

K974671

## Section 8: 510(k) Summary

MAR 11 1998

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

(800) 253-1771  
FAX (800) 722-4460

**Contact:** William T. Anderson

### **Date Prepared:**

**Device Name:** Trade or Proprietary Name - Athena 20R E Type Motor  
Common or Usual Name - Slow Speed Dental Handpiece Motor  
Classification Name - Air Powered Dental Handpiece

**Identification:** The following devices are identified to be equivalent in indications for use, design, material and energy source to Athena's 20R "E" Type Slow Speed Dental Handpiece motor:

- A. Champion Lowspeed Handpiece Motors marketed by Champion Dental Products Inc., 1941 Miraloma, Placentia, California 92870; and
- B. Lynx Low Speed Handpiece Motors marketed by MTI Precision Products, 175 Oberlin North Avenue, Lakewood, New Jersey 08701; and
- C. KaVo Handpieces marketed by KaVo America Corporation, 2401 West Hassell Road, Hoffman Estates, Illinois 60195; and
- D. Medidenta Slow Speed Motors marketed by Medidenta International, Inc., 39-23 62nd Street, Woodside, New York 11377.

**Description:** 20R "E" type slow speed dental handpiece motor; fully autoclavable (up to 135°C); utilizes an E type coupling to accept standard E type attachments. ISO couplings B, C and D are available.

**Device Function:** With the air driven motor, air is delivered through a port system which will allow forward, reverse or no operation to a vaned rotor system. The rotor spins as a result of the air delivery and that rotation is converted to RPM and torque used to operate any attachment coupled to the motor.

**Significant Physical and Performance Characteristics:** The exploded drawing (attached) illustrates the typical placement and function of the various components and parts of the motor. Air enters through the hose connector into the drive air port. That air is routed through the air delivery passages to the proper port which controls the direction of rotation of the motor. That porting arrangement is controlled by a rotary ring which permits the user to control either direction or operation. The air, having been ported, enters the motor stator body and impinges on the blades attached to the rotor causing them to spin in the appropriate direction. After approximately a 2/3 to 3/4 revolution, the air is permitted to exhaust from the stator cavity and is expelled from the motor through the exhaust porting to the exhaust tube attached to the air delivery and exhaust hose.

**Materials Used:** The motor is principally made of the following materials: aluminum; stainless steel and instrument quality stainless steel. Alternatively titanium is used in place of aluminum and stainless steel in certain applications. VITON is used for "O" rings. Flourosilicone is used for the hose to motor gasket.

**Material Physical Properties:** Aluminum Type 2011 or 6016 is used. Physical properties associated with these materials is defined by ASTM specification. Commonly used in medical and dental instruments and devices. Stainless steel type 300 series and 416 used. Physical properties associated with these materials is defined by ASTM specification. Commonly used in medical and dental instruments and devices. VITON is a medical grade, FDA approved elastomer commonly used in various of medical and dental instruments and devices. Flourosilicone is a commonly used gasket material for medical and dental instruments and devices.

**Statement of the Intended Use:** Use in combination with attachments, i.e., a nosecone or contra angle to prepare carious teeth for restorations; to perform prophylaxis; endodontic preparations or other procedures used by a dentist in the oral cavity.

**Technological Characteristics:** The Athena 20R "E" Type Slow Speed Handpiece Motor is similar to predicate devices in indications for use, design (E couplings and ISO couplings); material (aluminum, stainless steel, VITON and flourosilicone); energy source (air).

**Sterilization Test and Anaylsis:** Autoclave procedures for the 20R "E" type slow speed motor 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<sup>6</sup>, bacillus stearothermophilus. Manufacturers lot #S51703 with an expiration date of May 1999. The biological testing facility was Namsa, 9 Morgan, Irvine, CA 92718, (714) 951-3110.

One Athena 20R "E" type motor was disassembled and a spore strip inserted into the rotor area of the motor. The motor was reassembled, inserted into an Athena standard

autoclave bag and placed into the autoclave according to the recommendations received with the spore strips.

