle state.	The same as in Bingo-1020.
22.	Display Zoom Area	Zoom area with the following graphical indications of file tip position: 1.0, 0.9, 0.8, 0.7, 0.6, 0.5, 0.4, 0.3, 0.2, 0.1, and 0.0. Graphical indication of over-instrumentation.	Zoom area with the following graphical indications of file tip position: 2.0, 1.9, 1.8, 1.7, 1.6, 1.5, 1.4, 1.3, 1.2, 1.1, 1.0, 0.9, 0.8, 0.7, 0.6, 0.5, 0.4, 0.3, 0.2, 0.1, and 0.0. Additionally file tip position is indicated in numerical form. Over-instrumentation: graphical indication and additional alphanumerical presentation.
23.	Virtual Apex feature	Basic Virtual Apex with audio feedback.	Advanced Virtual Apex with visual and audio feedback.
24.	Training mode	Tutor Mode is implemented to demonstrate device operation and to shorten learning curve of the user.	DEMO mode is used for the same purposes.

5.7. **Brief discussion of the nonclinical tests** [807.92(b)(1)]

To evaluate the performance of BINGO PRO apex locator, ex-vivo test was performed on extracted teeth. The results obtained with BINGO PRO were compared to the results of reference device - Dentaport ZX apex locator, which is used in many scientific studies and has FDA clearance. The conclusion of the test was that the apex localization obtained with both devices is essentially equivalent and that BINGO PRO provides clinically acceptable results.

5.8. **Conclusions:** [807.92(b)(3)]

- BINGO PRO has the same intended use and fundamental scientific technology as its predicate device – Bingo-1020 (K992233).

- BINGO PRO was evaluated against its predicate device, and was found to be Substantially 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

NOV - 2 2011

Ms. Yuliya Yutkevich
Quality Assurance & Regulatory Affairs Manager
Forum Engineering Technologies (96) Limited
1 Platin Street
New Industrial Zone
Rishon Lezion
Israel 75653

Re: K111474
Trade/Device Name: BINGO PRO
Regulation Number: Unclassified
Regulation Name: None
Regulatory Class: None
Product Code: LQY
Dated: October 25, 2011
Received: October 28, 2011

Dear Ms. Yutkevich:

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 Watson, MS, MBA
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Forum Engineering Technologies (96) Ltd.		
BINGO PRO 510(k) File	Indication for Use Statement	Rev. 02
Document number: 5-B31-002.FDA	Effective Date: Aug 18, 2011	Page 1 of 1

Indication for Use Statement

510(k) Number (if known): K111474

Device Name: **BINGO PRO**

Indications for Use:

BINGO PRO is an electronic device used for precise apex localization and working length determination during root canal treatment. The device enables to obtain correct results in canals with different conditions - dry or wet.

Prescription Use __√__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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)

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

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