

K092053

55:65



A HENRY SCHEIN COMPANY

AUG 20 2009

510(K) SUMMARY: Henry Schein Maxima-M Straight Attachment & Contra Angle Sheath

a- Submitted by: HANDPIECE HEADQUARTERS
620 S. Placentia Ave., Placentia CA 92870
Tel. 714-579-0175 Fax. 714-579-0186

b- Contact person: Tina Steffanie-Oak, Tel. 717-335-7230, ext. 4150 Fax. 717-335-7240
Email: tina.steffanie-oak@henryschein.com

c- Date summary prepared: 06/26/09

d- Device Name:

Trade or Proprietary Name: Henry Schein Maxima-M Straight Attachment & Contra Angle Sheath

Common Name: Straight Attachment & Contra Angle Sheath
Classification Name: Handpiece Contra-And Right-Angle Attachment, Dental
(21CFR 872.4200), Class 1, Product Code EGS

e- Substantial Equivalency is claimed against the following devices:

MIDWEST STRAIGHT ATTACHMENT-K792445
NSK CONTRA ANGLE SHEATH-K962540

f- Description of the device: The Straight Attachment or the Contra Angle sheath is used to connect between the low-speed air-driven motor and the handpiece head. (1 to 1)

g- Statement of Intended Use:

The Straight Attachment and Contra Angle Sheath attachments are used with a Low Speed Dental Handpiece that is intended for removing carious material, cavity and crow preparations, finishing tooth preparations, reducing hard tooth structures, restorations and polishing teeth. These attachments are used by authorized persons in the practice of dentistry.

h- Safety and effectiveness of the device:

The Straight Attachment & Contra Angle Sheath are as safe and effective as the predicate devices as cited above.

I – Conclusion:

Based on the information provided in this submission Handpiece Headquarters believes that the Straight Attachment & Contra Angle Sheath are substantially equivalent to the predicate devices identified.



DEPARTMENT OF HEALTH & HUMAN SERVICES

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

AUG 20 2009

Mr. Tim Ropchan
General Manager
Handpiece Headquarters
620 South Placentia Avenue
Placentia, California 92870

Re: K092053

Trade/Device Name: Henry Schein Maxima-M Straight Attachment & Contra
Angle Sheath for use with Low Speed Handpiece

Regulation Number: 872.4200

Regulation Name: Dental Handpiece and Accessories

Regulatory Class: I

Product Code: EGS

Dated: June 25, 2009

Received: July 7, 2009

Dear Mr. Ropchan:

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 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,



Susan Runner, D.D.S., M.A.

Acting Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: Henry Schein Maxima-M Straight Attachment & Contra Angle Sheath for use with a Low Speed Handpiece

Indications for Use:

The Straight Attachment and Contra Angle Sheath attachments are used with a Low Speed Dental Handpiece that is intended for removing carious material, cavity and crown preparations, finishing tooth preparations, reducing hard tooth structures, restorations and polishing teeth.

These attachments are used by authorized persons in the practice of dentistry.

Prescription Use X
(Per 21 CFR 801 Subpart D)
Subpart C)

AND/OR

Over-The-Counter Use _____
(Per 21 CFR 801

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert Betz DDS for Dr. Kevin Mulry
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

Page 1 of 1

510(k) Number: K092053