K112673

FEB - 7 2012

5. 510(k) SUMMARY

Submitter:	Nakanishi, Inc. 700 Shimohinata Kanuma-Shi, Tochigi-Ken Japan 322-8666
Contact Person:	Mr. Toshihiko Shinozaki Assistant Manager, R&D Dept. Pharmaceutical Affairs Gr. TEL: 0289(64)3380 FAX: 0289(62)6665 t-shinozaki@nsk-nakanishi.co.jp
Date Prepared:	January 26, 2012
Trade Name:	Prophy-Mate neo
Common Name:	Air Powered Tooth Polishing System
Classification Name:	EFB 872.4200 Handpiece, Air-Powered, Dental
Predicate Device:	K032395 – Prophy-Mate K973876 – Prophyflex2, Model 2012 K022119 – EMS AIR-FLOW® handy 2
Device Description:	The *Prophy-Mate neo* is an air-powered tooth polishing system. The product expels a mixture of powders (sodium bicarbonate or calcium carbonate), water, and air onto the surfaces of the tooth. The Prophy-Mate neo consists of the Powder case, Handpiece, with a 60° and 80° Nozzle attachment.
Statement of Intended Use:	The *Prophy-Mate Neo* device is intended for use in dental applications to remove stains and plaque deposits from the teeth by shooting a mixture of sodium bicarbonate powders or calcium carbonate powders, air, and water onto tooth surfaces. Sodium bicarbonate should not be used on patients on a saltless diet, with a renal deficiency, with a chronic respiratory disease, or with chronic diarrhea. The *Prophy-Mate neo* can also be used in dental applications to prepare surface prior to bonding and to prepare for pit and fissure sealant.
Summary of Technological Characteristics:	The 360° twist free swivel joint at the handpiece end and the hose end of the powder case enables smooth operation even under high air pressure. The handpiece swivels so easily that access to hard to reach areas becomes effortless. The *Prophy-Mate neo* is designed to minimize stain and fatigue even during prolonged operation The choice of nozzle between 60° and 80° enables easy reach of all tooth surfaces and unobstructed vision.

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Performance Testing:	The *Prophy-Mate neo* was developed and is produced under consideration of all applicable technical standards, and internal specifications. The product's conformance with applicable international and internal standards was verified in the course of bench testing.
Conclusion:	*Nakanishi* considers the *Prophy-Mate neo* to be substantially equivalent to the predicate devices listed above. This conclusion is based on the similarities in intended use, principles of operation, functional design, and established medical use, and does not raise new issues of safety and effectiveness.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Nakanishi, Incorporated
Ms. Diane Rutherford
Regulatory Engineer
Ken Block Consulting
1201 Richardson Drive, Suite 280
Richardson, Texas 75080

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Re: K112673
Trade/Device Name: Prophy-Mate neo
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EFB
Dated: January 26, 2012
Received: February 1, 2012

Dear Ms. Rutherford:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
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: K112673

Device Name: *Prophy-Mate neo*

Indications for Use:

The Prophy-Mate Neo device is intended for use in dental applications to remove stains and plaque deposits from the teeth by shooting a mixture of sodium bicarbonate powders or calcium carbonate powders, air, and water onto tooth surfaces.

The Prophy-Mate neo can also be used in dental applications to prepare surface prior to bonding and to prepare for pit and fissure sealant.

Prescription Use ____X____ AND/OR Over-the-Counter Use _____
(21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDHR, Office of Device Evaluation (ODE)

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

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