JUN 3 0 2003

June 23, 2003 Revised -
Safety and Effectiveness and of Summary of Performance Data and Cytotoxicity Data Review for the
Apex™ Electric Handpiece System - Original 510(k) Premarket Notification, Lares® Research, Inc.

K031540

This 510(k) summary of safety and effectiveness information was submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

I. Submitted By: Lares Research, Inc.
295 Lockheed Avenue
Chico, CA 95973 USA
Contact: John Dahlgren
Telephone: 530-345-1767 x262
Fax: 530-345-1870
E-Mail: jdahlgren@laresdental.com

II. Date: 510(k) prepared April 6, 2003

III. 510(k) Reason: Marketing and commercial distribution of this device for the first time.

IV. Trade Name: Apex™ Electric Handpiece System

V. Classification Name: Dental Handpiece and Accessories (21 CFR 872.4200)

VI. Classification: The device is a general control of Class I according to 21CFR 872.4200

VII. The Apex™ Dental Device Description and List of Predicate Devices

Company	Device	510(k) No.	Date Cleared
Bien Air USA, Inc.	**ORL-E-92 Surgical Drill System**	**K984244**	**02/23/1999**
W & H	**Synea WA-99LT**	**K993526**	**01/11/2000**
NSK	**Speed Increaser Contra Angle**	**K972569**	**10/08/1997**

The **Apex™ Electric Handpiece System** is a pneumatic/electronic controlled drive for dental drilling applications. The system consists of (3) components: A commercially-available electronic control system and electric motor and, Contra Angle dental instrument.

VIII. Biocompatibility/Cytotoxicity Data Evaluation: Nelson Laboratories (Salt Lake City, UT) was contracted to carry out a biocompatibility-cytotoxicty evaluation of this Lares Research **Apex™ Electric Handpiece System** after treatment with the Lares Handpiece Conditioner (with lubricant and solvent). Nelson Labs performed a Minimum Essential Medium [MEM] Elution on three (3) separate Lares Handpiece samples [See Appendix #3: Nelson Laboratories MEM Elution [and Cytotoxicty Evaluation] Method and Appendix #4: Nelson Laboratories MEM Elution – Final Report for the Lares Research Apex 200LS Contra-Angle Electric Handpiece Instrument] beginning June 13 and ending June 19, 2003.

This type of testing was designed to evaluate the cytotoxicty of any extractable substances or residues associated with the 3 Lares Handpiece samples immediate after the described treatment protocol with the separately sold Lares Research Conditioner [with lubricant and solvent]. The extract of the samples was added to cell line monolayers (Mouse Heteroploid Connective Tissue L-929), and the extract and confluent monolayers incubated at 37°C with 5 +/-1% CO2 for 48 +/- 3 hrs. Cell monolayers were examined microscopically, and scored on the basis of the degree of cellular death and/or damage. Pages 5 – 8 of the attached Nelson Laboratories MEM Elution – Final Report [dated 6-19-03] for the Lares Research Apex 200LS Contra-Angle Electric Handpiece Instrument has provided results demonstration grade zero (0) = No Cellular Destruction was indicated. The 3 Lares Handpiece samples tested, even after the described treatment protocol with the separately sold Lares Research Device Conditioner [with lubricant and solvent], gave No indication that any cytotoxicity substances were extractable [page 8 of the Nelson report of 6/19/03]. Thus the Lares Handpiece Conditioner was deemed to be biocompatible for use with these Handpieces.

IX. Indications for Use: The Lares Research **Apex™ Electric Handpiece System** ("System" defined as and limited to: A. Contra Angle Dental Instrument B. Electric Motor and C. Control System) device consists of a dental handpiece and accessories as listed in 21 CFR 872.4200, product code EKX that is a Class I, non-exempt hand-held dental device for dental drilling applications. This device is indicated for use where high speeds are required in general dentistry with or without the use of coolant where precision control of the cutting bur is desired such as cutting a tooth for caries, and/or crown preparation and finishing, cutting and/or finishing for dentures, denture bases, crowns, inlays and metal plates and/or root canal preparation for restoration. The **Apex™ Electric Handpiece System** device is also indicated for use in difficult to reach areas in general dentistry with or without the use of coolant where precision control of the cutting bur is desired such as the preparing dental caries for restorations, and for use at low speeds in teeth cleaning applications and dental surface polishing. The **Apex™ Electric Handpiece System** device is driven by an electronically controlled DC *electric motor* with a pneumatic/electronic actuated *control system* that is connected to the *Contra Angle dental instrument* via an ISO-3964 coupling. **The Apex™ Electric Handpiece System** device is indicated for use by dental professionals only.

