K974670

Section 8: 510(k) Summary

MAR 13 1998

Submitted By: Athena Technology, Inc.
984 N. Amelia Ave.
San Dimas, CA 91773

(800) 253-1771

Contact: William T. Anderson

Date Prepared:

Device Name: Trade or Proprietary Name - Athena 1:1 Contra Angle, Athena 4:1 Speed Reduction Contra Angle, Athena 16:1 Speed Reduction Contra Angle, Athena 16:1 Speed Reduction Contra Angle to fit Midwest, Athena 64:1 Speed Reduction Contra Angle, Athena Heavy Duty 1:1 Four Ball Bearing Straight Nosecone for All E Type Motors, Athena Heavy Duty 4:1 Four Ball Bearing Straight Nosecone for All E Type Motors, Athena Heavy Duty 1:1 Four Ball Bearing Straight Nosecone for Midwest Motors, Athena Heavy Duty 4:1 Four Ball Bearing Straight Nosecone for Midwest Motors, Athena Heavy Duty 1:1 Four Ball Bearing Straight Nosecone for Star Motors, Athena Heavy Duty 4:1 Four Ball Bearing Straight Nosecone for Star Motors.
Common or Usual Name - Straight Nosecones and Contra Angles
Classification Name - Dental Handpiece Attachments

Identification: The following devices are identified to be equivalent to Athena attachments, nosecones and contra angles:

A. Lynx attachments marketed by MTI Precision Products, 175 Oberlin North Avenue, Lakewood, New Jersey 08701; and

B. Champion attachments marketed by Champion Dental Products Inc., 1941 Miraloma, Placentia, California 92870; and

C. NSK attachments marketed by NSK America Corporation, 700 B Cooper Court, Schaumburg, Illinois 60173

D. Midwest attachments marketed by Dentsply Midwest, 901 West Oakton Street, Des Plaines, Illinois 60018; and

E. Star attachments marketed by Star Dental (Division of DEN-TAL-EZ, Inc.), 1816 Colonial Village Lane, Lancaster, Pennsylvania 17601.

Description: Athena nosecones include models to fit "E" type slow speed motors, Midwest and Star slow speed handpiece in two versions, the standard 1:1 non-reduction model and the 4:1 speed reduction model. These have four ball bearing construction; durable stainless steel chuck and operating mechanism. Uses standard handpiece burs, disposable and metal prophy angles.

Device Function: Power is delivered to the nosecone through the drive dog and input shaft, usually rotating at a nominal 20,000 RPM. The rotation is carried through a direct drive (in the case of a 1:1 unit) or through a planetary gear system to control the overall speed reduction and output RPM delivered to the attachment placed and locked in the nosecone collet assembly.

Significant Physical and Performance Characteristics: The exploded drawing (attached) illustrates the placement and function of the various elements and parts. Drive power rotates the input shaft which in the 1:1 system directly drives the collet system. In the case of a geared system, drive power rotates the input shaft which rotates a "sun" gear element of the planetary gear system. The "ring" gear of the planetary gear system is locked and is prevented from rotating. The planet gears rotate at an RPM which is controlled by the ratio of teeth in the ring gear and sun gear. The output of the planetary system results in the carrier of the planets rotating and is provided to the collet system directly. By controlling the gear ratio of the planetary system, a wide range of rotational speeds is available. As the speed is reduced , the output torque is similarly increased. The collet is operated by rotating the "collet operating ring". Positive locking is provided by a detent system to prevent inadvertent opening of the collet during operation.

Materials Used: The nosecone is principally made of the following materials: Aluminum for the rear housing and color bezel denoting the gear ratio; stainless steel for all other metal parts except bearings; and instrument quality stainless steel for the bearings.

Material Physical Properties: Aluminum Type 2011 or 6016 is used. Physical properties associated with these materials is defined by ASTM specification. It is commonly used in medical and dental instruments and devices. Stainless steel Type 300 series and 416 is used. Physical properties associated with these is defined by ASTM specification. It is commonly used in medical and dental instruments and devices.

Athena contra angles include models to fit "E" type slow speed motors and Midwest slow speed handpieces. "E" type models include a standard 1:1 non-reduction model and three speed reduction models 4:1, 16:1 and 64:1. The Midwest version is a 16:1 speed reduction. They convert a straight handpiece to an angle for increased access in the oral cavity. The reduction angles use stainless steel gears and four ball bearings for durability and longevity. Uses latch type heads.

Device Function: Power is delivered to the contra angle through the drive dog and input shaft, usually rotating at a nominal 20,000 RPM. The rotation is carried through either a direct drive (in the case of a 1:1) unit or through one or more planetary gear systems operating sequentially to control the overall speed reduction and output RPM delivered to the attachment placed n the output of the contra angle.

