NSK

K121901

FEB 28 2013

510(k) Summary

a. Owner/Company name, address

NAKANISHI, INC.
700 Shimohinata, Kanuma-shi,
Tochigi, 322-8666, Japan

b. Contact

Toshihiko Shinozaki
Assistant Manager, R&D Department, Pharmaceutical Affairs Group
NAKANISHI, INC.
700 Shimohinata, Kanuma-shi,
Tochigi, 322-8666, Japan

Phone: 011-81-289-64-3380
Fax: 011-81-289-62-6665
Email: t-shinozaki@nsk-nakanishi.co.jp

c. Application Correspondent

Fumiaki Kanai, Ph.D.
President and CEO
MIC International
4-1-17 Hongo, Bunkyo-ku
Tokyo, 113-0033, Japan

Phone: 011-81-3-3818-8577
Fax: 011-81-3-3818-8573
Email: kanaif@mici.co.jp

d. Date prepared

June 28, 2012

e. Name of device

Trade Name:	TI-MAX Z45
Classification Name:	Handpiece, Contra-and Right-angle Attachment, Dental
Regulation Name:	Dental handpiece and accessories
Regulatory Class:	Class I
Product Code:	EGS

f. Predicate devices

The TI-MAX Z45 is substantially equivalent to the following legally marketed devices:

510(k):	K070663
Trade name:	A-DEC/W&H SYNEA AIR-DRIVEN HIGHSPEED HANDPIECE, MODELS TA-98, TA-97 A-DEC/W&H SYNEA HANDPIECE ATTACHMENT, MODELS WA-99LT, WA-86LT, WA-66LT, WA-56LT, HA-43LT
Product code:	EFB
Classification Name:	Handpiece, Air-powered, Dental

510(k):	K011061
Trade name:	SURGICAL CONTRA-ANGLE HANDPIECES TYPES WS-56E, WS-75-E/KM, WS-92E/3
Product code:	EGS
Classification Name:	Handpiece, Contra-and Right-angle Attachment, Dental

Hereinafter, the predicate devices are called "the SYNEA HANDPIECE (K070663)" and "the SURGICAL CONTRA-ANGLE HANDPIECES (K011061)", respectively, for convenience of discussion in this application. Regarding the SYNEA HANDPIECE (K070663), A-DEC/W&H SYNEA HANDPIECE ATTACHMENT is the exact predicate device for the TI-MAX Z45. Since the HA-43LT type of the A-DEC/W&H SYNEA HANDPIECE ATTACHMENT is a straight handpiece, the type is eliminated as the predicate device for the TI-MAX Z45 hereinafter in this submission. The SYNEA HANDPIECE (K070663) indicates A-DEC/W&H SYNEA HANDPIECE ATTACHMENT MODELS WA-99LT, WA-86LT, WA-66LT, WA-56LT in this application.

g. Description of the device

The TI-MAX Z45 is a contra-angle dental handpiece which is powered by either an air-motor or electronic-micromotor for use in general dentistry. The TI-MAX Z45 is intended for cutting and grinding teeth, cavity preparations, tooth and crown preparations, finishing and trimming teeth and filling materials, and removal of crowns and filling materials. The TI-MAX Z45 transmits rotational force from the motor to the gears through a clutch, and then the rotation force reaches the chuck and the dental bur receives the rotation force. The dental bur is able to cut and grind teeth and dentures using the rotation force.

h. Statement of Intended Use

TI-MAX Z45 is powered by either an air-motor or electronic micromotor for use in general dentistry.

The device is intended for cutting and grinding teeth, cavity preparations, tooth and crown

NAKANISHI INC. Headquarters : 700 Shimohinata Kanuma-shi Tochigi 322-8666, Japan
www.nsk-inc.com Tokyo Office : MY Building 1-13-3 Ueno Taito-ku Tokyo 110-0005, Japan

preparations, finishing and trimming teeth and filling materials, and removal of crowns and filling materials.

i. Summary of Technological Characteristics

The maximum rated speed in rotation of the TI-MAX Z45 is 168,000 min^{-1}. The rotation speed is increased by 4.2-fold at the chuck using the gears. Since the TI-MAX Z45 uses rotational force for the treatment, temperature increase may occur on the drilling point. Therefore, the TI-MAX Z45 has 4-port water spray outlet on the head in order to cool down the treatment area. It is possible to switch the type of coolant water flow, water jet or water spray. The TI-MAX Z45 has opticfiber for lighting.

The friction grip bur (not exceed 25 mm) which conforms ISO 1797-1 is intended to use for the TI-MAX Z45. The TI-MAX Z45 uses the push-button chuck mechanism.

