

K992216

BioMend Extend™
Absorbable Collagen Membrane
SUMMARY OF SAFETY AND EFFECTIVENESS

Submitter's name and address:

Integra LifeSciences Corporation
105 Morgan Lane
Plainsboro, NJ 08536

Contact person and telephone number:

Judith E. O'Grady
Senior Vice President, Regulatory Affairs, Quality Assurance and Clinical Research
(609) 275-0500

Date Summary was prepared:

June 30, 1999

Name of the device:

Proprietary Name: BioMend Extend™ *Absorbable Collagen Membrane*
Common Name: Resorbable Periodontal Barrier
Classification Name: Bone Filling Augmentation Material, Product Code LYC

Substantial Equivalence:

BioMend Extend™ *Absorbable Collagen Membrane* is substantially equivalent in function and intended use to the product, BioMend™ *Absorbable Collagen Membrane* which has been cleared to market under Premarket Notification 510(k) K924408.

Device Description:

BioMend Extend™ *Absorbable Collagen Membrane* is a white, compressed, non-friable matrix fabricated from collagen derived from bovine deep flexor (Achilles) tendon. Bovine tendon is known to be one of the purest sources of Type I Collagen that can be readily obtained and processed in commercial amounts. BioMend Extend™ is completely absorbable, eliminating the need for the second surgical procedure often required to remove a non-resorbable membrane. The collagen is currently used for general and dental surgery as absorbable hemostatic agents and absorbable wound dressings.

Under scanning electron microscopy, BioMend Extend™ has a morphology of condensed laminated sheets in cross-section and a textured surface. BioMend Extend™ appears paper-white in the dry state and translucent and non-slippery when wet. BioMend Extend™ can be cut to any size or shape in the wet or dry state, without tearing or fragmenting.

BioMend Extend™ has an effective pore size of 0.004 microns, which will effectively retard epithelial downgrowth during early phases of healing. Being semi-occlusive, it allows essential nutrients to pass through the membrane. BioMend Extend™ incorporates into the surrounding tissue and is completely absorbed within 18 weeks.

BioMend Extend™ is sterilized by ethylene oxide gas.

Statement of the intended use:

BioMend Extend™ Absorbable Collagen Membrane is an absorbable, implantable material that is indicated for guided tissue regeneration procedures in periodontal defects to enhance regeneration of the periodontal apparatus.

Comparison of technological characteristics to predicate devices:

A table comparing characteristics of BioMend Extend™ Absorbable Collagen Membrane and the predicate device is provided in Table 1.

Table I: BioMend Extend™ Absorbable Collagen Membrane and Predicate, BioMend® Absorbable Collagen Membrane Comparison Chart

	BioMend Extend™ Absorbable Collagen Membrane	BioMend® Absorbable Collagen Membrane
Intended Use	Used for guided tissue regeneration procedures in periodontal defects to enhance regeneration of the periodontal apparatus.	Used for guided tissue regeneration procedures in periodontal defects to enhance regeneration of the periodontal apparatus.
Incorporates Same Basic Design	Yes	Yes
Utilizes the same operating principle	Cell occlusive (effective pore size 0.004 microns) Implantable Resorbable Hemostatic	Cell occlusive (effective pore size 0.004 microns) Implantable Resorbable Hemostatic
Incorporates same materials?	Yes, Type I Collagen	Yes, Type I Collagen
Sterilization Process	ETO	ETO
Biocompatible	Yes	Yes
Non-pyrogenic	Yes	Yes
Shelf Life	24 months	24 months
Product Size	15 mm x 20 mm 20 mm x 30 mm 30 mm x 40 mm	15 mm x 20 mm 20 mm x 30 mm 30 mm x 40 mm

Safety

Biocompatibility studies have demonstrated BioMend Extend™ *Absorbable Collagen Membrane* to be: noncytotoxic, nonpyrogenic, nonirritating, and nonsensitizing. The following studies were conducted:

- a) Cytotoxicity
- b) Dermal Sensitization /Irritation
- c) ISO Acute Intracutaneous Reactivity
- d) Acute Systemic Toxicity
- e) Genotoxicity
- f) Implantation/ Absorption
- g) Sub-Chronic Toxicity
- h) Muscular Implantation
- i) Hemolysis

The BioMend Extend™ *Absorbable Collagen Membrane* manufacturing process complies with the United States Food and Drug Administration and European Standards for animal tissue sourcing and viral inactivation.

Conclusion

BioMend Extend™ *Absorbable Collagen Membrane* is substantially equivalent to the unmodified device, BioMend® *Absorbable Collagen Membrane*. The modifications do not affect the intended use or fundamental scientific technology of the device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 26 1999

Judith E. O'Grady, RN, MSN
Senior Vice President
Regulatory Affairs, Quality Assurance
and Clinical Research
Integra LifeSciences Corporation
105 Morgan Lane
Plainsboro, New Jersey 08536

Re: K992216
Trade Name: BioMed® Extend™ Absorbable Collagen
Membrane
Regulatory Class: Unclassified
Product Code: LYC
Dated: June 30, 1999
Received: July 1, 1999

Dear Ms. O'Grady:

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.

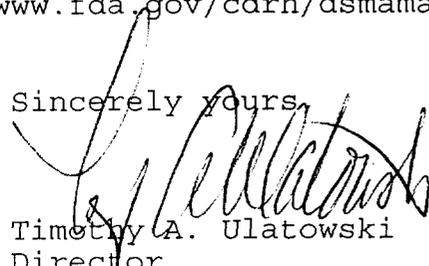
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

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

INDICATIONS FOR USE STATEMENT

510(k) Number:

Device Name: BioMend Extend™ *Absorbable Collagen Membrane*

Indications for Use:

BioMend Extend™ *Absorbable Collagen Membrane* is an absorbable, implantable material that is indicated for guided tissue regeneration procedures in periodontal defects to enhance regeneration of the periodontal apparatus.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
 (Per 21 CFR 801.109)

Or

Over-the-Counter Use

Optional Format 1-2-96)

Susan Russo

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number 1990016