Revised 10/31/03

NOV 25 2003

K033597

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 SMD 1990 and CFR 807.92.

14.1 SUBMITTER INFORMATION

a.	Company Name	Advanced Technology Research (A.T.R.)srl
b.	Company Address	Via del Pescino, 6 51100 PISTOIA Italy
c.	Company phone Company fax	+39 0573 364 254 +39 0573 364 002
d.	Contact Person	Daniele Poli President
e.	Date Summary Prepared	June 11, 2003

14.2 DEVICE IDENTIFICATION

a.	Trade/Proprietary Names:	ATR5000, LC5000, Implant System
b.	Classification Name:	Dental Handpieces and Accessories 21 CFR 872.4200
c.	Common Names:	Surgical Micromotor for implantology

14.3 IDENTIFICATION OF PREDICATE DEVICE

Company	Device	510(k) No.	Date Cleared
ATR	ATR3000	K991401	15 Dec. 1999

14.4 DEVICE DESCRIPTION

The ATR Surgical Micromotors ATR5000, LC5000 and Implant System, are microprocessor driven surgical micromotors used in implantology procedures. The ATR Surgical Micromotors ATR5000, LC5000 and Implant System consists of a microprocessor controlled unit, foot pedal, electric micromotor, support rods and sterile, disposable irrigation tubes.

The units also house the peristaltic pump.
The ATR Surgical Micromotors ATR5000, LC5000 and Implant System provide electronic control of velocity and torque.
The ATR Surgical Micromotors ATR5000, LC5000 and Implant System can be programmed and retain programs in memory.
The ATR Surgical Micromotors ATR5000, LC5000 and Implant System are fully operational from foot pedal.

14.5 SUBSTANTIAL EQUIVALENCE

The ATR Surgical Micromotors ATR5000, LC5000 and Implant System are substantially equivalent to the ATR3000 Surgical Micromotor in commercial distribution by ATR.
The fundamental technical characteristics of the ATR5000, LC5000 and Implant System are similar to those of the predicate device and are listed on the comparison chart provided in this 510(k) submission.
The ATR5000, LC5000 and Implant System and the predicate device have adjustable speed, torque and reduction rates, and are programmable. The micromotor handpiece of ATR5000, LC5000 and Implant System and the one of the predicate device are autoclavable.

14.6 INTENDED USE

The ATR5000, LC5000 and Implant System are intended for the preparation of intra-oral bone for implantology procedures.

14.7 TECHNICAL CHARACTERISTICS

The ATR5000, LC5000 and Implant System were designed and developed to provide a microprocessor controlled surgical system with similar performances compared to predicate device.
ATR5000, LC5000 and Implant System are equivalent in design and materials to the predicate device, have adjustable speeds and torque values (related to the reduction rate of the handpiece selected) that are fully customisable by the end user, have automatic motor shutdown system which provides to switch off the motor whenever torque set is reached, have a micromotor sterilizable according the recommended protocols, and can be operated by foot control.
Any of these feature is found in the predicate device also.
ATR5000, LC5000 and Implant System use for the central unit housing an ABS material with thickness sufficient to be classified V0 in flammability class as the predicate device.
ATR5000, LC5000 use the same micromotor and housing of the predicate device; Implant System uses the same material for micromotor housing with different dimension to fit the new brushless motor.

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ATR5000, LC5000 and Implant System were designed to use the same disposable tubing of the predicate device.
The difference between ATR5000, LC5000, Implant System and the predicate device are that :
Implant System uses a Brushless motor driving instead of a DC motor driving that is designed for the same intended use of the predicate device.