The TI-MAX Z45 can be connected only E-type motors which conforms ISO 3964.

j. Statement of substantial equivalence

The Indications for Use of the TI-MAX Z45 is similar to the SYNEA HANDPIECE (K070663). The principle of operation of the TI-MAX Z45 is identical to the predicates. That is, the TI-MAX Z45 and the predicates transmit rotational force from the motor to the dental bur using the gears. The dental bur is able to cut and grind teeth and dentures using the rotation force. In addition, design features (Contra-Angle, Push-Button Chuck, Motor coupling, Thermal safety system) of the TI-MAX Z45 are identical to those of the predicates.

Following table is comparison between the TI-MAX Z45 and the predicates.

Comparison table

	TI-MAX Z45	SYNEA HANDPIECE (K070663)	SURGICAL CONTRA-ANGLE HANDPIECES (K011061)
Indications for Use	TI-MAX Z45 is powered by either an air-motor or electronic micromotor for use in general dentistry. The device is intended for cutting and grinding teeth, cavity preparations, tooth and crown preparations, finishing and trimming	The A-dec/W&H Synea Air-Driven Highspeed Handpiece is an air-powered dental handpiece for use in general dentistry. This device is designed for removing carious material and excess filling material, cavity and crown preparation, root canal preparations,	Indications are very widespread in the field of implantology and surgery. The mentioned handpieces have been developed especially for the following applications: WS-56 E:for e,g. osteotomla on the upper and lower jaw. germectomls,

NAKANISHI INC. Headquarters : 700 Shimohinata Kanuma-shi Tochigi 322-8666, Japan
www.nsk-inc.com Tokyo Office : MY Building 1-13-3 Ueno Taito-ku Tokyo 110-0005, Japan

	teeth and filling materials, and removal of crowns and filling materials.	finishing tooth preparations, restorations and polishing teeth. *The A-dec/W&H Synea Handpiece Attachment is powered by either an air-motor or electric micromotor for use in general dentistry. This device is designed for removing carious material and excess filling material, cavity and crown preparation, root canal preparations, finishing tooth preparations, restorations and polishing teeth.	sequestrotomla WS-75 E/KM: for e.g. implantology (preparation of the bone cavity, placing the implants), surgical treatment of dysgnathia, osteosynthesis, segmentosteotomla and especially mild osteotomla. WS-92 E/3 : for e.g. hemisection, wisdom tooth extraction.
Product Code	EGS	EFB	EGS
Classification Name	Handpiece, Contra-and Right-angle Attachment, Dental	Handpiece, Air-powered, Dental	Handpiece, Contra-and Right-angle Attachment, Dental
Design features	Contra-Angle, Push-Button Chuck, Motor coupling, Thermal safety system	Contra-Angle, Push-Button Chuck, Motor coupling, Thermal safety system	Contra-Angle, Push-Button Chuck, Motor coupling, Thermal safety system
Gear ratio	1:4.2	1:5, 1:1, 2:1, 10:1	1:1, 20:1. 1:2,7
Maximum motor/drive speed	40,000 rpm	40,000 rpm	50,000 rpm
Materials	Stainless Steel, Titanium	Unknown	Stainless steel
Motor coupling	Compliant with ISO 3964	Compliant with ISO 3964	Compliant with ISO 3964
Source of power	Air-motor, Electronic-micromotor	Air-motor, Electronic-micromotor	Air-motor, Electronic-micromotor
Light	Glass Rod (Fiberoptic)	With light type/Without light type	With light type/Without light type
Dimension	Head Diameter: 9.6mm Head Height: 14.5mm Length: 96.2mm	Head Height: 12.3 mm or 13.7mm	Unknown
Weight	66.5 g	Unknown	Unknown

NAKANISHI INC. Headquarters : 700 Shimohinata Kanuma-shi Tochigi 322-8666, Japan
www.nsk-inc.com Tokyo Office : MY Building 1-13-3 Ueno Taito-ku Tokyo 110-0005, Japan

