



Food and Drug Administration
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October 23, 2014

Handpiece Headquarters
Tina Steffanie-Oak
Senior Regulatory Specialist
620 S. Placentia Avenue
Placentia, California 92870

Re: K141125

Trade/Device Name: Henry Schein/Handpiece Headquarters U-type Contra Angles and
U-type Sectional Contra Angle

Regulation Number: 21 CFR 872.4200

Regulation Name: Dental Handpiece and Accessories

Regulatory Class: I

Product Code: EGS

Dated: September 23, 2014

Received: September 25, 2014

Dear Ms. Steffanie-Oak:

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 Industry and Consumer Education 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 Industry and Consumer Education 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,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S
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): K141125

Device Name: Henry Schein/Handpiece Headquarters U-Type Contra Angles and U-Type Sectional Contra Angles

Indications for Use:

The U-Type Contra Angles and U-Type Sectional Contra Angles are used to mount on U-Type Nose Attachments and powered by either low speed air motors or electric micro motors. These U-Type are intended for removing carious material, cavity and crown preparations, finishing tooth preparations, reducing hard tooth structures, restorations and polishing teeth.

Prescription Use X

AND/OR

Over-The-Counter Use _____

(Per 21 CFR 801 Subpart D)

(Per 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)

ATTACHMENT 8 SMDA 510(K) SUMMARY



510(K) SUMMARY: Henry Schein / Handpiece Headquarters: U-Type Contra Angles & U-Type Sectional Contra Angles.

- a- Submitted by:** HANDPIECE HEADQUARTERS
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Tel. 714-579-0175 Fax. 714-579-0186
- b- Contact person:** Tina Steffanie-Oak, Tel. 717-335-7230, ext. 4150 Fax. 717-335-7240
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- c- Date summary prepared:** 09/22/14

d- Device Name:

Trade or Proprietary Name: Henry Schein / Handpiece Headquarters:

- 1- U-Type Contra Angle 20,000 rpm
- 2- U-Type Contra Angle 40,000 rpm
- 3- U-Type Contra Angle Friction Grip
- 4- U-Type Sectional Contra Angle 20,000 rpm
- 5- U-Type Sectional Contra Angle 40,000 rpm
- 6- U-Type Sectional Contra Angle Friction Grip

Common Name: U-Type Contra Angle Handpiece Attachments.

Classification Name:

Class I Device, 21CFR 872.4200, Dental Handpiece and Accessories. EGS

e- Substantial Equivalency is claimed against the following devices:

ND U-TYPE PROPHYLAXIS ANGLES (SEVERAL MODELS)
NAKAMURA DENTAL HANDPIECE MFG. CO., LTD. - K073652

f- Description of the device:

U-Type contra angles and U-Type sectional contra angles are used to mount on U-Type Nose Attachments and powered by either low speed air motors or low speed electric motors. These U-Type Contra Angle Attachments are gear 1:1 to the low speed air motors or low speed electrical motors. As results, they transmit the same speed and torque from the connected air motors or electric motors.

g- Statement of Intended Use:

The U-Type Contra Angles and U-Type Sectional contra angles are used to mount on U-Type Nose Attachments and powered by either low speed air motors or electric micro motors. These U-Types are intended for removing carious material, cavity and crown preparations, finishing tooth preparations, reducing hard tooth structures, restorations and polishing teeth.

H1-Summary table of comparing the technological characteristics between the subjects to predicate devices:

comparison	Henry Schein/Handpiece Headquarters U-TYPE contra angle	Predicate: Nakamura Dental U-Type contra angle	Conclusion
	U-Type Contra angle 40,000 rpm & U-Type contra angle 20,000 rpm	Model DC-10L	
Indications of use	The U-Type Contra Angles and U-Type Sectional contra angles are used to mount on U-Type Nose Attachments and powered by either low speed air motors or electric micro motors. These U-Types are intended for removing carious material, cavity and crown preparations, finishing tooth preparations, reducing hard tooth structures, restorations and polishing teeth.	ND u-type prophylaxis angle is use to mounted on U-type nose attachment powered by either low speed air motor or electric micro motor for hygiene dentistry work. All devices are fully Autoclavable.	Similar
Technical characteristic			
Body length	3.114"	3.117"	Similar
Weight	29.4g	29.9g	Similar
Bearing type	Precision ball bearings	Phosphor Bronze bushing bearings	Precision Ball bearings can performance better and less friction (less heat generating) compare to Phosphor Bronze bushing bearings
Speed range	0-40,000 rpm	0-15,000 rpm	Precision ball bearing can handle higher speed
Speed ratio	1:1	1:1	Identical
Attachments	Low speed motor	Low speed motor	Identical
Chuck type	Latch	Latch	Identical
Mount	U-Type	U-type	Identical
Patient contact surfaces	Brass with Nickel Chrome Plating	Brass and Nickel Chrome Plating	Identical
Heat generate after 5 minutes free run	From 21 °C to 26°C	From 21 °C to 29.5°C	Similar
Head type	Contra angle	Contra angle	Identical
	U-Type Contra angle Sectional 40,000 rpm & U-Type contra angle 20,000 rpm	Model DC-20L	
Indications of use	The U-Type Contra Angles and U-Type Sectional contra angles are used to mount on U-Type Nose Attachments and powered	ND u-type prophylaxis angle is use to mounted on U-type nose attachment	Similar