Significant Physical and Performance Characteristics: The exploded drawing (attached) illustrates the placement and function of the various elements and parts. Drive power rotates the input shaft, in the 1:1 system directly drives the output shaft through the angled fitting and associated gears. In the case of a geared system, drive power rotates the input shaft which rotates a "sun" gear element of the first planetary gear system. The "ring" gear of the planetary gear system is locked and prevented from rotating. The planet gears rotate at an RPM which is controlled by the ratio of teeth in the ring hear and on the sun gear. The output of the planetary system results in the carrier of the planets rotating and, in the case of a single planetary system is provided to an "angle" fitting and associated gears and shaft to the output shaft directly. If the system includes more than one planetary system, the output of the first becomes the input to the next planetary system until the output is finally directed to the angle fitting and the output shaft. By controlling the gear ratio of the planetary system(s) a wide range of rotational speeds is available. As the speed is reduced, the output torque is similarly increased.

Materials Used: The contra angles are principally made of the following materials: Aluminum for the rear housing and color bezel denoting the gear ratio; stainless steel for all other metal parts except for the bearings which are made of instrument quality stainless steel; and brass for the output bearing carrier.

Material Physical Properties: Aluminum Type 2011 or 6016 is used. The physical properties associated with these materials is defined by ASTM specification. It is commonly used in medical and dental instruments and devices. Stainless steel Type 300 series and 416 is used. The physical properties associated with these materials is defined by ASTM specification. It is commonly used in medical and dental instruments and devices. Standard and brass alloys are used. The physical properties associated with these are defined by ASTM specification. Usually the material is in the "half hard" heat treat condition to provide sufficient strength and wear characteristics as required by the application.

All are fully autoclavable (up to 135°C).

Statement of the Intended Use: Attachments are used in combination with a 20R "E" type slow speed handpiece motor to prepare carious teeth for restoration; to perform prophylaxis or other general procedures performed by the dentist in the oral cavity.

Technological Characteristics: Athena attachments are similar to predicate devices in indications for use, design (Nosecones: E type/Midwest/Star coupling, mechanically driven, accepts U type attachments as well as standard burs. Contra angles: E type/ Midwest coupling, mechanically driven, accepts standard 14 tooth attachments.); material (aluminum, stainless steel and brass); energy source (air).

Sterilization Test and Anaylsis: Autoclave procedures for the Compact Nosecone, 1:1Contra Angle, 64:1 Contra Angle, Heavy Duty 1:1 Straight Nosecone and Heavy Duty 4:1 Straight Nosecone were conducted in a Pelton & Crane Validator 8 at Athena Technology, Inc., 984 N. Amelia Ave., san Dimas, CA 91773, (800) 253-1771. Biological indicator used was Sportrol Spore Strip @10^6, bacillus stearothermophilus. Manufacturers lot #S51703 with an expiration date of May 1999. The biological testing facility was Namsa, 9 Morpan, Irvine, CA 92718, (714) 951-3110.

A spore strip was inserted into the drive tubes of one each of the above named devices. The devices were placed in Athena standard autoclave bags and then placed in the autoclave according to the recommendations received with the spore strips.

The devices were placed on a tray with a pair of tweezers to be used for the removal of the spore strips. In addition, a stainless steel plate was inserted into the autoclave to provide a sterile surface for the device on the removal from the autoclave.

The sterilization cycle in the Pelton & Crane Validator 8 consisted of 12 minutes at 132 degrees Celsius and 210 kPa pressure.

The devices were removed from the autoclave using sterile gloves and the spore strips removed with the sterile tweezers. The spore strips were sealed in individual bags and identified. They were then forwarded to Namsa for incubation.

The spore strips were cultured at Namsa for a period of 7 days using the procedure/test medthod S-04491-01-00/Immersion. The spore strips tested sterile by Namsa (report included.)

In conclusion, Athena devices ssterilized in a Pelton & Crane Validator 8 or similar autoclave at 132 degrees Celsius at 210 kPa for 12 minutes will be sterile.

Life Cycle Estimates: The Athena Compact Nosecone, 1:1 Contra Angle, 64:1 Contra Angle, Heavy Duty 1:1 Straight Nosecone and Heavy Duty 4:1 Straight Nosecone have estimated minimum life cycles of 500 cycles when autoclaved for 12 minutes at 132 degrees Celsius and 210 kPa pressure.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 13 1998

Mr. William T. Anderson
President
Athena Technology, Incorporated
984 North Amelia Avenue
San Dimas, California 91773

Re: K974670
Trade Name: Athena 1:1 Contra Angle, Athena 4:1 Contra Angle, Athena 16:1
Regulatory Class: I
Product Code: EFB
Dated: December 12, 1997
Received: December 15, 1997

Dear Mr. Anderson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531

through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 3: Statement of Indications for Use

Intended Use: Attachments are used in conjunction with a 20R "E" type slow speed handpiece motor to prepare carious teeth for restorations; to perform prophylaxis or other general procedures performed by the dentist in the oral cavity or in a laboratory environment.

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K974470

Prescription Use ✓
(Per 21 CFR 801.109)