October 3, 2019

Dentsply Sirona
Karl Nittinger
Director, Corporate Regulatory Affairs
221 West Philadelphia Street
Suite 60W
York, Pennsylvania 17401

Re: K191806
Trade/Device Name: Propex IQ Apex Locator
Regulatory Class: Unclassified
Product Code: LQY
Dated: September 4, 2019
Received: September 5, 2019

Dear Karl Nittinger:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Srinivas Nandkumar, Ph.D.
Acting Director
DHT1B: Division of Dental Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191806

Device Name
Propex IQ® Apex Locator

Indications for Use *(Describe)*
Propex IQ® Apex Locator supports the dentist in the determination of the working length during the endodontic treatment. The use of this product is intended exclusively for duly qualified dental practitioners.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Dentsply Sirona
221 West Philadelphia Street
Suite 60W
York, PA 17401

SECTION 5. 510(k) SUMMARY
for
K191806
Propex IQ® Apex Locator

1. Submitter Information**:**

Dentsply Sirona
221 West Philadelphia Street
Suite 60W
York, PA 17401

Contact Person: Karl Nittinger
Telephone Number: 717-849-4424
Fax Number: 717-849-4343

Date Prepared: September 20, 2019

2 Device Name:

- Proprietary Name: Propex IQ® Apex Locator
- Classification Name: Locator, Root Apex
- CFR Number: N/A
- Device Class: Unclassified
- Product Code: LQY

3. Primary Predicate Device:

- Primary Predicate Device Name: RAYPEX® 6
- 510(k): K131907
- Company Name: Dentsply Sirona

Reference Devices:

1. Reference Device: X-Smart IQ®
   510(k): K161213
   Company Name: Dentsply Sirona
2. Reference Device: Root ZX II Apex Locator
   510(k): K071190
   Company Name: J. Morita Manufacturing Corp.

4. Description of Device:

The proposed Propex IQ® Apex Locator is a microprocessor-controlled device that supports the dentist during endodontic treatments for the determination of the proximity of the file to the reference point for endodontic working length determination. To do so, the proposed Propex IQ® Apex Locator assesses the electrical resistance of the tooth and surrounding tissues while the file is inserted and moving along the root canal. The proposed Propex IQ® Apex Locator product configuration consists of the following components:

- The proposed Propex IQ® Apex Locator
- The proposed Propex IQ® Apex Locator Measurement cable
- The Proposed X-Smart IQ® Measurement Cable
- The proposed Propex IQ® Apex Locator External Tester
- The Propex IQ® Disposable Barrier Sleeve
- The proposed Propex IQ® Lip clip
- The proposed Propex IQ® File clip
- The proposed Propex IQ® Clamp
- Propex IQ® Charger and AC Adapter Plugs

Modes of Operation:

The proposed Propex IQ® Apex Locator can be used with X-Smart IQ® Handpiece (K161213) and/or Endo IQ® App (K161213) in different modes. Summary of different modes of operations of the proposed Propex IQ® Apex Locator along with its interaction with X-Smart IQ®Handpiece (K161213) and Endo IQ® App (K161213) is summarized in the Table 5.1 below ("Yes" indicates that the device or components is utilized in the referenced Mode, "No" indicates that it is not utilized in the referenced Mode):

Table 5.1 Summary of the different modes of Operation of the proposed Propex IQ® Apex Locator

Mode	Proposed Propex IQ® Apex Locator	X-Smart IQ® Handpiece	Endo IQ® App
Uncombined, Unconnected (Stand-Alone)	yes	no	no
Combined, Unconnected (combined with X-Smart IQ® Handpiece) (stand-alone connected to the iPad application)	yes	yes	no
Uncombined, Connected (combined with X-Smart IQ® Handpiece) (stand-alone, connected to the Endo IQ® App)	yes	no	yes
Combined, Connected (combined to X-Smart IQ® Handpiece and connected to the Endo IQ® App)	yes	yes	yes

5 Indications for Use:

Propex IQ® Apex Locator supports the dentist in the determination of the working length during the endodontic treatment. The use of this product is intended exclusively for duly qualified dental practitioners.

6. Substantial Equivalence:

Table 5.2 compares the proposed device, Propex IQ® Apex Locator, and the primary predicate device, RAYPEX 6®. Technological similarities and differences are as follows:

Table 5.2 Comparison between the primary predicate device, RAYPEX® 6 (K131907), and the proposed, Propex IQ® Apex Locator