X. Technical Characteristics: The Apex™ Electric Handpiece System consists of a console type desktop housing with the electronic microprocessor with integrated electric and pneumatic-electric controls, a high-torque motor sealed against lubrication from handpieces with removable motor sleeve and, Contra Angle dental instrument.

The Apex™ Electric Handpiece System uses a DC controlled micromotor as the driving element of the system, controlled by an electronic microprocessor that is actuated by the practicing dentist's existing air delivery system via foot pedal. Rotation of the dental instrument is controlled by the translation of air to electrical power wherein a wide range of speeds can be achieved and maintained resulting in a precise control of torque and light at the procedure site.

XI. Principle of Operation: The three components of the Apex™ Electric Handpiece System work in unison to deliver precise torque, speed and light at the procedure site. The principle of operation is as follows:

Apex™ Control System: The Apex™ Control System connects to an existing air unit allowing the use of the Apex™ Electric Motor. Connection of the Apex™ Control System is accomplished via existing four-hole tubing from air supply. The air pressure is reduced to accommodate proper connection of the control. The Control System is then plugged into an existing 110V electrical outlet.

Apex™ Electric Motor: The output tubing from the Apex™ Control System is located and connected to the Apex™ Electric Motor. When connected, the existing air supply foot pedal is depressed and the air pressure is increased to operating levels while the electric motor is running.

Apex™ Contra Angle Dental Instrument: The Apex™ Contra Angle Dental Instrument is connected to the Apex™ Electric Motor via an ISO 3964 coupler. The Apex™ Electric Handpiece System is now ready for use. The dental professional then mounts the bur of choice for the procedure.

At this time, the operator then selects an appropriate speed via the Apex™ Control System control panel labeled "Motor Speed". Rotation direction can be set at the Apex™ Control System control panel to either "forward" or "reverse". Once desired speed and proper rotation initiated, the operator can proceed with the dental procedure accordingly.

XII. Substantial Equivalence Comparison – Micromotor and Control:

	Bien Air ORL-E-92	**Lares Apex™**	**Substantial Equivalence**
Indications for Use	Indicated for the preparation of intra-oral bone for microsurgery and implantology and for apicoectomies. The device is driven by an electric micromotor or an air motor handpiece that has the IS0-3964 Coupling.	Indicated for use where high speeds are required in general dentistry with or without the use of coolant where precision control of the cutting bur is desired such as cutting a tooth for caries, and/or crown preparation and finishing, cutting and/or finishing for dentures, denture bases, crowns, inlays and metal plates and/or root canal preparation for restoration. The device is driven by an electronically controlled DC electric motor with a pneumatic/electronic actuated control system that is connected to the Contra Angle dental instrument via an ISO-3964 coupling.	Yes
Input Voltage	115V/230V AC 50/60 Hz	110V/220V AC 50/60 Hz	Yes
Materials	Electronic and mechanical parts and components	Electronic and mechanical parts and components	Yes
Drive Delivery	DC Micromotor with Controller	DC Micromotor with Controller	Yes
Sterilization	Removable Motor Cover is Autoclavable at 135°C	Removable Motor Cover is Autoclavable at 135°C	Yes

XII. Substantial Equivalence Comparison – Contra Angle:

	Bien Air ORL-E-92	Lares Apex™	Substantial Equivalence
Indications for Use	When used in conjunction with the micromotor and control indicated above, the device is intended for use where high speed is required in general dentistry with or without use of coolant; such as cutting a tooth for cavity and/or crown preparation and finishing, cutting and/or finishing of dentures, denture bases, crowns, inlays and metal plates.	When used in conjunction with the micromotor and control indicated above, the device is indicated for use where high speeds are required in general dentistry with or without the use of coolant where precision control of the cutting bur is desired such as cutting a tooth for caries, and/or crown preparation and finishing, cutting and/or finishing for dentures, denture bases, crowns, inlays and metal plates and/or root canal preparation for restoration. The device is also indicated for use in difficult to reach areas in general dentistry with or without the use of coolant where precision control of the cutting bur is desired such as the preparing dental caries for restorations, and for use at low speeds in teeth cleaning applications and dental surface polishing.	Yes
Speeds	Bien Air CA 1541 1:5 0-200K Bien Air CA 1142 1:1 0-40K Bien Air CA 10141 10:1 0-4K	Apex™ 200LS 1:5 0-200K Apex™ 40LS 1:1 0-40K Apex™ 10LS 5:1 0-7K	Yes
Lighting	Yes	Yes	Yes
Water Spray	Yes-Triple Port	Yes-Triple Port	Yes
Bur Release	Push Button	Push Button	Yes
Coupler	ISO 3964 Compatible	ISO 3964 Compatible	Yes
Sterilization	135°C Autoclavable	135°C Autoclavable	Yes

