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

Mr. Shinichi Nakamura
President
Nakamura Dental Handpiece MFG. Company, Limited
59-2 Minami-Cho
Itabashi-Ku, Tokyo
Japan 173-0027

FEB 2 3 2012

Re: K113222
Trade/Device Name: ND LOW SPEED AIRMOTOR / Model Number: MP-50M, ND LOW SPEED AIRMOTOR (SEVERAL MODELS) MS-10M / MS-55M, ND STAR-TYPE STRAIGHT NOSECONE ATTACHMENT Model Number: STS-30H, ND STAR-TYPE CONTRA ANGLE ATTACHMENT (SEVERAL MODELS) Model Number: STC-20L / STU-20ML/ STU-35BL / STU-30BLP, ND HIGHSPEED AIRTURBINE HANDPIECE (SEVERAL MODELS) Model Number: TCP-70QM / TCP-70QB / TC-80QM / TC-80QB
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EFB, EGS
Dated: January 24, 2012
Received: January 30, 2012

Dear Mr. Nakamura:

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

4. Indications for Use

510(k) Number (if known) : K113222

Device Regulation : 21 CFR 872 4200

Device Name : ND LOW SPEED AIRMOTOR

Model Number : MP-50M

Product Code : EFB

Indications for Use :

ND lowspeed airmotor, MP-50M, is used to power prophy angle attachment that helps dental clinician perform the hygiene dentistry work such as cleaning. The device is autoclavable.

Prescription Use _____X_____ AND/OR Over-The-Counter Use_____

(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 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 Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K113222

4. Indications for Use

510(k) Number (if known) : K113222

Device Regulation : 21 CFR 872 4200

Device Name : ND LOW SPEED AIRMOTOR (SEVERAL MODELS)

Model Number : MS-10M / MS-55M

Product Code : EFB

Indications for Use :

ND low speed airmotor, MS-10M / MS-55M, are used to power attachment that helps dental clinician perform various dental work such as cleaning, tooth carving, others. The device is autoclavable.

Prescription Use _____X_____ AND/OR Over-The-Counter Use_____

(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

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510(k) Number: K113222

4. Indications for Use

510(k) Number (if known) : K113222

Device Regulation : 21 CFR 872 4200

Device Name : ND STAR-TYPE STRAIGHT NOSECONE ATTACHMENT

Model Number : STS-30H

Product Code : EGS

Indications for Use :

ND star-type straight nosecone attachment, STS-30H, is powered by either lowspeed airmotor or electric micromotor for removing carious material and excess filling material, cavity and crown preparation, root canal preparations, finishing tooth preparations, restorations and polishing teeth. The device is autoclavable.

Prescription Use ____X____ AND/OR Over-The-Counter Use_____

(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

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

510(k) Number: K113222

4. Indications for Use

510(k) Number (if known) : K113222

Device Regulation : 21 CFR 872 4200

Device Name : ND STAR-TYPE CONTRA ANGLE ATTACHMENT (SEVERAL MODELS)

Model Number : STC-20L / STU-20ML / STU-35BL / STU-30BLP

Product Code : EGS

Indications for Use :

ND star-type contra angle attachment, STC-20L / STU-20ML / STU-35BL / STU-30BLP, are powered by either lowspeed airmotor or electric micromotor for removing carious material and excess filling material, cavity and crown preparation, root canal preparations, finishing tooth preparations, restorations and polishing teeth. The device is autoclavable

Prescription Use _____X_____ AND/OR Over-The-Counter Use_____

(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

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Susan Runner

(Division Sign-Off)

Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K113222

4. Indications for Use

510(k) Number (if known) : K113222

Device Regulation : 21 CFR 872 4200

Device Name : ND HIGHSPEED AIRTURBINE HANDPIECE (SEVERAL MODELS)

Model Number : TCP-70QM / TCP-70QB / TC-80QM / TC-80QB

Product Code : EFB

Indications for Use :

ND highspeed airturbine handpiece, TCP-70QM / TCP-70QB / TC-80QM / TC-80QB, are air-powered dental handpiece for removing carious material and excess filling material, cavity and crown preparation, root canal preparations, finishing tooth preparations, restoration and polishing teeth. The device is autoclavable.

Prescription Use _____X_____ AND/OR Over-The-Counter Use_____

(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

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