K091913

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.

OCT 30 2009

14.1 SUBMITTER INFORMATION

a.	Company Name	BY DENTAL SRL
b.	Company Address	Via Vecchia Prov.le Lucchese 47/F 51030 Serravalle Pistoiese Italy
c.	Company phone Company fax	+39 0573 994 355 +39 0573 919 480
d.	Contact Person	Daniele Poli President
e.	Date Summary Prepared	June 22, 2009

14.2 DEVICE IDENTIFICATION

a.	Trade/Proprietary Names:	HI TECH IMPLANT /HT PHYSIO IMPLANT
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	Implant System	K033597	25 Nov. 2003

14.4 DEVICE DESCRIPTION

The HI TECH IMPLANT and HT PHYSIO IMPLANT consist of a microprocessor controlled unit, foot pedal, electric micromotor, support rods and sterile, disposable irrigation tubes.
The unit also houses the peristaltic pump.
The HI TECH IMPLANT and HT PHYSIO IMPLANT provide electronic control of velocity and torque.

The HI TECH IMPLANT and HT PHYSIO IMPLANT can be programmed and retain programs into memory.
The HI TECH IMPLANT and HT PHYSIO IMPLANT are fully operational from foot pedal.

14.5 SUBSTANTIAL EQUIVALENCE

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

14.6 INTENDED USE

HI TECH IMPLANT and HT PHYSIO IMPLANT are intended for the preparation of intra-oral bone for implantology procedures.

14.7 TECHNICAL CHARACTERISTICS

HI TECH IMPLANT and HT PHYSIO IMPLANT were designed and developed to provide a microprocessor controlled surgical system with similar performances compared to predicate device.

- HI TECH IMPLANT and HT PHYSIO IMPLANT
- is equivalent in functions to the predicate device,
- has adjustable speeds and torque values (related to the reduction rate of the handpiece selected) that are fully customisable by the end user,
- has automatic motor shutdown system which provides to switch off the motor whenever set torque is reached,
- has a sterilizable micromotor according the recommended protocols,
- can be operated by foot control.

Any of these feature is found in the predicate device also.

14.8 PERFORMANCE DATA

HI TECH IMPLANT and HT PHYSIO IMPLANT were tested in accordance with the technical requirements of IEC 60601-1 and IEC 60601-1-2.
All evaluation of the HI TECH IMPLANT and HT PHYSIO IMPLANT were performed by Notified Laboratory, and all the results comply to standard listed below.

The conclusions drawn from the performance test are that HI TECH IMPLANT and HT PHYSIO IMPLANT comply with:

- 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
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Dr. Daniele Poli
President
By Dental S.R.L.
Via Vecchia Prov. le Lucchese 49/FG
Serravalle Pistoiese, Pistoia
ITALY 51030

OCT 30 2009

Re: K091913
Trade/Device Name: Hi-Tech Implant/HT Physio Implant
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
8Regulatory Class: I
Product Code: EKX
Dated: September 21, 2009
Received: September 29, 2009

Dear Dr. Poli:

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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Susan Runner, D.D.S., M.A.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K091913

BY DENTAL: Hi-Tech Implant/HT Physio Implant
510(k): Original Submission Traditional

INDICATIONS FOR USE

510(k) Number: To be Assigned by FDA

Device Name: **Hi-Tech Implant/HT Physio Implant**

Indications for Use: Hi-Tech Implant/HT Physio Implant 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 X OR Over-The-Counter Use_____

(Per 21 CFR 801.109)

Kei Mulay for MSR

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

510(k) Number: K091913