The Lares Research **Apex™ Electric Handpiece System** device is substantially equivalent to the Bien Air ORL-E-92 Surgical Drill System in commercial distribution by Bien Air USA, Inc. The fundamental technical characteristics of the **Apex™ Electric Handpiece System** are similar to those of the predicate devices, principally the Bien Air ORL-E-92 Surgical Drill System. The **Apex™ Electric Handpiece System** is equivalent to the Bien Air ORL-E-92 Surgical Drill System in design, speed, rotation, irrigation and autoclavability. Both **Apex™ Electric Handpiece System** and Bien Air ORL-E-92 Surgical Drill System use an electric micromotor, parts of which are autoclavable and an electronic control for speed regulation and direction. The range of speed of this device is equivalent to predicate devices and both systems use contra angled handpieces.

XIII. Performance Data: No formal performance data was submitted for this Class I device. Lares Research, Inc. has taken all steps necessary to assure that the **Apex™ Electric Handpiece System** meets all applicable ISO, IEC and FDA Guidance Standards listed in Section XV of this document and all data supporting this statement is available at Lares Research for review by any authorized agents of the Food and Drug Administration (FDA).

XIV. 510(k) Checklist: This notification contains all information required by 21 CFR 807.87

XV. Applicable Standards:

Guidance Documents:

Guidance Document on Dental Handpieces, issued July 1995 via the Internet at:
http://www.fda.gov/cdrh/ode/556.pdf

Dental Handpiece Sterilization as issued September, 1992 via the Internet at:
http://www.fda.gov/cdrh/comp/589.pdf

Device Safety:

IEC 601-1, IEC 601-1-2, IEC-IA (as equivalent and fully corresponding to the European standards EN 60601-1, EN 60601-1-2, EN 60601-14)

EMC Compatibility:

IEC 601-1-2 with reference to EN 55011, EN 610004-2, EN 610004-3, EN 6100044, EN 610004-5: conformity has been certified during an independent examination by a competent body.

Dental Handpieces:

ISO 3964 Dental Handpieces – Coupling Dimensions

ISO 7785-2 Dental Handpieces – Part 2: Straight and geared angle handpieces

ISO 9687 Dental Equipment – Graphical Symbols

ISO 11498.1 Dental Handpieces – Dental Low Voltage Electrical Motors

XVI. 510(k) Contact Person:

For further information, please contact:

John Dahlgren, Director of Regulatory Affairs
Lares Research, Inc., 295 Lockheed Avenue,
Chico, CA 95973 USA
Telephone: 530-345-1767 x262; Fax: 530-345-1870
E-Mail: jdahlgren@laresdental.com

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 3 0 2003

Lares Research, Incorporated
C/O Mr. Alfredo J. Quattrone
Responsible Third Party Official
California Department of Health Services
Food & Drug Branch
P.O. Box 942732 (MS-357)
Sacramento, California 94234-7320

Re: K031540
Trade/Device Name: Apex™ Electric Handpiece System
Regulation Number: 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EKX
Dated: June 23, 2003
Received: June 24, 2003

Dear Mr. Quattrone:

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), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K031540

INDICATIONS FOR USE

510(k) Number (if known): _____

Device Name: Apex™ Electric Handpiece System

Indications for Use:

The Lares Research Apex™ Electric Handpiece System ("System" defined as and limited to: A. Contra Angle Dental Instrument B. Electric Motor and C. Control System) device consists of a dental handpiece and accessories as listed in 21 CFR 872.4200, product code EKX that is a Class I, non-exempt hand-held dental device for dental drilling applications. This device is indicated for use where high speeds are required in general dentistry with or without the use of coolant where precision control of the cutting bur is desired such as cutting a tooth for caries, and/or crown preparation and finishing, cutting and/or finishing for dentures, denture bases, crowns, inlays and metal plates and/or root canal preparation for restoration. The device is also indicated for use in difficult to reach areas in general dentistry with or without the use of coolant where precision control of the cutting bur is desired such as the preparing dental caries for restorations, and for use at low speeds in teeth cleaning applications and dental surface polishing. The Apex™ Electric Handpiece System device is driven by an electronically controlled DC *electric motor* with a pneumatic/electronic actuated *control system* that is connected to the *Contra Angle dental instrument* via an ISO-3964 coupling. The Apex™ Electric Handpiece System device is indicated for use by dental professionals only.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ken Melly for NSR

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

510(k) Number: K031540

Prescription Use: X OR Over-The-Counter Use: _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)