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510(k) SUMMARY

APR 29 2009

Nakanishi Inc.
Primado Surgical System

Name of Device and Name/Address of Sponsor

Trade or Proprietary Name:	Primado Surgical System
Common Name:	electric surgical motorsystem; ENT surgical drill system
Classification Name:	motor, drill, electric; ear, nose, and throat electric or pneumatic surgical drill (21 CFR 882.4360 and 874.4250)
Product Code:	HBC, ERL

Nakanishi Inc.
700 Shimohinata
Kanuma-shi
Tockigi-ken 322-8666
Japan

Contact: Ms. Tomoko Hirabayashi
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Date Prepared: April 23, 2009

Intended Use

The Primado Surgical System is an AC-electrically powered total surgical system that allows for the use of multiple attachments to perform delicate bone dissection in neurological, maxillofacial, craniotomy, and spinal procedures, and in the ear, nose, and throat area. A wide range of attachments includes a perforator drive, craniotome, straight/angle/malleable drills, and microsaws.

Technological Characteristics and Substantial Equivalence

The Primado Surgical System is an AC-electrically powered total surgical system that allows for the use of multiple attachments to perform delicate bone dissection in neurological procedures. The device consists of a control unit, foot controller, micromotor, motor cord, AC power cord, perforator drive, craniotome, straight/angle/malleable drills, and microsaws. The device does not come sterile and all parts that contact the patient as well as the AC power cord should be sterilized prior to the first use and after each use. The Primado has already been cleared for marketing for "delicate bone dissection in the ear, nose, and throat areas" under K#080722.

The Primado Surgical System is substantially equivalent in terms of safety and effectiveness to NSK's own previously authorized Primado device (K#080722) and the Advantage Drive System (K#002523). A chart comparing the Primado to the predicate devices is attached.

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Substantial Equivalency Chart

ITEMS	NEW DEVICE	PREDICATE DEVICE	PREDICATE DEVICE
1. Classification No.	HBC, ERL	ERL	HBC, GEY
2. C.F.R. Section No.	882.4360 and 874.4250	874.4250	882.4360 and 878.4820
3. Classification Panel	Neurology and Ear, Nose & Throat	Ear, Nose & Throat	Neurology and General and Plastic Surgery
4. Classification Name	Motor, Drill, Electric	Drill, Surgical, ENT (Electric Or Pneumatic) Including Handpiece	Motor, Drill, Electric and Motor, Surgical Instrument, Ac-Powered
5. Class	II	II	II
6. 510(k) Number	N/A	K#080722	K#002523
7. Manufacturer	NAKANISHI INC.	NAKANISHI INC.	LINVATEC CORP
8. Proprietary Name	Primado Surgical System	Primado Neurological Drill	Advantage Drive System
9. Description	Electrically powered drill and surgical motor system and attachments operated by foot controller	Identical	Electrically powered surgical instrument system and handpieces operated by foot controller

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10. Intended use	Delicate bone dissection in neurological, maxillofacial, craniotomy, and spinal procedures, and in the ear nose, and throat areas	Delicate bone dissection in the ear, nose, and throat areas	Cutting of soft tissue and bone in arthroscopic, foot, hand, medial sternotomy, neurosurgical, orthopedic, otolaryngological, oral/maxillofacial, plastic/ reconstructive, and spinal surgical procedures
11. Compliance with standards	IEC 60601-1 IEC 60601-1-2	Identical	IEC 601-1 IEC 601-1-2 UL2601-1
12. High speed	Up to 100,000 rpm	Identical	Identical
13. Low speed	Up to 234 rpm	Identical	Up to 30 rpm
14. Oscillating saw	Up to 20,000 cpm	Identical	Identical
15. Sagittal saw	Up to 20,000 cpm	Identical	Identical
16. Reciprocating saw	Up to 19,300 cpm	Identical	Up to 17,000 cpm
17. Patient contact materials	Surgical stainless steel; diamond	Identical	Unknown

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Nakanishi, Inc.
c/o Keith A. Barritt
Fish & Richardson P.C.
1425 K Street, N.W.
Suite 1100
Washington, DC 20005

APR 29 2009

Re: K083112
Trade/Device Name: Primado Surgical System
Regulation Number: 21 CFR 882.4360
Regulation Name: Electric cranial drill motor
Regulatory Class: Class II
Product Code: HBC
Dated: March 10, 2009
Received: March 11, 2009

Dear Mr. Barritt:

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 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 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 the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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,

M. B. Eydelman, MD

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K083112

Indications for Use

510(k) Number (if known): 083112

Device Name: Primado

Indications For Use:

The Primado is an AC-electrically powered total surgical system that allows for the use of multiple attachments to perform delicate bone dissection in neurological, maxillofacial, craniotomy, and spinal procedures, and in the ear, nose, and throat area. A wide range of attachments includes a perforator drive, craniotome, straight/angle/malleable drills, and microsaws.

Prescription Use _ x __ AND/OR Over-The-Counter Use _____
(Part 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 CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic and Ear, Nose and Throat Devices

510(k) Number K083112

Prescription Use
(Per 21 CFR 801.109)