

K973926

JAN - 5 1998

510(K) SUMMARY

September 30, 1997

Contact Person: David D. Dalise
President / owner, "O" Company, Inc.

Trade Name: "O" Butment HS Implant
Common Name: Endosseous Screw Implant
Classification Name: Dental Implant Endosseous / Code 76DZE

Substantial Equivalence to: "O" Butment ES Implant referenced as K923889 and
Screw-Vent Implant referenced as K900179

Description of Device: A cylinder shaped commercially pure titanium dental
implant with external threads and a Hydroxylapatite Coating.

Intededed Use: The titanium endosseous implant is a device intended to be surgically
placed in the bone of the upper or lower jaw arches to provide support for
prosthetic devices.

Substantial Equivalence: Substantial Equivalence for the "O" Butment HS Implant is
is based on the following comparison of predicate devices such as "O"
Company's "O" Butment ES Implant and Dentsply's Screw Vent
Implant. The design, function, labeling, material composition and intended use is
equivalent to the devices currently marketed.

Non-clinical tests: Based on lateral and vertical stress analysis performed by Rocky Mountain
Testing, it has been determined that the physical integrity of the implant
has not been compromised by the modifications.

This data supports our determination that the "O" Butment HS Implant is substantially equivalent to the "O"
Company's "O" Butment ES Implant (K923889) and Dentsply's Screw Vent Implant (K900179).



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 5 1998

Dr. David D. Dalise
President/Owner
"O" Company, Incorporated
600 Paisano, N.E., Suite A
Albuquerque, New Mexico 87123

Re: K973926
Trade Name: "O" Butment HS Implant
Regulatory Class: III
Product Code: DZE
Dated: September 30, 1997
Received: October 15, 1997

Dear Dr. Dalise:

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.

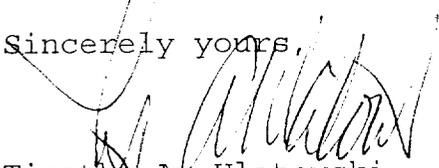
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) 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 pre-market 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) 594-4618. 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

K973926
n/a

510(k) Number (if known): _____

Device Name: Dental Implant Endosseous

Indications For Use:

"O" Company's Titanium CP Endosseous Implant is intended to be surgically placed in the bone of the upper or lower jaw arches providing support for prosthetic devices resulting in the restoration of the patient's chewing function.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donald Shupps

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

510(k) Number K973926

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____