

MAR 16 1998

K980442

**XIV. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS DATA. (Separate Page)**

A. Submitter: Clint Folsom, Crystal Medical Technology, Inc., 181 Cahaba Valley Pkwy, Pelham, AL 35124. Registration No. 51805.

I. Classification Name and Number: Endosseous Implant (76DZE),

II. Common/Usual Name: Dental Implant, Endosseous, Post (or screw)-type, titanium or titanium alloy.

III. Proprietary Name: CRYSTAL and CRYSTAL-SEAL Implants System

IV. Classification: This device is being finally classified by the Dental Devices Panel (Title 21 CFR 872.3640).

V. Performance standards: None applicable. Materials meet ASTM voluntary standards

VI. Description: The CRYSTAL Implants System implants are post-type endosseous dental implants with design and manufacturing concepts, materials, surgical procedures, and intended uses quite similar to the preamendment device and to others rated substantially equivalent to the preamendment device. This CRYSTAL-SEAL system is most similar to the Crystal and Crystal Plus Implants System which received concurrence of substantial equivalence from the Food and Drug Administration in premarket notification submission K-954432. Like many commercial implants, the CRYSTAL devices are manufactured of high-purity (99+ %) titanium, or titanium alloy (ASTM F 136-84 titanium - 6 aluminum - 4 vanadium). See Appendix V for composition and characteristics of the titanium and/or titanium alloy used.

CRYSTAL Implants also are available in coated form, either hydroxyapatite or titanium plasma spray. These devices are equivalent to various coated endosseous implants on the market, for example the Sabertech implants of Genentech, Inc., which were cleared under K-924112.

VII. Labels and Instructions for Use are provided, as are labels for competitive products.

VIII. Intended Use: These devices are intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices and to restore the patient's chewing function.

VII. Substantial Equivalence: This device is equivalent to devices manufactured and sold before 1976, having a U. S. classification number of 76 DZE, and those described under 21 CFR 872.3640. It is also equivalent to several devices currently on the market that have been determined by the FDA to be substantially equivalent to the above preamendment devices, particularly to Crystal and Crystal Plus System cleared by K-954432. Some examples of other equivalent products are:

Bofors Nobelpharma, Goteborg, Sweden: Titanium Implant Device, K-820013,  
Core-Vent Corp., Encino, CA: Screw-Vent Endosseous Implants, K-861426, A, B.  
Impla-med, Inc., Sunrise, FL: P.M.T. Surgical Implant Components, K-892124A, (Titanium  
Grade 3, ASTM F67-83); K-921854.  
Steri-Oss (Subs. Denar, Anaheim, CA.), Denar Dental Implant, K-852802; Steri-Oss Implant,  
K-884845.  
Artech, Inc., Chantilly, VA: Artech Submerged Screw Implant, K-891346, K-895267.  
Odontit, SA, Buenos Aires, Argentina, Osseo. Implants System, K-915375.  
Genentech, Seattle WA: K-924112

VIII. Clinical Discussion and Brief Literature Review: Endosseous implants, and especially those of titanium or titanium alloy, in the "post" or "screw" configuration, have been proved safe and effective through the years. The possible adverse effects summarized in this 510(k) cover those listed by the United States classification panel [Federal Register, vol. 45, No. 251, pp 86025-6, Dec. 30, 1980], as well as to those revealed in a recent literature search. Matukas, "Medical Risks Associated with Dental Implants," states, "Little or no hard data could be found on the medical risks associated with [dental] implants." Because of the wide-spread usage of dental implants, Smith and Zarb made a careful review of the literature and proposed criteria for implant success.

A thorough computerized Medline literature search produced 585 entries. An update of this search produced 68 new review articles. The Journal of Dental Education published a special issue "Proceedings of the Consensus Development Conference on Dental Implants [National Institutes of Health, Bethesda, MD, June 13-15, 1988], Vol. 52, No. 12, pp. 677-831, Dec. 1988. This added to the literature search above, with some especially pertinent reprints from the scientific literature, provide a comprehensive summary of available scientific data.

Zarb completed his report of the detailed Toronto 10-year study by concluding that "the tried and tested Branemark implant technique has revolutionized the treatment options open to the prosthodontist. For the edentulous patient...the prospect for a lifetime of restored oral comfort, function, and appearance have now become predictable and reliable." These results are ample evidence of the safety and effectiveness of these endosseous implants.

END OF 510(k) SUMMARY



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAR 16 1998

Mr. Clint Folsom  
President  
Crystal Medical Technology  
181 Cahaba Valley Parkway  
Pelham, Alabama 35124

Re: K980442  
Trade Name: Crystal and Crystal-Seal Implants System  
Regulatory Class: III  
Product Code: DZE  
Dated: January 30, 1998  
Received: February 4, 1998

Dear Mr. Folsom:

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.

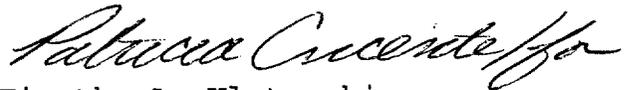
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

Page 2 - Mr. Folsom

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

IX. Indications for Use: [Separate Page]

510(k) Number: NA K980442

Device Name: Crystal Seal™

This device is intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, and to restore 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)

Prescription Use Yes  
(Per 21 CFR 801.109)

or

Over-The-Counter Use No

(Optional Format 1-2-96)

*[Signature]*  
(Division Sign-Off)  
Division of Dental, Infection Control,  
and General Hospital Devices  
510(k) Number K980442