K 101172

510(k) SUMMARY
REDENT NOVA's RDT3 Handpiece Head

Submitter's Name, Address, Telephone Number, Contact Person: and Date Prepared

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Date Prepared: July 21, 2010

JUL 27 2010

Name of Device and Name/Address of Sponsor:

RDT3 Handpiece Head

Redent Nova Ltd.
15 Hataasia street
P.O.B 4159
Ra'anana
43000, Israel

Common or Usual Name

Handpiece head attachment

Classification Name

Name:	Dental Handpiece and Accessories
Product code:	EFA
Classification regulation:	872.4200
Class:	I
Panel:	Dental

Predicate Devices

Intra Lux Head 3LDSY (K092446)

Intended Use / Indications for Use

RDT3 Handpiece Head is a reciprocating dental handpiece attachment intended for use in root canal preparations using the Self Adjusting File, SAF (ReDent Nova LTD., Ra'anana Israel).

Technological Characteristics

RDT3 handpiece attachment is compatible with the KaVo GENTLE power low-speed handpiece. The RDT3 is able to operate the SAF during root canal treatment procedures, while working with continuous sodium hypochlorite irrigation.

RDT3 is a reciprocating vertical vibrating handpiece attachment and is capable of providing the SAF with an impact movement of approximately 0.4 mm and up to 5,000 rpm drive speed required for conducting endodontic treatment. Low torque (max 9.5 gr cm) rotation motion is integrated in order to ease insertion of the file into the root canal.

The file is attached to the RDT3 head via friction grip.

Performance Data

Performance tests were carried out to evaluate the properties of the RDT3.

The tests were carried in accordance with ISO 7785-2 Dental Handpieces Part 2: Straight and Geared Angle Handpieces:

- Handpiece head Chuck Friction Grip
- Handpiece Head Resistance to Sterilizing Procedure
- Handpiece Head Temperature Rise
- Handpiece Head Resistance to Corrosion

In addition Redent performed an In-house test:

- Handpiece Head Sodium Hypochlorite Exposure

In all instances the RDT3 functioned as intended and results observed were as expected.

Substantial Equivalence

The RDT3 is substantially equivalent to the Intra Lux Head 3LDSY (manufactured by KaVo GmbH & Co (Sybron Dental Specialties Inc)). The RDT3 has the same intended use and similar indications, technological characteristics, and principles of operation as its predicate device. The minor technological differences between the RDT3 and its predicate device identified below raises no new issues of safety or effectiveness.

The technological and operational differences between the RDT3 and its predicate are:

- Higher maximal drive speed.
- RDT3 has a low torque 360° rotation motion whereas the 3LDSY has a free 360° rotation.
- Different means of attaching the file to the handpiece head.
- Different materials used for internal components.

These differences do not raise new questions of safety or efficacy. Additionally, performance testing in compliance with ISO 7785-2 demonstrates that the RDT3 is comparable to the Intra Lux Head 3LDSY. Accordingly, the RDT3 is 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

Redent Nova Limited
C/O Mr. Jonathan S. Kahan
Hogan Lovells US LLP
Columbia Square,
555 13th Street, NW
Washington, District of Columbia 20004

JUL 29 2010

Re: K101172
Trade/Device Name: RDT3 Handpiece Head
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EFA
Dated: July 21, 2010
Received: July 21, 2010

Dear Mr. Kahan:

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

Indications for Use Statement

K101172

510(k) Number (if known):_____

Device Name:

JUL 27 2010

RDT3 Handpiece Head

Indications for Use:

RDT3 Handpiece Head is a reciprocating dental handpiece attachment intended for use in root canal preparations using the Self Adjusting File, SAF (K092933) (ReDent Nova LTD., Ra'anana Israel).

Prescription Use __X__ (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 OF 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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