

510(k) Summary of Safety & Effectiveness

K071803

Pursuant to CFR 807.92, the following 510(k) Summary is provided:

- SEP - 5 2008
1. (a) **Submitter Address:** George J. Hattub
MedicSense, USA
291 Hillside Avenue
Somerset, MA 02726
www.medic sense.com
 1. (b) **Manufacturer Address:** ARDS, Ltd.
4 Hasikma St.
Rishon Lezion, Israel 75201
Mfg. Phone: 972-3-969-0954
Contact Person: Dr. Uri Arny, CEO
Date: March 7, 2008
 2. **Device & Classification Name:** Endosseous Dental Implant, Class 2, Product Code DZE, 21 CFR 872.3640
ARDS Dental Implants
 3. **Predicate Device:** Alpha Bio Dental Implant System (K063364)
 4. **Description:** ARDS implants are made from Titanium alloy. The ARDS implants geometrical shape is characterized by altering drilling profile, with double thread at the upper part that change to one thread at the lower part, which increases its surface, and as a result, increases in the preliminary contact surface with the bone.

The ARDS dental implants are :
S type: Internal hex implants, length 10/13 mm, diameter 3.75/4.5 mm, with double thread at the upper part that goes over in a single thread at the lower part.

S implant types are supplied sterile in a double vial system, inside a plastic box which includes the covering screw and the Instructions For Use.

The abutments are for single use only and supplied non-sterile.

The tools are reusable and supplied non-sterile, they must be sterilized by autoclave before use.
 5. **Intended Use:** ARDS dental implants are indicated for use in surgical and restorative applications for placement in the bone of the upper and lower jaw to provide support for prosthetic devices in order to restore the patient's chewing function. ARDS dental implants are indicated for two-stage surgery.
 6. **Comparison of Technological Characteristics:** With respect to technology and intended use, the ARDS dental implants are substantially equivalent to its predicate device which is the Alpha Bio Dental Implant System. The primary differences are propriety in nature. Based upon its testing results, ARDS believes these differences do not raise additional safety of efficacy concerns.

Revised March 9, 2008



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 5 2008

Ards, Limited, RAC & CQE
Mr. George J. Hattub
Senior Staff Consultant
Medicsense, USA
291 Hillside Avenue
Somerset, Massachusetts 02726

Re: K071803
Trade/Device Name: ARDS Dental Implants
Regulation Number: 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: August 12, 2008
Received: August 14, 2008

Dear Mr. Hattub:

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 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 postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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,



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

Enclosure

Indications for Use

510(k) Number (if known): K071803

Device Name: ARDS Dental Implants

Indications For Use: ARDS dental implants are indicated for use in surgical and restorative applications for placement in the bone of the upper and lower jaw to provide support for prosthetic devices in order to restore the patient's chewing function. ARDS dental implants are indicated for two-stage surgery.

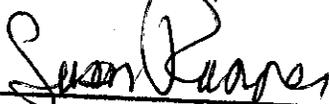
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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