K092446

sybron dental specialties

Submitter:

Sybron Dental Specialties, Inc.
1717 West Collins Drive
Orange, CA 92656
Claudia Ortiz - Contact Person

NOV - 3 2009

Date Summary Prepared: August 2009

Device Name:

- Trade Name – INTRA Lux Head 3 LDSY
- Common Name – Dental Handpiece Attachment
- Classification Name – Handpiece, contra- and right-angle attachment, dental, per 21 CFR § 872.4200

Devices for Which Substantial Equivalence is Claimed:

- A-Dec Inc., A-dec/W&H Synea Profin Reciprocating Contra-Angle Handpiece Attachments WA-67/0.4 LT, WA-67/0.4 A (K082827)
- Micro Motors Inc., EndoPulse Reciprocating Handpiece (K896878)

Device Description:

The INTRA Lux Head 3 LDSY reciprocating dental handpiece attachment is for use by a trained professional in general dentistry. The device is attached to air-powered or electrical handpieces. The reciprocating dental handpiece attachment is re-usable and ergonomically shaped, and can be sterilized by the steam autoclave method.

Intended Use of the Device:

The INTRA Lux Head 3 LDSY reciprocating dental handpiece attachment is intended for use in root canal preparations using hand-held endodontic files.

Substantial Equivalence:

The INTRA Lux Head 3 LDSY is substantially equivalent to other legally marketed devices in the United States. The intended use of the devices is identical to that of the predicate devices. The INTRA Head 3 LDSY is substantially equivalent in design, application and function to the A-dec/W&H Synea Profin Reciprocating Contra-Angle Handpiece Attachments WA-67/0.4 LT, WA-67/0.4 A marketed by A-Dec Inc., and to the EndoPulse Reciprocating Handpiece marketed by Micro Motors, Inc. (now Endo Technic).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Kaltenbach & Voigt GmbH & Company
C/O Ms. Claudia Ortiz
Compliance Director, Regulatory Affairs
Sybron Dental Specialties, Incorporated
1717 West Collins Drive
Orange, California 92867

NOV - 3 2009

Re: K092446
Trade/Device Name: INTRA Lux Head 3 LDSY
Regulation Number: 21CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EFA
Dated: August 7, 2009
Received: August 10, 2009

Dear Ms. Ortiz:

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 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

Susan Runner, D.D.S., M.A.
Acting Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K092446

Indications for Use

510(k) Number (if known):

Device Name: INTRA Lux Head 3 LDSY

Indications for Use:

The INTRA Lux Head 3 LDSY reciprocating dental handpiece attachment is intended for use in root canal preparations using hand-held endodontic files.

Prescription Use X AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kevin Mulley for MSL

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

510(k) Number: K092446