K073121

FEB 12 2009

510(k) SUMMARY

NuBrace Inc.'s NuBrace Invisible Removable Orthodontics

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

Jonathan S. Kahan, Esq.
Hogan and Hartson LLP
Columbia Square
555 Thirteenth Street, NW
Washington DC, 20004
Phone: (202) 637-5794
Facsimile: (202) 637-5910

Date Prepared: November 5, 2007

Name of Device and Name/Address of Sponsor

NuBrace Invisible Removable Orthodontics

Tom Kalili, D.M.D.
NuBrace, Inc.
416 N. Bedford Drive
Suite 307
Beverly Hills, CA, 90210
Phone: (310) 273-0153

Common or Usual Name

Invisible Removable Orthodontic Stint

Classification Name

Preformed Tooth Positioner

Predicate Device

Align Technology, Inc.'s Align System (K981095)

Intended Use / Indications for Use

The NuBrace IRO is indicated for the treatment of tooth malocclusion and for pre-prosthetic orthodontic cosmetic movement in patients with permanent dentition (*i.e.*, all

second molars). The NuBrace IRO is intended to position teeth by way of continuous gentle force.

Technological Characteristics

The NuBrace IRO consists of dual laminated polymers that enhance patient comfort and move teeth at a longer, more gradual rate of tooth movement.

Performance Data

In vitro testing has demonstrated that laminating a softer layer onto the traditional polycarbonate outer shell allows for a longer duration of action. In addition, the softer layer allows for more patient comfort during wear. In all instances, NuBrace IRO functioned as intended and the tooth movement observed was as expected.

Substantial Equivalence

NuBrace IRO is as safe and effective as the predicate device. NuBrace IRO has similar intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor technological differences between NuBrace IRO and its predicate device raise no new issues of safety or effectiveness. Thus, NuBrace IRO is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NuBrace IRO
C/o Mr. Jonathan S. Kahan
Hogan and Hartson, LLP
555 Thirteenth Street, NW Columbia Square
Washington, District of Columbia 20004

FEB 12 2009

Re: K073121
Trade/Device Name: NuBrace IRO
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: II
Product Code: NXC
Dated: February 10, 2009
Received: February 10, 2009

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.

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Anthony D. Watson for

Ginette Y. Michaud, M.D.
Acting 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

510(k) Number (if known):

Device Name: NuBrace IRO

Indications for Use: K073121

The NuBrace IRO is indicated for the treatment of tooth malocclusion and for pre-prosthetic orthodontic cosmetic movement in patients with permanent dentition (*i.e.*, all second molars). The NuBrace IRO is intended to position teeth by way of continuous gentle force.

Prescription Use __X__ AND/OR Over-The-Counter Use____
(Part 21 C.F.R. 801 Subpart D) (21 C.F.R. 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: K073121