K071838

SECTION 2.

A. 510(k) SUMMARY

OCT 19 2007

Summary of Safety and Effectiveness

In accordance with 21 CFR 807.92, the following information constitutes the Neoss Ltd summary for the ***Neoss various Titanium Abutments***

SUBMITTER'S NAME:	Neoss Ltd
ADDRESS:	Windsor House Cornwall Road Harrogate, HG1 2PW, UK
CONTACT PERSON:	Fredrik Engman
TELEPHONE NUMBER:	+44 (0) 1423 817733 , +46 (0)709 792 892
FAX NUMBER:	+44(0) 1423 817744
E-MAIL	fredrik.engman@neoss.com
DATE OF SUBMISSION:	June 26, 2007

1. Identification of device

Classification name:	Abutment, Implant, Dental, Endosseous
Proprietary Name:	Neoss Various Titanium Abutments including accessories
Common Name:	Dental Abutment
Classification Status:	Class II per regulations 872.3630
Product Codes:	NHA

2. Equivalent devices

Neoss various Titanium Abutments consist of preparable 15° and 20° abutments, Express abutments and the Locator Abutment system,

Neoss Ltd believes the ***Neoss Titanium Prepable Abutment 15°and 20°*** is substantially equivalent to the Angulated Abutment previously cleared in K974738 and to the abutment connection in the Neoss Abutments previously cleared in K043195.

The Neoss Express Abutment is substantially equivalent to the Neoss Abutments previously cleared in K043195.

The ***Neoss Locator Abutment system*** is substantially equivalent to Zest Anchors Inc. Locator components initially cleared in K994257 by Zest Ancors Inc and also in K012911 submitted by Implant Innovations Inc.

The accessories are equal to Neoss previous K043195.

3. Description of the Device

The ***Neoss Titanium Prepable Abutment 15°and 20°*** is designed to be modified and secured directly to the implant using an abutment screw and supplied non-sterile.

The ***Neoss Express Abutment*** requires no modification and allows for abutment level impression taking.

The ***Neoss Locator Abutment system***, made by commercially pure titanium, designed to secured directly to the implant using an abutment screw and supplied non-sterile.

4. **Intended use**
The ***Neoss Titanium Preparable Abutment 15°and 20°*** and ***Neoss Express abutments*** are designed to be connected to the Neoss implant and are intended for use as an aid in prosthetic rehabilitation.

The ***Neoss Locator Abutment system*** is intended for use with over dentures or partial dentures retained in whole or in part by endosseous implants in the mandible or maxilla.

5. **Technological characteristics, comparison to predicate device.**
Substantial equivalence of the ***Neoss Various Titanium Abutments and accessories*** is based on design similarities between the predicative device and the devices in this application, since the devices are very similar in terms of material, size, preparation and basic design.

6. **Discussion of performance testing.**
Mechanical testing requested for Dental Implant Systems are described in the Guidance for industry and FDA staff, Class II Special Controls Guidance Document: Root-form Endosseous Dental Implant and Endosseous Dental Implant Abutments, dated May 12, 2004.

The The ***Neoss Various Titanium Abutment*** has, where applicable, been tested in accordance to the Guideline (Doc. No. 0043 – Guidance for industri and FDA staff, Class II Special Controls Guidance Document: Root-form Endosseous Dental Implant and Endosseous Dental Implant Abutments, dated May 12, 2004) and the test results show that the abutment fills the recommended requirements.

7. **Conclusion**
Based on comparison and performed testing, the The ***Neoss Various Titanium Abutment*** and **accessories** are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 19 2007

Mr. Fredrik Engman
CTO
Neoss Limited
Windsor House
Cornwall Road
Harrogate, HG1 2PW
UNITED KINGDOM

Re: K071838
Trade/Device Name: Neoss various Titanium Abutments
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: June 26, 2007
Received: July 24, 2007

Dear Mr. Engman:

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.

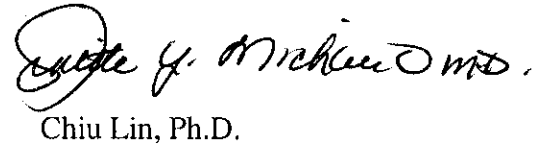
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

B. INDICATIONS FOR USE

510(k) Number K071838

Device Name: ***Neoss various Titanium Abutments***

Indications for Use:

The ***Neoss various Titanium Abutments*** are designed to be connected to the Neoss implants and intended for use as an aid in prosthetic rehabilitation.

(Please do not write below this line - continue on another page if needed)

~~Concurrence of CDRH, Office of Device Evaluation (ODE)~~

Prescription Use ✓ OR Over the Counter Use _____
(Per 21 CFR 801.109)

Susan Runner

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

510(k) Number: K071838