K990846

Section 6
510(k) Summary

Manufacturer Information:

Submitter's Name:	Nobel Biocare USA, Inc.
Address:	22895 Eastpark Drive Yorba Linda, CA 92887 USA
Contact Name:	Kim Rendon Regulatory Affairs Analyst
Phone:	714-282-4800
Date Prepared:	March 1999

Device Name:

Common Name:	Surgical Drill.
Trade Name:	Amorphous Diamond Coated Drill.
Classification Name:	Bone cutting instrument and accessories.

Predicate Device:

Substantial equivalence is claimed to Nobel Biocare USA, Inc. Steri-Oss System Surgical Drill.

Device Description:

Device Function: The Amorphous Diamond Coated Drill is designed for use in the preparation of an osteotomy for an endosseous dental implant site.

Scientific Concepts: Bone cutting instrument.

Characteristics: The Amorphous Diamond Coated Drill is constructed of surgical grade stainless steel. The bone cutting portion of the drill is coated with amorphous diamond coating.

Intended Use:

The drill is used to cut into the maxilla or mandible to create an osteotomy for endosseous dental implant placement.

Comparison to Predicate:

Characteristic	**Nobel Biocare Steri-Oss System Titanium Nitride Coated Drills**	**Amorphous Diamond Coated Drill**
Material	Stainless Steel	Same
Coating	Titanium Nitride	Amorphous Diamond
Design	Latch end to use with handpiece	Same
Cutting Flutes	Two	Three
Irrigation	Internal	Internal or external
Sterility	Non-sterile	Same
Packaging	Plastic vial with foam inserts	Same

Performance Data:

Biological and mechanical test data were performed to support the indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 10 1999

Ms. Kim Rendon
Regulatory Affairs Analyst
Nobel Biocare USA, Incorporated
22895 East Park Drive
Yorba Linda, California 92887

Re: K990846
Trade Name: Amorphous Diamond Coated Drill
Regulatory Class: II
Product Code: DZI
Dated: March 12, 1999
Received: March 15, 1999

Dear Ms. Rendon:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 8
Indications for Use

510(k) Number (if known): _____

Device Name: Amorphous Diamond Coated Drill

Indications For Use:

The intended use for this device is to cut into the maxilla or mandible to create an osteotomy for endosseous dental implant placement. The amorphous diamond coated drill design is intended to minimize corrosion and to increase longevity of the tool.

(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 Dental, Infection Control,
and General Hospital Devices
510(k) Number K990846

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)