	by either low speed air motors or electric micro motors. These U-Types are intended for removing carious material, cavity and crown preparations, finishing tooth preparations, reducing hard tooth structures, restorations and polishing teeth.	powered by either low speed air motor or electric micro motor for hygiene dentistry work. All devices are fully Autoclavable.	
Technical characteristic			
Body length	3.100"	3.110"	similar
Weight	32.9g	35.0g	similar
Bearing type	Precision ball bearings	Phosphor Bronze bushing bearings	Precision Ball bearings can performance better and less friction (less heat generating) compare to Phosphor Bronze bushing bearings
Speed range	0-40,000 rpm	0-20,000 rpm	Precision ball bearing can handle higher speed
Speed ratio	1:1	1:1	Identical
Attachments	Low speed motor	Low speed motor	identical
Chuck type	Latch	Latch	identical
Mount	U-Type	U-type	Identical
Patient contact surfaces	Brass with Nickel Chrome Plating	Brass and Nickel Chrome Plating	identical
Heat generate after 5 minutes free run	From 21 °C to 27°C	From 21 °C to 29°C	Similar
	U-Type Contra angle Friction Grip 20,000 rpm	Model DC-10FG	
Indications of use	The U-Type Contra Angles and U-Type Sectional contra angles are used to mount on U-Type Nose Attachments and powered by either low speed air motors or electric micro motors. These U-Types are intended for removing carious material, cavity and crown preparations, finishing tooth preparations, reducing hard tooth structures, restorations and polishing teeth.	ND u-type prophylaxis angle is use to mounted on U-type nose attachment powered by either low speed air motor or electric micro motor for hygiene dentistry work. All devices are fully Autoclavable.	Similar
Technical characteristics			
Body length	3.14"	3.14"	Identical
Weight	31.16g	30.4g	similar
Bearing type	Precision ball bearings	Phosphor Bronze bushing bearings	Precision Ball bearings can performance better and less friction (less

			heat generating) compare to Phosphor Bronze bushing bearings
Speed range	0-20,000 rpm	0-15,000 rpm	Precision ball bearing can handle higher speed
Speed ratio	1:1	1:1	Identical
Attachments	Low speed motor	Low speed motor	identical
Chuck type	Friction Grip	Friction Grip	identical
Mount	U-Type	U-type	Identical
Patient contact surfaces	Brass with Nickel Chrome Plating	Brass and Nickel Chrome Plating	identical
Heat generate after 5 minutes free run	From 21 °C to 29.7°C	From 21 °C to 29.7°C	Identical
	U-Type Sectional Contra angle Friction Grip 20,000 rpm	Model DC-20FG	
Indications of use	The U-Type Contra Angles and U-Type Sectional contra angles are used to mount on U-Type Nose Attachments and powered by either low speed air motors or electric micro motors. These U-Types are intended for removing carious material, cavity and crown preparations, finishing tooth preparations, reducing hard tooth structures, restorations and polishing teeth.	ND u-type prophylaxis angle is use to mounted on U-type nose attachment powered by either low speed air motor or electric micro motor for hygiene dentistry work. All devices are fully Autoclavable.	Similar
Technical characteristic			
Body length	3.14"	3.15"	Similar
Weight	32.7g	31.2g	similar
Bearing type	Precision ball bearings	Phosphor Bronze bushing bearings	Precision Ball bearings can performance better and less friction (less heat generating) compare to Phosphor Bronze bushing bearings
Speed range	0-20,000 rpm	0-15,000 rpm	Precision ball bearing can handle higher speed
Speed ratio	1:1	1:1	Identical
Attachments	Low speed motor	Low speed motor	identical
Chuck type	Friction Grip	Friction Grip	identical
Mount	U-Type	U-type	Identical
Patient contact surfaces	Brass with Nickel Chrome Plating	Brass and Nickel Chrome Plating	identical
Heat generate after 5 minutes free run	From 21 °C to 28.1°C	From 21 °C to 28.1°C	Identical

H2-Summary of comparing technical characteristic:

Base on comparing table above, the principles of operation and design features of the Handpiece Headquarters/Henry Schein U-Type contra angles are identical to Nakamura Dental ND U-type prophylaxis angles. The indications for use of the Handpiece Headquarters/Henry Schein U-Type contra angles are similar to the predicate devices. Heat generating after 5 minutes of free run for these U-type contra angles are similar to predicate devices.

Handpiece Headquarters/Henry Schein U-Type contra angles can achieve a higher speed of rotation compare to Nakamura Dental ND U-type prophylaxis angles because of the improving bearing type that using in these U-type contra angles. Precision ball bearings in high speed handpieces which have proven to improve the life cycles of the handpieces due to minimal friction in operation of these bearings. On the other hand, Phosphor bronze bushing bearings used in Nakamura Dental U-type prophylaxis angles which could not achieve higher speed of rotation due to higher friction generated in these bearings in operation. In order to evaluate differences these devices which do not affect safety and effectiveness, the comparison testing was conducted testing in house per ISO 7785-2:1995 (section 7 of this 510(k)) which was used for comparison the performance between Handpiece Headquarters/Henry Schein U-type contra angles to predicate devices. Base on the results, the Handpiece Headquarters/Henry Schein U-type contra angles are substantially equivalent to the predicates and do not raise any new safety and effectiveness concern.

H-3 summary of Lead testing results:

Negative lead testing results for these U-types

H-4 Biocompatibility

Patient-contact portion of these U-type handpieces are made of brass and plated with Nickel Chrome which commonly used for most dental handpieces. They have history of biocompatibility.

i- Safety and effectiveness of the device:

U-Type Contra Angles and U-Type Sectional Contra Angles are as safe and effective as the predicate devices as cited above.

J – Conclusion:

The non-clinical tests did not raise any safety or efficacy concerns. Based on our assessment of the non-clinical tests that were completed, which include comparative testing between the subject and predicate device, review of technological characteristics, performance testing, and material testing, Handpiece Headquarters believes that the U-Type Contra Angles and U-Type Sectional Contra Angles are substantially equivalent to the predicate devices identified.