K991401 DEC 15 1999

SECTION 14: 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.

14.1 SUBMITTER INFORMATION

a. Company Name:	Advanced Technology Research
b. Company Address:	Via Giovanni Verga, 7 51100 Pistoia ITALY
c. Company Phone: Company Facsimile:	39 (0) 573 364 254 39 (0) 573 364 002
d. Contact Person:	Sandra Giusti President
e. Date Summary Prepared:	April 21, 1999

14.2. DEVICE IDENTIFICATION

a. Trade/Proprietary Names:	ATR 3000, ATR 2000, Implant-Pro
b. Classification Name:	Dental Handpiece and Accessories 21 CFR 872.4200

14.3 IDENTIFICATION OF PREDICATE DEVICE

Company	Device	510(k) No.	Date Cleared
MicroMotors	Dynasurg Electric Handpiece and Irrigation System	K911068	05/15/91

14.4 DEVICE DESCRIPTION

The ATR Surgical Micromotors are microprocessor driven surgical micromotors used in implantology procedures. The ATR Surgical Micromotors consist of a

microprocessor control unit, foot pedal, electric micromotor, support rods and sterile irrigation tubes. The microprocessor unit also houses the peristaltic pump. The ATR Surgical Micromotors provide electronic control of velocity and torque. The ATR Surgical Micromotors can be programmed and retains up to five programs in memory. The ATR Surgical Micromotors are also fully operational from the foot pedal. The foot pedal not only controls the functions of the ATR Surgical Micromotors, but it can also be used for programming.

14.5 SUBSTANTIAL EQUIVALENCE

The ATR Surgical Micromotors are substantially equivalent to the Dynasurg Electric Handpiece and Irrigation System in commercial distribution by Micro Motors.

The fundamental technical characteristics of the ATR Surgical Micromotors are similar to those of the predicate device and are listed on the comparison charts provided in this 510(k) submission. The ATR Surgical Micromotors and the predicate device consist of a control unit, electric micromotor, footswitch and irrigation system. The ATR Surgical Micromotors and the predicate device have adjustable speeds, torque and reduction rates, and are programmable. The micromotor of the ATR Surgical Micromotors and the predicate device is autoclavable.

14.6 INTENDED USE

The ATR Surgical Micromotors are intended for the preparation of intraoral bone for implantology procedures.

14.7 TECHNOLOGICAL CHARACTERISTICS

A comparison of the technological characteristics of the ATR Surgical Micromotors with the predicate device is provided within this submission. The ATR Surgical Micromotors are programmable and retain the programs in

memory. The ATR Surgical Micromotors have adjustable speeds and torque that are related to the reduction rate of the handpiece selected. The device has an automatic shut off safety feature in the event that the dynamic resistance of the bone exceeds the set torque value. The ATR Surgical Micromotors can be fully programmed and operated using the foot pedal.

14.8 PERFORMANCE DATA

The ATR Surgical Micromotors were subjected to performance bench testing in accordance with applicable industry and clinical standards. Physical performance studies were conducted to verify that the ATR Surgical Micromotors conformed to applicable emission, immunity and electromagnetic compatibility standards in accordance with EN and IEC regulations. Results of the testing showed that the ATR Surgical Micromotors perform as intended.

14.9 510(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

DEC 15 1999

Advanced Technology Research, S.A.S.
Ms. Carol Patterson, Consultant for
Advanced Technology Research, S.A.S.
Patterson Consulting Group, Inc.
21911 Erie Lane
Lake Forest, CA 92630

Re: K991401
Trade Name: Advanced Technology Research ATR Surgical Micromotors
Regulatory Class: I
Product Code: EFB
Dated: October 28, 1999
Received: October 29, 1999

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: ~~To Be Assigned By FDA~~ K991401

Device Name: ATR Surgical Micromotors

Indications for Use: The ATR Surgical Micromotors are intended to prepare intraoral bone for implantology procedures.

(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)

(Division Sign-Off) Susan Runner

Division of Dental, Infection Control, and General Hospital Devices

510(k) Number K991401

CONFIDENTIAL