

K974106

JUN 1 1998

XIV. 510(k) SUMMARY [21 CFR 807.92(c)]

Applicant name:

Bio Science Technologies, Inc.
3639 Harbor Boulevard, Suite #121
Ventura, CA 93001
(805) 677-4920
(805) 677-4922 (fax)

Contact Person: Mr. Sergio F. Cifuentes, President

Date Summary Prepared: October 30, 1997

DEVICE NAME

Trade Name: Icon Implant System
Common Name: Dental Implant
Classification Name: Endosseous Implant

THE PRODUCT AND ITS INTENDED USE

The Bio Science Technologies, Inc.'s Icon Implant System consists of a screw implant and a cover screw which are contained within a titanium (CP) canister. An actual implant is provided for the Reviewer. The implant and cover screw are nearly identical to the Branemark System® Mk II Self-Tapping Fixture (K945398) manufactured by Nobelpharma USA, Inc. The Icon Implant System is intended for use in either partially or fully edentulous mandibles and maxillae in the following areas:

- Support of fixed (cemented) restorations utilizing multiple abutments;
- Support of fixed detachable (screw retained) prosthetics utilizing multiple abutments;
- Overdenture retention by means of a ball overdenture attachment, o-ring attachment, dalla bona, or hader bar;
- Terminal or intermediate abutment support for fixed bridgework;
- Free standing restorations without involvement of adjacent dentition when the external hex is engaged.

TABLE #1 -- ICON IMPLANT SYSTEM

DIAMETERS (in <i>mm.</i>)	LENGTHS (in <i>mm.</i>)				
3.3	8	10	13	15	
3.75	8	10	13	15	18
4	7	10	13	15	18

Composition of Finished Device:

The Icon Implant System is manufactured from commercially-pure titanium grade 3 or 4.

TABLE #2 -- TABLE OF SUBSTANTIAL EQUIVALENCE

ATTRIBUTES	Icon Implant System	Branemark System® Mk II Self-Tapping Fixture
Intended Use	<p>The Icon Implant System is intended for use in either partially or fully edentulous mandibles and maxillae in the following areas:</p> <ul style="list-style-type: none"> • Support of fixed (cemented) restorations utilizing multiple abutments; • Support of fixed detachable (screw retained) prosthetics utilizing multiple abutments; • Overdenture retention by means of a ball overdenture attachment, o-ring attachment, dalla bona, or hader bar; • Terminal or intermediate abutment support for fixed bridgework; • Free standing restorations without involvement of adjacent dentition when the external hex is engaged. 	<p>The Branemark System® Mk II Self-Tapping Fixture is intended for use to be surgically placed in the bone of the upper and the lower jaw arches to provide support for prosthetic devices such as artificial teeth and to restore the patient's chewing function.</p>
Material	Commercially-pure titanium grade 3 or 4	Commercially-pure titanium grade 1
Diameters (<i>mm</i>)	3.3, 3.75, 4.0	3.75
Lengths (<i>mm</i>)	7, 8, 10, 13, 15, 18	10, 13, 15, 18
Design	Polished Collar	Polished Collar
Design	Self-Tapping	Self-Tapping
Design	External Hex	External Hex
Design	Passivated	Passivated

STATEMENT OF SUBSTANTIAL EQUIVALENCE

Bio Science Technologies, Inc. considers the Icon Implant System to be substantially equivalent to FDA-cleared devices marketed by other dental product manufacturers.

SUMMARY OF SUBSTANTIAL EQUIVALENCE

Both the Icon Implant System and the Branemark System® Mk II Self-Tapping Fixture 510(k) (reference number K945398) are substantially equivalent with respect to the following characteristics:

1. Both devices are endosseous implants which work through osseointegration.
2. They have the same indications for use. Please refer to page 24, Table #2 – Table for Substantial Equivalence.
3. Both devices utilize the same design principles.
4. Both devices are made of the same material, commercially-pure titanium.
5. Both devices are implanted using similar surgical protocols.
6. Both devices require that the same routine be followed during the healing period following the implantation.

As the above list of similarities indicates, the Icon Implant System and the Branemark System® Mk II Self-Tapping Fixture have the same basic features. Furthermore, both devices are indicated for similar purposes. Therefore, the Icon Implant System and the Branemark System® Mk II Self-Tapping Fixture are substantially equivalent.

Performance Data: N/A

Nonclinical Data: N/A

Clinical Data: N/A

-- END OF 510(k) SUMMARY --



JUN 1 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Bio Science Technologies, Incorporated
C/O Alan Donald, MS, MBA, RAC
Consultant to Bio Science Technologies, Incorporated
Pacific Regulatory Services, Incorporated (PRSI)
The Aventine Office Building
8910 University Center Lane, Suite 265
San Diego, California 92122-1085

Re: K974106
Trade Name: Icon Implant System
Regulatory Class: III
Product Code: DZE
Dated: January 19, 1998
Received: January 20, 1998

Dear Mr. Donald:

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 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

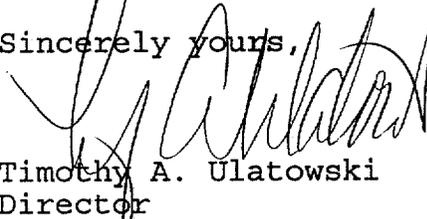
Page 2 - Mr. Donald

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) 594-4692. 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

510(k) Number (if known): K974106

Device Name: ICON IMPLANT System

Indications For Use:

Device Description/Intended Use:

The Bio Science Technologies, Inc.'s Icon Implant System consists of a screw implant and a cover screw which are contained within a titanium (CP) canister. An actual implant is provided for the Reviewer. The implant and cover screw are nearly identical to the Branemark System® Mk II Self-Tapping Fixture (K945398) manufactured by Nobelpharma USA, Inc. The Icon Implant System is intended for use in either partially or fully edentulous mandibles and maxillae in the following areas:

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- Terminal or intermediate abutment support for fixed bridgework;
- Free standing restorations without involvement of adjacent dentition when the external hex is engaged.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

[Signature]

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

510(k) Number: K974106

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)