ATR5000/LC5000 and ATR ImplantSystem have new features.
All the three devices are equipped with a wider display with larger characters, and with a new larger keyboard.
ATR5000/LC5000 are equipped with the beep approaching set torque function, that warns the user when reaching 75% of set torque value. This can aid the user because increasing applied torque may depends by reaching the lower cortical part of the bone, or by reaching the mechanical breaking limit of the burr and otherwise reminds that when reaching the torque value set, the micromotor automatically shuts off.
ATR5000/LC5000 and Atr ImplantSystem footpedal control have the same control functions as predicate device.
ATR5000 and LC 5000 are equipped with I/O devices such parallel port and serial port for printer and PC connection, and smart card reader. Those devices were not present on the predicate devices. In order to maintain safety a designed hardware prevent the use of I/O devices when motor runs.
Those new features are useful to create patients archive on software or paper support, so user can quickly remind patient status and operations advancement.
Safety recommends about I/O use, and safety system that prevent the use of I/O devices when motor runs, are reported in ATR5000/LC5000 and ATR ImplantSystem user manuals.
In order to verify new devices safety issues they were designed and tested following standard requirements:

- **UL 2601-1 Standard for Medical Electrical Equipment, General requirements for Safety (IEC 60601-1 with U.S. deviations)**
- **IEC 60601-1 Medical Electrical Equipment Part 2,"Genaral Safety Norms"**
- **IEC 60601-1-2 Medical Electrical Equipment Part 1 EMC**

No I/O devices in Implant System model as in the predicate device.

14.8 PERFORMANCE DATA

The ATR 5000, LC 5000 and Implant System were tested in accordance with the technical requirements of UL 2601-1 (IEC 60601-1 with U.S. deviations), IEC 601-1 and IEC 60601-1-2 and successive variants .
We remember here that LC5000 unit is different from ATR5000 only for frontal plate graphics and model label.
Whitstanding voltage test and leak current test were performed on devices in conformance with requirements from UL 2601-1.

All evaluation of the ATR 5000, LC5000 and Implant System were performed by certified body Laboratory, and all the results comply to standard listed below.
Also the predicate device has been evaluated with the same regulation standard.
So ATR5000/LC5000 and ATR ImplantSystem and predicate device can be considered substantially equivalent in performance.

The conclusions drawn from the performance test are that ATR 5000, LC5000 and Implant System complies with:

- **UL 2601-1 Standard for Medical Electrical Equipment, General requirements for Safety (IEC 60601-1 with U.S. deviations)**
- **UL 601-1 Medical Electrical Equipment, General Requirement for Safety**
- **IEC 55011 EMC Conducted RF emissions**
- **IEC 60529 Degrees of protection provided by enclosures (IP Code)**
- **IEC 60601-1 Medical Electrical Equipment Part 2,"Genaral Safety Norms"**
- **IEC 60601-1-2 Medical Electrical Equipment Part 1 EMC**
- **IEC 61000-4-2 EMC Electrostatic Discharge Immunity**
- **IEC 61000-4-3 Radiated RF immunity**
- **IEC 61000-4-4 Fast Transient Immunity**
- **IEC 61000-4-5 Pulse immunity**
- **IEC 61000-4-6 Conducted RF immunity**
- **IEC 61000-4-11 Supply Voltage Hole Immunity**
- **IEC 61558-1 Transformer safety**
- **IEC 61558-2-6 Transformer safety-Particular prescriptions**
- **ISO 11498:1997 Dental handpieces – Dental low-voltage electrical motors**

and are effective and safe to use.
Declaration of conformity to a standard in Chapter 12.1 of this submission.

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

NOV 25 2003

Advanced Technology Research (A.T.R) S.R.L
C/O Ms. Elizabeth Drew
Responsible Third Party Official
Underwriters Laboratories, Incorporated
1655 Scott Boulevard
Santa Clara, California 95050

Re: K033597
Trade/Device Name: Surgical Micromotors
Regulation Number: 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EKX
Dated: November 12, 2003
Received: November 14, 2003

Dear Ms. Drew:

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,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

INDICATIONS FOR USE

510(k) Number: K033597
To be Assigned by FDA

Device Name: Surgical Micromotors

Model: ATR5000
LC 5000
Implant System

Indications for Use: These 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)

R.Beth DDS for Dr. Runner
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices
510(k) Number: K033597

Prescription Use ✓ OR Over-The –Counter Use _____

(Per 21 CFR 801.109)