K112640

NOV 16 2011

510(k) Summary

Submitter:

Sybron Dental Specialties, Inc.
1717 West Collins Avenue
Orange, California 92867
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Wendy Garman - Contact Person

Date Summary Prepared: September 2011

- Trade name – *HYPERELASTIC ARCHWIRE*
- Common name – orthodontic appliance & accessories
- Classification name – orthodontic wire (21 CFR 872.5410, Product Code DZC)

Devices for Which Substantial Equivalence is Claimed:

- CuTiNi Wire, Class I, Exempt, Product Code DZC, Ormco Corporation

Summary

Device Description

Hyperelastic Archwire is a metallic shape memory alloy orthodontic archwire for maxillary and mandibular arches. This alloy exerts low constant forces, retains elastic properties at large strains, with low frictional binding properties.

Intended use of the Device

The *Hyperelastic Archwire* is indicated for use as an orthodontic arch wire to aid in the movement of teeth during the early phase of orthodontic treatment. The *Hyperelastic Archwire* may be used in conjunction with metallic, ceramic, or plastic brackets.

Technological Characteristics Compared to Predicate

Hyperelastic Archwire functions in a manner similar to and is intended for the same use as CuTiNi Archwire which is currently being marketed by Ormco Corporation. Both products are made of similar materials, must be placed and removed by the dental practitioner, and both have equivalent corrosion resistance.

Hyperelastic Archwire differs from the predicate device, CuTiNi Archwire in that the physical and mechanical property testing of *Hyperelastic Archwire* demonstrates greater superelastic strain recovery, a significant reduction in orthodontic binding friction, significantly less stress hysteresis in tensile loading, and greater fatigue life.

Non-Clinical Performance Data

Biocompatibility studies have been completed, which demonstrate that the material used to produce *Hyperelastic Archwire* is safe for its intended use.

The 510(k) submission also includes data from bench testing used to evaluate the performance characteristics of *Hyperelastic Archwire* compared to the predicate device, CuTiNi Archwire. The characteristics evaluated include tensile plateau, tensile hysteresis, flexure hysteresis, binding, hardness, roughness, set angle after 90° bend, elastic recovery and fatigue.

Clinical Testing

Clinical resting has not been conducted on this product.

Conclusion

Based upon the biocompatibility tests and bench testing, the clinical performance of *Hyperelastic Archwire* is substantially equivalent to the predicate device.

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

Ormco Corporation
% Ms. Wendy Garman
Director, Regulatory Affairs
Sybron Dental Specialties, Incorporated
1717 West Collins Avenue
Orange, California 92867

NOV 16 2011

Re: K112640
Trade/Device Name: Hyperelastic Archwire
Regulation Number: 21 CFR 872.5410
Regulation Name: Orthodontic Appliance and Accessories
Regulatory Class: I
Product Code: DZC
Dated: September 8, 2011
Received: September 12, 2011

Dear Ms. Garman:

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 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

510(k) Number (if known): K112640

Device Name: *Hyperelastic Archwire*

Indications For Use:

The *Hyperelastic Archwire* is indicated for use as an orthodontic arch wire to aid in the movement of teeth during the early phase of orthodontic treatment. The *Hyperelastic Archwire* may be used in conjunction with metallic, ceramic, or plastic brackets.

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)

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

510(k) Number: K112640