

JAN 30 1998

K974392

510(k) SUMMARY

1. Applicant's Name and Address

Company Name: Biovision GmbH
Address: Merzhauser Straße 112, D-79100 Freiburg, Germany
Telephone Number: 49-761/45 84-344
Facsimile Number: 49-761/45 84-541
Contact Person: Michael Nagel, Clinical Research Manager
Date Summary Prepared: October 24, 1997

2. Device Name

Trade Name: LEADfix[®] Bioresorbable Membrane Pin System
Common/Usual Name: Membrane fixation pin
Classification Name: Screw, fixation, intraosseous
per Dental Products Panel 21 CFR section 872.4880

3. Predicate Devices

IMZ Membrane Tack System (K960945)
MemFix[™] System (K955369)

4. Device Description

The LEADfix Bioresorbable Membrane Pin System consists of components and instruments designed to fixate and stabilize bioresorbable barrier membranes in the oral cavity during the healing process following dental surgery. The system provides an anchoring mechanism for the membranes to resident and adjacent bone at the surgical site. The LEADfix membrane pin is fabricated from a bioresorbable polymer. The pin has a low profile, round, lens shaped head and a shaft with two circular ribs. The system also consists of stainless steel instrumentation designed to place the pin at the surgical site.

5. Intended Use

The LEADfix Bioresorbable Membrane Pin System is intended to be used to fixate and stabilize bioresorbable barrier membranes used for regeneration of tissue and/or bone in the oral cavity. The LEADfix membrane pin is similar in intended use to other marketed membrane screws, including the IMZ Membrane Tack System and the Memfix screws, which are intended to fixate and stabilize non-resorbable barrier membranes used for regeneration of tissue and/or bone in the oral cavity.

6. Technological Characteristics

The LEADfix[®] Bioresorbable Membrane Pin System is similar in design and principles of operation to the predicate systems. The membrane pin, however, does not require subsequent removal after the completion of the membrane treatment and healing phase.

Materials of construction for the pin differs from the predicate devices. The LEADfix[®] pin is composed of a Polylactid copolymer. The Polylactid copolymer is absorbable while the predicate systems are non-absorbable metals that must be removed at the completion of the membrane treatment and healing phase. Both *in vitro* and *in vivo* examination and use of this material do not raise new questions of safety or effectiveness as compared to predicate devices.

7. Nonclinical Test Conclusions

Pull force testing of the LEADfix Bioresorbable Membrane Pin demonstrate that the pin has sufficient strength to fix an absorbable membrane material to bone. Results showed that the absorbable membrane material does not possess the strength to pull the implanted LEADfix pin out of bone without compromising itself in the process.

8. Clinical Use Conclusions

Clinical use of the LEADfix pin in conjunction with absorbable barrier membranes demonstrate that the LEADfix pin effectively assists clinicians to fixate membranes without new health risks and is a predictable means to achieve clinical success in guided bone and/or tissue regeneration.

9. Conclusions

In summary, Biovision believes that the LEADfix Bioresorbable Membrane Pin System is substantially equivalent to currently marketed predicate devices. The device does not raise new issues or questions of safety and effectiveness as compared to predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 30 1998

Mr. Foster Boop
Regulatory Affairs Associate
Biovision GmbH
C/O Sulzer Calcitek, Incorporated
2320 Faraday Avenue
Calrsbad, California 92008-7216

Re: K974392
Trade Name: Leadfix Bioresorbable Membrane Pin System
Regulatory Class: II
Product Code: DZL
Dated: October 24, 1997
Received: November 21, 1997

Dear Mr. Boop:

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 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 premarket notification submission does not affect any obligation you might have under sections 531

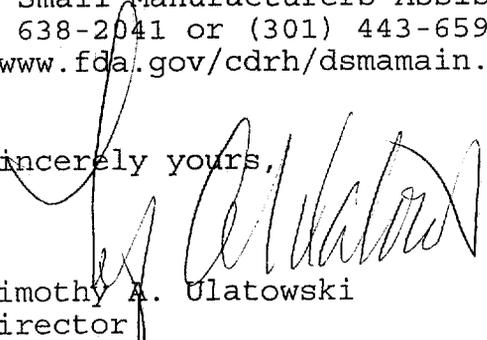
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through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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

510(K) Number (if known): K974892

Device Name: LEADfix Bioresorbable Membrane Pin System

Indications For Use:

The LEADfix Bioresorbable Membrane Pin System is designed to fixate and stabilize resorbable barrier membranes during the healing process by providing an attachment mechanism for the membrane to resident and adjacent bone at the surgical site. The LEADfix membrane pin is indicated for use with absorbable guided tissue and guided bone regeneration membranes.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Rimmer

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K974892

Prescription Use Yes
(Per 21 CFR 801.109)

OR

Over-The-Counter Use No

(Optional Format 1-2-96)