Element	**Primary Predicate Device** RAYPEX® 6 (K131907)	**Proposed Device** Propex IQ® Apex Locator	**Similarities/Differences**
Indication for Use	RAYPEX® 6 is a microprocessor controlled device used for locating the apex.	Propex IQ® Apex Locator supports the dentist in the determination of the working length during the endodontic treatment. The use of this product is intended exclusively for duly qualified dental practitioners.	Both the proposed Propex IQ® Apex Locator and the primary predicate RAYPEX® 6 (K131907) are indicated to assist in the determination of the length of the root canal space.
Use with X-Smart IQ® Handpiece (Product code: EBW, K161213)	Cannot be used with any hand-piece	Can be used with only X-Smart IQ® Handpiece (K161213) (in combined mode).	The proposed Propex IQ® is designed to function in combined mode with the reference X-Smart IQ® handpiece (K161213). Combined mode facilitates consolidation of working steps when the X-Smart IQ® Handpiece (K161213) is used.
Use with Endo IQ® App (K161213)	Cannot be used with Endo IQ® App (K161213)	Can be used in standalone mode without Endo IQ® App (K161213) or with the Endo IQ® App	Endo IQ® App (K161213) gives interactive information (real time graphs, images) and access to pre- and post-operation information. The predicate device (K131907) incorporates interactive real-time information in its integral user interface display.

Table 5.2 Comparison between the primary predicate device, RAYPEX® 6 (K131907), and the proposed, Propex IQ® Apex Locator			
Element	**Primary Predicate Device** RAYPEX® 6 (K131907)	**Proposed Device** Propex IQ® Apex Locator	**Similarities/Differences**
Bluetooth	No Bluetooth functionality	Can be connected to Endo IQ® App (K161213) via Bluetooth and have Bluetooth function to transfer the data to the Endo IQ® App	Bluetooth is used to connect and transfer the data with Endo IQ® App. The Endo IQ® App (K161213) interactive information (real time graphs, images) and access to pre- and post- operation information. The predicate device (K131907) incorporates interactive real-time information in its integral user interface display.
Working Environment	This product must be used in hospital environments, clinics or dental offices by qualified dental personnel.	This product must be used in professional healthcare facility environment by qualified dental personnel.	The proposed Propex IQ® Apex Locator and the predicate RAYPEX® 6 (K131907) are both intended for use within the same clinical environments.

Table 5.2 Comparison between the primary predicate device, RAYPEX® 6 (K131907), and the proposed, Propex IQ® Apex Locator			
Element	**Primary Predicate Device** RAYPEX® 6 (K131907)	**Proposed Device** Propex IQ® Apex Locator	**Similarities/Differences**
Means of input	On/off pushbutton Touch Panel	• On/off pushbutton • Bluetooth button • Endo IQ® App (K161213)	The proposed Propex IQ® Apex Locator can be connected to Endo IQ® App (K161213) via Bluetooth. In Stand-alone mode it can be used without Endo IQ® App (K161213) using on/off push buttons. The predicate RAYPEX® 6 (K1311907) incorporates an integral touch screen user interface.
Patient contacting components material composition	Lip Clip: Stainless steel File Clip: Gold plated beryllium copper, glass filled nylon	Lip Clip: Stainless Steel File Clip: Gold plated beryllium copper, glass filled nylon	The proposed Propex® IQ Apex Locator and the predicate device (K131907) utilize the same patient contacting accessory components.
Power supply	Rechargeable Ni-MH battery	Rechargeable Ni-MH batteries	Both the proposed Propoex® IQ Apex locator and the predicate device (K131907) utilize rechargeable Ni-MH batteries.

Table 5.2 Comparison between the primary predicate device, RAYPEX® 6 (K131907), and the proposed, Propex IQ® Apex Locator			
Element	**Primary Predicate Device** RAYPEX® 6 (K131907)	**Proposed Device** Propex IQ® Apex Locator	**Similarities/Differences**
Display	3.5 inch color display.	No display on the device, only multi-color LEDs to indicate status during the working length determination.	Different user interface, no screen in Propex IQ® Apex Locator. When working in unconnected mode, the proposed Propex IQ® Apex Locator gives an indication of estimated file position using visual signals (the color of the central LED) and auditory signals. When connected to Endo IQ® App (K161213), the larger display of the iPad® will display the file progression along the root canal in the form of colored bars.
Adjustment before measurement	Not required	Not required	Neither the proposed Propex IQ® Apex Locator nor the predicate device (K131907) require adjustment prior to estimation of the length of the root canal space.
Calibration	Not required	Not required	Neither the proposed Propex IQ® Locator nor the predicate RAYPEX® 6 (K131907) require calibration prior to estimation of the length of the root canal space.

Table 5.2 Comparison between the primary predicate device, RAYPEX® 6 (K131907), and the proposed, Propex IQ® Apex Locator			
Element	**Primary Predicate Device** RAYPEX® 6 (K131907)	**Proposed Device** Propex IQ® Apex Locator	**Similarities/Differences**
Electronic design	The electronic design utilizes microcontroller based electronic circuit and TFT color matrix graphic display.	The electronic design is based on a custom PCB design with miniaturized electronic components. A Bluetooth module is included for connectivity with iPad. The audio-visual feedback to the user is generated using a buzzer for sound emission and multi-color LEDs for visual feedback. No screen or graphic display is available on the device, there are only multi-colored LEDs for visual feedback.	The difference in electronic design of two devices relates to functionality, performance and dimensions of the proposed device.
Sterilization	Lip clip and file clip are user sterilized by steam sterilization	Lip clip and file clip are user sterilized by steam sterilization.	Both the proposed Propex® IQ Apex Locator and the predicate device utilize the same lip clip and file clip accessory components to facilitate the estimation of the length of the root canal space. These reusable components are intended in both cases as reusable accessories which are end-user sterilized by steam sterilization.

