

OCT 22 2004

K041136

510(k) Summary

SUBMITTER:

Submitted on behalf of:

Company Name: Bio-Lok International Inc.
Address: 368 South Military Trail
Deerfield Beach, FL 33442
Telephone: (954) 698-9998
Fax: (954) 698-9925

by: Elaine Duncan, M.S.M.E., RAC
President, Paladin Medical, Inc.
PO Box 560
Stillwater, MN 55082
Telephone: 715-549-6035
Fax: 715-549-5380

CONTACT PERSON: Elaine Duncan

DATE PREPARED: April 27, 2004

TRADE NAME: Laser-Lok™ surface treatment for use with Silhouette™ & Silhouette™ IC dental implant system

COMMON NAME: Dental implant, Endosseous

SUBSTANTIALLY EQUIVALENT TO: Laser-Lok surface treatment is a line extension (optional surface modification) to the Silhouette™ and Silhouette™ IC dental implants. These surface modified implants are substantially equivalent to the predicate the Silhouette™ and Silhouette™ IC dental implants previously cleared under 510(k) # 032454. Additionally, FDA has cleared similar surface treatments for dental implants, such as the surface treatment on the Astra Tech Fixture ST.

DESCRIPTION of the DEVICE: Laser-Lok™ is a surface technology in which two laser generated patterns of microscopic grooves are applied to the collar of the implant to engineer the biological width and tissue attachment to either the Silhouette™ (hex-top) or Silhouette™ IC (internal connection) dental implants.

Soft tissue attachment to the Laser-Lok surface treatment and the alignment of its micro-grooves inhibits epithelial down-growth on Silhouette Implants.

The LaserLok treated collar on the Silhouette Dental Implant has been shown to attach and retain bone adjacent to the implant.^{a,b}

a. *Bone Response to Laser Microtextured Surfaces* by Ricci, J.L., Charvet, J., Frenkel, S.R., Chang, R., Nadkarni, P., Turner, J., Alexander, H.: Chapter 25 in: *Bone Engineering*, ed; JE Davies, 2000, Em2 Inc., Toronto (pages 8 & 9).

b. *Advanced Surface Microtexturing Techniques to Enhance Bone and Soft Tissue Response to Dental Implants* by Weiner, S., Simon, J., Ehrenberg, D.S., Zweig, B., Ricci, J.L.: presented at the Academy of Osseointegration 2003 Annual Meeting, Boston and pending publication in the *International Journal of Oral and Maxillofacial Implants*.

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The Laser-Lok surface treatment on the collar does not reduce the safety and inflammation performance of Silhouette Implants.

INDICATIONS FOR USE: The implant is designed for use in edentulous sites for support of complete denture prosthesis, a terminal or intermediate abutment for fixed bridgework or partial dentures, or a single tooth replacement, overdenture, or hybrid denture.

SUMMARY of TESTING: The Laser-Lok surface treatment does not introduce new issues for biocompatibility as documented in a summary of all testing conducted to-date.

Mechanical testing was done in accordance with the FDA guidance "Information for premarket notification submissions for screw-type endosseous implants" issued on December 9, 1996. Results from an independent laboratory showed the Silhouette™ and Silhouette™ IC with Laser-Lok™ surface treatment to have sufficient mechanical static and dynamic strength.

Additional test reports include finite element analysis, animal and clinical testing.



OCT 22 2004

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Bio-Lok International, Incorporated
C/O Ms. Elaine Duncan
President
Paladin Medial, Incorporated
P.O. Box 560
Stillwater, Minnesota 55082-0560

Re: K041136
Trade/Device Name: Laser-Lok Surface Treatment for Silhouette™ and
Silhouette™ IC Endosseous Implant
Regulation Number: 872.3640
Regulation Name: Endosseous Implant
Regulatory Class: II
Product Code: DZE
Dated: August 10, 2004
Received: August 11, 2004

Dear Ms. Duncan:

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 Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Chiu Lin, Ph.D.

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): K041136

Device Name: **Laser-Lok surface treatment for Silhouette™ and Silhouette™ IC endosseous implant**

Indications for Use:

The implant is designed for use in edentulous sites for support of complete denture prosthesis, a terminal or intermediate abutment for fixed bridgework or partial dentures, or a single tooth replacement, overdenture, or hybrid denture.

Prescription Use

AND/OR

Over-The-Counter Use

(Part 21 CFR 801 Subpart D)

(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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