2/23/99

K984244

SECTION 13: SUMMARY OF SAFETY AND EFFECTIVENESS

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

13.1 SUBMITTER INFORMATION

a.	Company Name:	Bien-Air USA, Inc.
b.	Company Address:	19600 Fairchild Road, Suite 250 Irvine, CA. 92612
c.	Company Phone: Company Facsimile:	(949) 477-6050 (949) 477-6051
d.	Contact Person:	Arthur Mateen Branch Manager
e.	Date Summary Prepared:	February 17, 1999

13.2. DEVICE IDENTIFICATION

a.	Trade/Proprietary Name:	ORL-E-92 Surgical Drill System
b.	Classification Name:	Dental Handpieces and Accessories 21 CFR 872.4200

13.3 IDENTIFICATION OF PREDICATE DEVICES

Company	Device	510(k) No.	Date Cleared
KaVo America	Intrasept 905	K934783	05/16/94
Jedmed	Fisch Drill System	K792159	11/27/79

13.4 DEVICE DESCRIPTION

The Bien-Air ORL-E-92 Surgical Drill System is a series of components used in implantology and microsurgery. The system consists of a foot pedal control unit, BASCH electric micromotor and cable and transformer. Several models of straight and contra-angled microsurgery handpieces are available for use with the ORL-E-92 system. A separate irrigation system consisting of peristaltic pump, irrigation tubing and solution supports complements the ORL-E-92 system.

13.5 SUBSTANTIAL EQUIVALENCE

The Bien-Air ORL-E-92 Surgical Drill System is substantially equivalent to the Intrasept 905 System in commercial distribution by KaVo America and the Fisch Drill System in commercial distribution by Jedmed.

The fundamental technical characteristics of the Bien-Air ORL-E-92 Surgical Drill System are similar to those of the predicate devices. The Bien-Air ORL-E-92 System is equivalent to the Intrasept 905 in design, speed, rotation, irrigation and autoclavablity. Both the ORL-E-92 system and the predicate devices use an electric micromotor which is autoclavable. The range of speed of the system is equivalent with all systems. The ORL-E-92 system and the Intrasept 905 use similar models of straight and contra-angled handpieces. The ORL-E-92 system is identical to the Fisch Drill System with the exception of the indications for use.

13.6 INDICATIONS FOR USE

The Bien-Air ORL-E-92 Surgical Drill System is indicated for the preparation of intraoral bone for microsurgery and implantology and for apicoectomies.

13.7 TECHNOLOGICAL CHARACTERISTICS

A comparison of the technological characteristics of the Bien-Air ORL-E-92 Surgical Drill System with the predicate device is provided within this submission. The ORL-E-92 Surgical Drill System consists of a multifunctional foot pedal, electric micromotor and cable and various straight and contra-angled handpieces. There are four speed ranges to select from with the maximum speed being 40,000 rpm. The foot pedal controls all functions of the system and a supporting irrigation system. The ORL-E-92 can accommodate two BASCH electric micromotors with adjustable speed and rotation.

13.8 PERFORMANCE DATA

No formal performance data was submitted for this Class I device. Sterilization certification of the product by steam sterilization was provided within this notification.

13.9 510(K) CHECKLIST

This notification contains all information required by 21 CFR 807.87. A completed copy of the Premarket Notification 510(k) Reviewer's Checklist is provided in this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 23 1999

Bien-Air USA, Incorporated
C/O Ms. Carol Patterson
Consultant
Patterson Consulting Group, Incorporated
18140 Smokesignal Drive
San Diego, California 92127

Re: K984244
Trade Name: ORL-E-92 Surgical Drill System
Regulatory Class: I
Product Code: EFB
Dated: October 28, 1998
Received: November 27, 1998

Dear Ms. Patterson

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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) 594-4692. 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

INDICATION FOR USE

510(k) Number: K984244

Device Name: Bien-Air ORL-E-92 Surgical Drill System

Indications for Use: The Bien-Air ORL-E-92 Surgical Drill System is indicated for the preparation of intraoral bone for microsurgery and implantology and for apicoectomies.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K984244