K081851

SECTION 2.

A. 510(k) SUMMARY

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Summary of Safety and Effectiveness

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

SUBMITTER'S NAME:	Neoss Ltd
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DATE OF SUBMISSION:	June 2, 2008

1. Identification of device

Classification name:	Abutment, Dental, Endosseous
Proprietary Name:	Neoss Access Abutments
Common Name:	Dental Abutment
Classification Status:	Class II per regulations 872.3630
Product Codes:	NHA

2. Equivalent devices

K061477 Nobel Biocare Multi-Unit Abutment

3. Description of the Device

The internal connection of the Neoss Access Abutment provides a solution with a minimum height of the complete prosthesis of 5 mm and allows an overall implant alignment of up to 60 degrees without restraining the fabrication of a multiple-unit screw-retained restoration.

The angulated 10°, 20° and 30° abutments are intended for multi-unit cases in order to improve the position of the screw access hole.

Restorations can be based on Neolinks being incorporated into gold or ceramic frameworks, or solid titanium and ceramics frameworks. The frameworks are then tightened with prosthetic screws onto the Neoss Access Abutments.

4. Intended use

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

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Neoss Access Abutments represent a two piece abutment system and are designed to be connected to the Neoss implants, to receive another abutment or framework and intended for use as an aid in multiple-unit prosthetic rehabilitation such as dental bridge restorations.

5. **Technological characteristics, comparison to predicate device.**
Substantial equivalence of the Neoss Access Abutments is based on the design similarities between the predicate Nobel Biocare Multi-Unit Abutments and Neoss Access abutments since they are very similar in terms of material, size, basic design and intended use.

6. **Discussion of performance testing.**
The Neoss Access Abutments has, where applicable, been tested in accordance to the Guideline (Doc. No. 0043 – 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) and the test results show that the abutment fills the recommended requirements.

7. **Conclusion**
Based on comparison and performed testing, the Neoss Access Abutments are substantially equivalent to the predicate Nobel Biocare Multi-Unit Abutments and do not generate additional risks.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 2009

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

Re: K081851
Trade/Device Name: Neoss Access Abutments
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: February 27, 2009
Received: March 2, 2009

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 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,

Ginette Y. Michaud, M.D.

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

A. INDICATIONS FOR USE

510(k) Number: K081851

Device Name: ***Neoss Access Abutments***

Indications for Use:

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

Neoss Access Abutments represent a two piece abutment system and are designed to be connected to the Neoss implants, to receive another abutment or framework and intended for use as an aid in multiple-unit prosthetic rehabilitation such as dental bridge restorations.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use___x____ OR Over the Counter Use_____
(Per 21 CFR 801.109)

Susan Runyon

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

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