7. Summary of Non-Clinical Performance Data

Biocompatibility: The patient contacting part of the proposed Propex IQ® Apex Locator (the lip clip component) is composed of identical materials and fabricated using the same methods as the same component used with the primary predicate device (K131907). Therefore, no new biocompatibility data is included in support of substantial equivalence.

Electromagnetic compatibility and electrical safety:

The proposed Propex IQ® Apex Locator was tested for Electrical safety and Electromagnetic testing. Table 5.3 below summarizes EMC and Electrical safety testing.

Table 5.3 Summary of Electrical safety and Electromagnetic compatibility

Test	Standard	Results
Electrical safety	IEC 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012 (or IEC 60601-1: 2012 reprint) Medical electrical equipment - Part 1 : general requirements for safety	The proposed Propex IQ® Apex Locator conforms to the standard requirements.
Electromagnetic compatibility	IEC 60601-1-2:2014 (Fourth Edition) Medical electrical equipment - Part 1-2 : General requirements for basic safety and essential performance - Collateral standard: electromagnetic compatibility Requirements and tests	The proposed Propex IQ® Apex Locator conforms to the standard requirements.

Software Verification and Validation: Software Verification and Validation tests were conducted in accordance with IEC 62304:2015 and FDA software validation guidance "General Principles of Software Validation; Final Guidance for Industry and FDA Staff, Document issued on: January 11, 2002".

Performance Testing: In addition to biocompatibility, electrical safety, EMC and software testing, the following non-clinical tests are included in support of substantial equivalence.:

Table 5.4 Performance testing on the proposed Propex IQ® Apex Locator

Test	Standard/Method	Results
Accuracy Testing with RAYPEX® 6 (K131907)	Internal test method	It is shown that the performance of the proposed Propex IQ® Apex Locator is equivalent to that of primary predicate device RAYPEX6 (K131907) within the scope of this test.

Table 5.4 Performance testing on the proposed Propex IQ® Apex Locator		
Test	**Standard/Method**	**Results**
Accuracy Testing with Root ZX II Apex Locator (K071190)	Internal test method	It is shown that the performance of the proposed Propex IQ® Apex Locator is equivalent to that of reference device: Root ZX II Apex Locator (K071190) within the scope of this test.
Disinfectant Resistance Testing	ISO 21530 (*Dentistry -- Materials used for dental equipment surfaces -- Determination of resistance to chemical disinfectants*)	Applicable device components were assessed for resistance to chemical disinfectants and the results support substantial equivalence.
Information display latency	Internal test method	Device display latency in all modes was assessed and the results support substantial equivalence.
Hardware requirements verification tests.	Internal Test Methods	Verification testing of the device hardware requirements including: battery performance, audio alarm performance, temperature testing, liquid ingress resistance, and mating components connection cycling is included, and the results support substantial equivalence.
Wireless coexistence	AAMI TIR69: Risk Management of Radio-frequency Wireless Coexistence for Medical Devices and Systems ANSI C63.27-2017 American National Standard for Evaluation of Wireless Coexistence	The proposed Propex IQ® Apex Locator maintained functional wireless performance in the presence of unintended signals.

Table 5.5 Usability testing on the proposed Propex IQ® Apex Locator		
Test	**Standard/Guidance**	**Results**
Usability Study	• FDA Guidance: "Applying Human Factors and Usability Engineering to Medical Devices - Guidance for Industry and Food and Drug Administration Staff • ANSI-AAMI_HE75:2009/ (R) 2013 Human factors engineering - Design of medical devices • AAMI / ANSI / IEC 62366-1:2015 Medical devices –Part 1: Application of usability engineering to medical devices (General I (QS/RM)) • IEC TR 62366-2:2016 Medical devices – Part 2: Guidance on the application of usability engineering to medical devices • IEC 60601-1-6 Edition 3.1 2013-10 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability	Usability Studies conducted showed that users were able to use the device correctly and safely without use error.

8. Clinical Performance Data

No human clinical data were included to support substantial equivalence.

9. Conclusion Regarding Substantial Equivalence

Information included in this premarket notification supports the substantial equivalence of the proposed Propex IQ® Apex Locator. The proposed device has the identical intended use as the primary predicate device cleared under premarket notification K131907. The proposed Propex IQ® Apex Locator also has similar indications for use and incorporates the same fundamental technology as the primary predicate device (K131907).

Performance, safety, and software validation test data demonstrate the performance of the subject Propex IQ® Apex Locator device against its design, functional, and safety requirements. The results of the testing support a determination of substantial equivalence.