

K032104

DEC 12 2003

510(k) SUMMARY

ProKera™

Bio-Tissue, Inc.

This 510(k) summary of safety and effectiveness for the ProKera™ is submitted in accordance with the requirements of the SMDA and follows Office of Device Evaluation guidance concerning the organization and content of a 510(k) summary.

Applicant: Bio-Tissue, Inc.

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Contact Person: David J. Bloch
Regulatory Counsel

Telephone: (202) 414-9209 (telephone)
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Preparation Date: July 2, 2003

Device Trade Name: ProKera™

Common Name: Ophthalmic Conformer, with Amniotic Membrane

Classification Name: Ophthalmic Conformer, 21 CFR §886.3130

Product Code: NQB

Predicate Device: Symblypharon Ring, 510(k) # K921221

Device Description: The ProKera™ is a corneal-epithelial insert, consisting of an ophthalmic conformer that incorporates amniotic membrane. The device is intended for use in eyes in which the ocular surface cells have been damaged, or underlying stroma is inflamed and scarred.

The device is inserted between the eyeball and the eyelid to maintain space in the orbital cavity and to prevent closure or adhesions. Insertion of the conformer also enables application of the amniotic membrane to the ocular surface without the need for sutures.

Performance Data:

Bio-Tissue has performed testing to confirm that the conformers hold the amniotic membrane in place firmly, and that the device does not pose a risk of coming loose. The strength of the fastening of amniotic membrane by these two rings was tested by dropping stainless steel balls weighing either 12.138 g or 16.567 g onto the attached membrane.

In addition, because the amniotic membrane is preserved through cryopreservation prior to use, the ProKera™ would be stored at freezing temperatures once the membrane is in place. Bio-Tissue has performed testing to confirm that cryopreservation does not negatively affect the rings or the amniotic membrane. The conformer ring was placed in the –80°C temperatures at which the membrane is stored for up to three weeks, and has shown no change in the fastening strength or in the integrity of the skirt or the inner ring. Microscopic evaluation has revealed no cracks or chipping.

Statement of
Conformance:

Bio-Tissue conforms to the requirements of 21 C.F.R. § 1270 and 1271 for establishments that process human tissue, as well as the standards of the American Association of Tissue Banks (AATB), ISO 11737.1 and EN 11743-3, the United States Pharmacopeia standards USP XXV <1227> Validation of Microbial Recovery from Pharmacopeial Articles, USP XXIV <61> Microbial Limits Tests, USP XXIV <71> Sterility Tests, and PDA Technical Report No. 21, Bioburden Recovery Validation.

CONCLUSIONS:

Based on the foregoing and other information in this application, Bio-Tissue, Inc. believes that the ProKera™ is substantially equivalent to its claimed predicates under conditions of intended use.



DEC 12 2003

Bio-Tissue Inc.,
c/o David J. Bloch
1301 K Street, N.W.
Suite 1100 – East Tower
Washington, D.C. 20005

Re: K032104

Trade/Device Name: ProKera™ Ophthalmic Conformer
Regulation Number: 21 CFR 886.3130
Regulation Name: Ophthalmic Conformer
Regulatory Class: Class II
Product Code: NQB
Dated: November 10, 2003
Received: November 15/2003

Dear Mr. Bloch:

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 (301) 594-4613. 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,



A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K032104

Device Name: ProKera™

Indications For Use:

The ProKera™ is a corneal-epithelial insert, consisting of an ophthalmic conformer that incorporates amniotic membrane. The device is intended for use in eyes in which the ocular surface cells have been damaged, or underlying stroma is inflamed and scarred.

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Prescription Use X

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 Ophthalmic Ear,
Nose and Throat Devices
510(k) Number K032104