K053629

Attachment A

MAY 31 2006

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: September 10, 2005

1. Company and Correspondent making the submission:

Name – KJ MEDTECH
Address – 974-3 Wolchul-dong, Buk-gu, Gwangju-city, KOREA, 500-460
Telephone – +82(62) 972-5476
Fax – +82(62) 973-2809
Contact – Mrs. Jin-Sook Kim / Manager
Internet – http://www.kjmedich.co.kr

2. Device :

Proprietary Name – Anchor plus / Neo Anchor plus
Common Name – Orthodontic Screw
Classification Name – Endosseous Dental Implant

3. Predicate Device :

1) Nobel Biocare USA, Inc.
Nobel Biocare's InPlant™ Orthodontic Anchor System
K000643(Decision Date - 10/07/2000)

2) Jeil Medical Corporation
Dual Top Anchor Systems Screws
K033767(Decision Date - 02/24/2004)

4. Classifications Names & Citations :

K053629

21CFR 872.3640, DZE, Endosseous Dental Implant, Class2

5. Description :

Anchor plus / Neo Anchor plus is a dental titanium alloy for the fabrication of Porcelain-Fused-to-Metal Dental Crowns, Bridges, and implant-supported prosthesis substructures, which is composed of 98% of titanium bearing titanium color.

6. Indication for use :

It is to provide absolute Orthodontic anchorage to establish a good and stable occlusion for the patients and also to improve their facial esthetics. Orthodontic Screw is temporarily placed in either the maxilla or the mandible until Orthodontic treatment is completed successfully and is removed.

□ Orthodontic Screw Head Part : loading with a orthodontic element (ex: Ni-Ti coil, ligature wire).

□ Orthodontic Screw Part : It is unnecessary pilot hole and consequently provide the primary stability for orthodontic use and so be able to immediately loading .

□ Orthodontic Screw Plate : Fixed with two Fixation Screws loading with a Orthodontic element (ex: bracket)

7. Comparison with predicate device :

Anchor plus / Neo Anchor plus have been compared with the automatically inflated Nobel Biocare's InPlant™ Orthodontic Anchor System of Nobel Biocare USA, Inc. and Dual Top Anchor Systems Screws of Jeil Medical Corporation. The intended use of this device and the predicate devices is the same. The principle of usage is identical and there are no significant differences on operating features. It is concluded that there are no technologic differences between the subject and predicate devices that raise new questions concerning either safety or effectiveness.

8. Contra-indications :

Potential complications associated with the use of Orthodontic Screw may include, but not limited to:

- Allergies to metals

9. Review :

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Anchor plus / Neo Anchor plus has the same device characteristics as the predicate device. Material, design and use concept is similar.

Anchor plus / Neo Anchor plus has been subjected to extensive safety, performance, and product validations prior to release. Safety tests have been performed to ensure the devices comply with applicable industry and US regulations.

An extensive review of literature pertaining to the safety and biocompatibility of dental gold alloy has been conducted. Appropriate safeguards have been incorporated in the design of Orthodontic Screw.

10 Conclusions :

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807, based on the information provided in this premarket notification KJ MEDITECH concludes that Anchor plus / Neo Anchor plus is safe and effective and substantially equivalent to predicate devices as described herein.

11. KJ MEDITECH will update and include in this summary any other information deemed seasonably necessary by the FDA.

END

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 3 1 2006

JK Meditech
C/O Mr. Charlie Mack
Principal Engineer
International Regulatory Consultants
340 Groove Road
Flintville, Tennessee 37335

Re: K053629
Trade/Device Name: Anchor Plus/Neo Anchor Plus
Regulation Number: 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: January 29, 2006
Received: April 9, 2006

Dear Mr. Mack:

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.

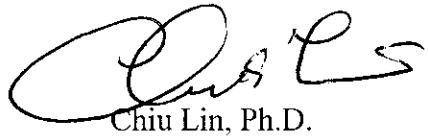
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

Enclosure

Indications for Use

510(k) Number(if known): K053629

Device Name: Orthodontic Screw

Indications for Use:

This device is intended to provide a fixed anchorage point for attachment of orthodontic appliances to facilitate the orthodontic movement of teeth. It is used temporarily and is removed after orthodontic treatment has been completed. Screws are intended for single use only.

Prescription Use ✓ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (Part 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 K053629