Performance	Compliant with ISO 7785-2	Compliant with ISO 7785-2	Compliant with ISO 7785-2
-Eccentricity	0.016 mm	Unknown	Unknown
-Force for bur extraction	25.3N	Unknown	Unknown
Sterilization	Sterilized by user (Autoclave)	Sterilized by user (Autoclave)	Sterilized by user (Autoclave)
Thermal safety	Air/Water spray, compliant with ISO7785-2	Air/Water spray, compliant with ISO7785-2	Air/Water spray, compliant with ISO7785-2
-Air/Water Spray port	4-port	Single or 5-port	Single or 3-port
-Coolant Water Type	Water spray/Water jet	Water spray	Water spray
-Flow Rate	More than 50 ml/min	More than 50 ml/min	More than 50 ml/min
-Water pressure setting range	2 bar	0.5-2 bar	Unknown
-Chip air pressure setting range	2 bar	1.5-3bar	Unknown
Lubricant	PANA Spray (510(k) number is K052700)	W&H Service oil F1	W&H Service oil F1
Bur	FG burs	FG burs, contra-angle burs	FG burs, contra-angle burs
-Maximum bur length	25 mm	25mm (FG burs), 34mm (contra-angle burs)	34mm (WS-56E contra-angle burs), 45 mm (WS-75 E/KM, contra-angle bur), 25 mm (WS-92 E/3, FG bur)

Note*: The models for "the A-DEC/W&H SYNEA HANDPIECE ATTACHMENT" are used as the predicate device for the Ti-Max Z45 in the submission.

As shown in the comparison table, the indications for use of the TI-MAX Z45 is similar to the SYNEA HANDPIECE (K070663). As described above, the principle of operation and design features of the TI-MAX Z45 are identical to those of the predicates. However, the dimensions and materials of the TI-MAX Z45 are different from the predicates. The gear ratio of the TI-MAX Z45 is also different from that of the predicates. Therefore, the maximum rotation speed at the chuck is different between the TI-MAX Z45 and the predicates. In addition, the number of the air/water spray port is different between the TI-MAX Z45 and the predicates. In order to evaluate that those differences do not affect safety and effectiveness of the TI-MAX Z45, bench testing was performed. Bench testing demonstrated that the TI-MAX Z45 met the requirement of ISO7785-2 which was used for evaluation of the predicate devices. Based on above result, the TI-MAX Z45 is substantially equivalent to the predicates and does not raise any new safety and effectiveness concern.

NAKANISHI INC. Headquarters : 700 Shimohinata Kanuma-shi Tochigi 322-8666, Japan
www.nsk-inc.com Tokyo Office : MY Building 1-13-3 Ueno Taito-ku Tokyo 110-0005, Japan

k. Bench Testing

The bench tests were performed in order to ensure the safety and effectiveness of the TI-MAX Z45, verify conformity to ISO 7785-2 and demonstrate substantial equivalence to the predicates.

All TI-MAX Z45 samples were compliant with ISO 7785-2 and demonstrated substantial equivalence to the predicates.

l. Conclusion

The indications for use of the TI-MAX Z45 is similar to the SYNEA HANDPIECE (K070663). In addition, the principle of operation and design features of the TI-MAX Z45 are identical to those of the predicates. However, the dimensions and materials of the TI-MAX Z45 are different from the predicates. The gear ratio of the TI-MAX Z45 is also different from that of the predicates. Therefore, the maximum rotation speed at the chuck is different between the TI-MAX Z45 and the predicates. In addition, the number of the air/water spray port is different between the TI-MAX Z45 and the predicates. Although there are those differences in characteristics between the TI-MAX Z45 and the predicates, a number of performance testing indicated that the TI-MAX Z45 met the requirement of the recognized consensus or voluntary standard. Based on above result, we conclude the TI-MAX Z45 is substantially equivalent to the predicates and does not raise any new safety and effectiveness concern.

NAKANISHI INC. Headquarters : 700 Shimohinata Kanuma-shi Tochigi 322-8666, Japan
www.nsk-inc.com Tokyo Office : MY Building 1-13-3 Ueno Taito-ku Tokyo 110-0005, Japan

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

February 28, 2013

Nakanishi, Incorporated
C/O Fumiaki Kanai, Ph.D.
President and Chief Executive Officer
MIC International
4-1-17 Hongo, Bunkyo-ku
Tokyo, Japan 113-0033

Re: K121901
Trade/Device Name: TI-MAX Z45
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EGS
Dated: February 5, 2013
Received: February 11, 2013

Dear Dr. Kanai:

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,

Kwame O. Ulmer for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (If known): K121901

Device Name: TI-MAX Z45

Indications for Use
TI-MAX Z45 is powered by either an air-motor or electronic micromotor for use in general dentistry.

The device is intended for cutting and grinding teeth, cavity preparations, tooth and crown preparations, finishing and trimming teeth and filling materials, and removal of crowns and filling materials.

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

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner, DDS, MA Mary S. Runner -S 2013.02.28 07:38:56 -05'00'

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

510(k) Number: K121901