K122955

510(K) SUMMARY
August 10, 2012

MAR 0 1 2013

SUBMITTER INFORMATION: (3003103749)

Wright Health Group Ltd.
Dunsinane Industrial Estate
Kingsway West
Dundee, Scotland
DD2 3QD UK

FDA AGENT/CORRESPONDING OFFICIAL INFORMATION:

North American Technical Services (NATS) Corp.
30 Northport Rd
Sound Beach, NY 11789
Tel: 631-744-0059 Fax: 631-744-0192 Email: natscorp@aol.com
Contact: Stephen T. Mlcoch

DEVICE NAME:

Name: Denture Preformed Plastic Teeth
Proprietary Models: Dentavit, Monarch, Acrotone, Senator, Dentorium
Classification: II
Product Code: ELM
Regulation: 21 CFR 872.3590

PREDICATE DEVICES:

Union Dental S.A./ Unidesa Odi K070591 – model Replica
Dental Vipi Ltd K022300 – model Vipi Dent Plus
Vident K914476 – model Vitapan
Huge Dental Material Co., Ltd. K101029 – model Kaili

DESCRIPTION:

The synthetic plastic teeth are used in the production of dentures. They are produced from a dough molding process. Polymethylmethacrylate or PMMA is mixed with methylmethacrylate monomer, a cross linking agent and non-toxic pigments under heat and pressure. Once the polymerization process is completed, the teeth are checked for flash and polished according to the relevant model characteristics.

SUBSTANCIAL EQUIVALENCE AND TECHNOLOGY:

The plastic teeth have comparable chemical composition as the predicate devices. The models are similar in size, shape, color, and usage to the predicate devices. Also, preamendment compliance exists for original plastic teeth made by Wright. The added models use the same materials and controls established for over 20 years.

The intended use for these plastic teeth is to make partial or full dentures. These dentures are made to fit the patient's mouth as a removable device, not implanted. These plastic teeth may also be attached to dental implants.

Federal law restricts this device to sale by or on the order of a physician. It is intended to be used only by appropriately trained and qualified healthcare professionals and servicing staff in clinical environments.

SUMMARY OF NONCLINICAL TESTS AND DESIGN CONTROL ACTIVITIES:

The performance and safety testing activities were conducted on acceptable dental materials to establish the reliability characteristics of these teeth devices. Validation and verification of compliance with the following mandatory and voluntary standards has been made:

- CE Medical Directive 93/42/EEC 2007/47/EC

- ISO9001/GMP/ISO13485: Quality System Certification
  Factory control procedures are established for production QA and QC with use of ADA specification No.15:2008 Artificial Teeth, and BS EN ISO22112:2006, with Biocompatibility Standards ISO10993-1, ISO7405:2008

This control activity shows that there are no new questions of safety and effectiveness for the plastic teeth models made by Wright.

CONCLUSION:

The plastic teeth are substantially equivalent to the predicate teeth and have the same intended use. They are suitable for equivalent use on dentures according to the specifications stated based on the same materials, production process and technology.

Wright has been a manufacturer for about 100 years and has been in the market for over 40 years and has met preamendment rules. There are no significant health incidents in that time. These models have the same intended use and similar indications, technical characteristics and function as the predicate devices. Suitable dental industry materials have been used by Wright and predicate companies that solve biocompatibility, durability and esthetic concerns. The minor differences raise no new issues of safety or effectiveness. These models are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 1, 2013

Wright Health Group, Limited
C/O Mr. Stephen Mlcoch
Chief Executive Officer
North American Technical Services (NATS) Corporation
30 Northport Road
Sound Beach NY 11764

Re: K122955
Trade/Device Name: Plastic Teeth Models Dentavit, Monarch, Acrotone, Senator, and Dentorium
Regulation Number: 21 CFR 872.3590
Regulation Name: Prosthetic Devices
Regulatory Class: II
Product Code: ELM
Dated: January 15, 2013
Received: February 13, 2013

Dear Mr. Mlcoch:

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,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K122955

INDICATIONS FOR USE

510(K) Number (if known):

Device Name: Plastic teeth models Dentavit, Monarch, Acrotone, Senator, and Dentorium.

Indications for Use: These dental plastic teeth are parts used for denture fabrication. PMMA is mixed with monomer in a polymerization process. The plastic teeth are part of dentures made to fit a patient's mouth which are removable or may be attached to dental implant devices.

Prescription Use __X__ 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)

Mary S. Runner -S
2013.02.27
15:20:12 -05'00'

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

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