K 052477

NOV 3 0 2005

SYBRON DENTAL SPECIALTIES

Section III - 510(k) Summary of Safety and Effectiveness

Submitter:

Sybron Dental Specialties, Inc.
1717 W. Collins Avenue
Orange, California 92867
(714) 516-7484 - Phone
(714) 516-7488 - Facsimile
Colleen Boswell - Contact Person

Date Summary Prepared: September 2005

Device Name:

- Trade Name – *Damon 3Modified*
- Common Name – Plastic Orthodontic Bracket
- Classification Name – Bracket, Plastic, Orthodontic, per 21 CFR § 872.5470

Devices for Which Substantial Equivalence is Claimed:

- Ormco Corporation, *Damon 3*

Device Description:

The device is a polycarbonate orthodontic bracket which will encompass maxillary and mandibular brackets from second bicuspid to second bicuspid. The *Damon 3 Modified* appliance has both aesthetic and self-ligating qualities. The *Damon 3 Modified* bracket was modified to enhance the reinforcement of the metal assembly to the molded plastic body, **to enhance the strength of the bracket against the over-travel of the metal slide and to improve the ease of its opening and closing mechanisms.**

Intended Use of the Device:

The intended use of *Damon 3 Modified* is as a plastic orthodontic bracket that is designed for the movement of teeth during orthodontic treatment.

Substantial Equivalence:

Damon 3 Modified is substantially equivalent to other legally marketed devices in the United States. *Damon 3 Modified* functions in a manner identical to and is intended for the same use as the original Damon 3 bracket that is currently manufactured by Ormco Corporation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 3 0 2005

Ormco Corporation
C/O Ms. Colleen Boswell
Director, Corporate Compliance
Sybron Dental Specialties, Incorporated
1717 West Collins Avenue
Orange, California 92867

Re: K052477
Trade/Device Name: Damon 3 Modified
Regulation Number: 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: II
Product Code: DYW
Dated: September 8, 2005
Received: September 12, 2005

Dear Ms. Boswell:

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.

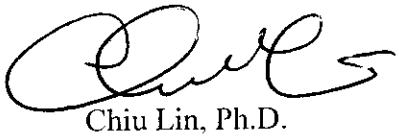
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

K052477

Indications for Use

510(k) Number (if known):

Device Name: *Damon 3 Modified*

Indications For Use:

Damon 3 Modified is a polycarbonate bracket system intended to aid in the movement of patient's teeth during orthodontic treatment.

Prescription Use ✓ 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)

Susan Runner

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

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