K132264

DEC 17 2013

5. 510(k) SUMMARY

Submitter:	Nakanishi, Inc. 700 Shimohinata Kanuma-Shi, Tochigi-Ken Japan 322-8666
Contact Person:	Ms. Diane Rutherford Submissions Manager, Ken Block Consulting TEL: 972-480-9554 FAX: 972-767-4325 rutherford@kenblockconsulting.com
Date Prepared:	July 12, 2013 *Revised December 17, 2013*
Trade Name:	Primado2 Total Surgical System
Common Name:	Electrical Surgical System

Classification Name:	HBC	882.4360		Motor, Drill, Electric, Cranial
Secondary Classification Name:	ERL	874.4250		Drill, Surgical, ENT (Electric or Pneumatic), Including Handpiece
Additional Product Codes for Accessories:	DZI	872.4120	Class 2	Drill, Bone, Powered
	DZJ	872.4120	Class 2	Driver, Wire, and Bone Drill, Manual
	ERL	874.4250	Class 2	Drill, Surgical, ENT (Electric or Pneumatic), Including Handpiece
	GEY	878.4820	Class 1*	Surgical instrument motors and accessories / attachments
	HBC	882.4360	Class 2	Motor, Drill, Electric, Cranial
	HBE	882.4310	Class 2	Drills, Burs, Trephines & Accessories (Simple, Powered), cranial
	HWE	878.4820	Class 1*	Instrument, Surgical, Orthopedic, AC-Powered Motor and Accessory/Attachment
	GFF	878.4820	Class 1*	Bur, Surgical, General & Plastic surgery
	EQJ	874.4140	Class 1*	Bur, Ear, nose and throat

* 510(k) Exempt

Predicate Device:	K083112 – Nakanishi Primado Surgical Drill K040369 – Stryker CORE K040300 – Stryker CORE K081475 – Medtronic IPC K053526 – Aesculap microspeed™ uni
Device Description:	The Primado2 consists of the Control Unit, the Motor, the Foot Control (optional) and various handpieces for use with specific motors. Available Motors include Slim, High Torque, Micro Bone Saw, and Wire Pin Driver. Each motor series has handpieces or attachments specific to that series. Burs, drills, blades (saws), and rasps are available for use with specific handpieces / attachments. Handpieces and attachments are available for cranial surgery, trephination, oral surgery, and craniotomy. Sagittal, reciprocating, and oscillation saw blades are available, including for intra oral use.

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5. 510(k) SUMMARY *(continued)*

Device Description: (continued)	The control unit drives the motors during procedures and is used to control the functions related to that motor such as speed and rotational direction. Two motors can be connected to the control unit at one time for asynchronous use. The control unit also incorporates the irrigation pump and controls the irrigation functions. The foot control is an optional additional user interface. The foot control is available as a single or multi control. The single foot control has one button that can be programmed. The multi foot control has three buttons that can be programmed. The features available for allocation to the buttons include Foot Control ON/OFF, A/B Control Switching, Speed Control, Reverse Rotation, Irrigation ON/OFF, Flush, and Disable.
Statement of Intended Use:	The Primado 2 is an AC-electrically powered total surgical system that is intended for cutting, drilling, sawing, and otherwise manipulating soft tissue, hard tissue, bone, bone cement, prosthesis, implant, and other bone related tissue in a variety of surgical procedures, including but not limited to Cranial (Craniofacial / Maxillofacial), ENT, Endoscopic / Arthroscopic, Neuro, Orthopedic, Spinal, and General surgical procedures.
Summary of Technological Characteristics:	As with the predicate devices referenced above, the Primado2 is an AC-electrically powered software driven total surgical system that powers and controls the functions of compatible motor attachments. The software allows for the control of the device features such as brightness, volume, speed control, rotational direction, irrigation control, priming control, footswitch control and confirmation, and configuration settings. The proposed device shares technological characteristics with the predicate devices. The proposed device also has some differences in technological characteristics from those of the predicate devices. Any differences in the technological characteristics are minor and reflect market strategy and/or perceived user preferences and do not impact the safety, effectiveness, or substantial equivalence of the device.
Performance Testing:	Tests were performed on the Primado2 including verification/validation testing to internal functional specifications (including software) which demonstrated that the device is safe and effective. Documentation was provided demonstrating compliance of the Primado2 to all FDA requirements stated in Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, including results of verification/validation plus traceability of verification/validation tests to software requirements and software risk hazards. Testing confirmed that the Primado2 complies with relevant voluntary safety standards for Electrical safety and Electromagnetic Compatibility testing, specifically IEC standards 60601-1 and 60601-1-2. In addition, evaluations and validations have been performed to demonstrate compliance to the applicable standards for biocompatibility and sterilization.
Conclusion:	*Nakanishi, Inc.* considers the Primado2 to be substantially equivalent to the predicate devices listed above. This conclusion is based on the similarities in primary intended use, principles of operation, functional design, and established medical use.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Nakanishi Incorporated
c/o Ms. Diane Rutherford
Ken Block Consulting
1201 Richardson Dr., Suite 280
Richardson, Texas 75080

December 17, 2013

Re: K132264
Trade/Device Name: Primado2 Total Surgical System
Regulation Number: 21 CFR 882.4360
Regulation Name: Electric cranial drill motor
Regulatory Class: Class II
Product Code: HBC
Additional Product Codes: ERL, HBE, HWE
Dated: November 6, 2013
Received: November 7, 2013

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 contact 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. 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,

Joshua C. Nipper -S

Binita S. Ashar, M.D., M.B.A., F.A.C.S.
For Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: **K132264**

Device Name: Primado2 Total Surgical System

Indications for Use:

The Primado 2 is an AC-electrically powered total surgical system that is intended for cutting, drilling, sawing, and otherwise manipulating soft tissue, hard tissue, bone, bone cement, prosthesis, implant, and other bone related tissue in a variety of surgical procedures, including but not limited to Cranial (Craniofacial/Maxillofacial), ENT, Endoscopic / Arthroscopic, Neuro, Orthopedic, Spinal, and General surgical procedures.

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)

Neil R Ogden -S
2013.12.16 16:37:52 -05'00'

(Division Sign-off) for BSA
Division of Surgical Devices
510(k) Number: K132264