The 20R "E" type motor was 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 device was removed from the autoclave using sterile gloves and the spore strip removed with the sterile tweezers. The spore strip was sealed in bag and identified. It was then forwarded to Namsa for incubation.

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

In conclusion, Athena devices sterilized 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 20R "E" Type Slow Speed Motor has an estimated minimum life of 500 cycles when autoclaved for 12 minutes at 132 degrees Celsius and 210 kPa pressure.

Confidential  
MS017-101

Lab No. 97C 22873 00  
P.O. No. 97112006

ATHENA TECHNOLOGY INC  
984 N. AMELIA AVE.

ID No. Not Applicable

SAN DIMAS, CA 91773  
ATTN: WILLIAM T. ANDERSON

### STERILITY TEST

Testing Follows USP Methods or the Client's Procedures

**Test Article:** ATHENA 20R "E" Type Slow Speed Handpiece Motor, ATHENA Compact Nosecone, ATHENA 1:1 Contra Angle, ATHENA 64:1 Contra Angle, ATHENA Heavy Duty 1:1 Straight Nosecone, ATHENA Heavy Duty 4:1 Straight Nosecone  
**Procedure/Test Method:** S-04491-01-00/Immersion  
**Test Article Received:** 11-21-97  
**Test Start Date:** 11-21-97  
**Test Termination Date:** 11-28-97

### STERILITY TEST RESULTS

Test Article Identity Maintained as Submitted by Client

**BIOINDICATOR:** *B.subtilis*

**B.I. Lot Number:** Not Supplied

Articles Tested	Number of Articles Tested	Type of Media	Incubation Temperature (Degrees C)	Number of Days Incubated	Number of Positive Articles
Spore Strip	6	SCDB 15 ml	30-35	7	0
Positive Control	2	SCDB 15 ml	30-35	1	2

Results and conclusions apply only to the test article tested. No further evaluation of these results is made by NAMSA. Any extrapolation of these data to other samples is the responsibility of the sponsor.

**Conclusion:** TEST ARTICLE MEETS THE REQUIREMENTS OF THE STERILITY TEST

SCDB = Soybean Casein Digest Broth

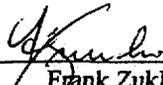
**Record Storage:**

All raw data pertaining to this study and a copy of the final report are to be retained in designated NAMSA archive files.

**Test Facility:**

North American Science Associates, Inc., California Division.

rh Date Completed 11/25/97

Approved By   
Frank Zuklic, M. S.



JUN 18 2002

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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

Re: K974671

Trade/Device Name: Athena 20R "S" Type Slow Speed Handpiece Motor  
Regulation Number: Air Powered Dental Handpiece  
Regulation Name: 872.4200  
Regulatory Class: I  
Product Code: EFB  
Dated: December 12, 1997  
Received: December 15, 1997

Dear Mr. Anderson:

This letter corrects our substantially equivalent letter of March 11, 1998 regarding the product code.

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.

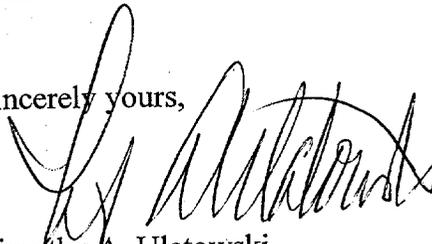
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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); 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.

This letter will allow you to begin marketing your device as described in your Section 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 21 CFR Part 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/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: Use in combination with attachments, i.e., nosecone or contra angle to prepare carious teeth for restorations; to perform prophylaxis; endodontic preparation or other procedures used by a dentist in the oral cavity.

*Susan Runner*

(Division Sign-Off)

Division of Dental, Infection Control,  
and General Hospital Devices

510(k) Number

K974671

3-1

Prescription Use   
(Per 21 CFR 801.109)