APR 14 2006

K053481

5. 510(k) Summary

This 510(k) summary of safety and effectiveness is provided in accordance with 21 CFR 807.92.

Date of preparation: March 29, 2006

Sponsor

Advanced Bio-Technology, Inc.
3100 Bucklin Hill Rd., #220
Silverdale, WA 98383

Contact

Steven Chernoff
Drug & Device Development Co.
Phone: 425-861-8262
Fax: 425-869-5854
Email: schernoff@druganddevice.com

Device identification

Proprietary name: Kelo-Cote Spray
Classification name: elastomer, silicone, for scar management
CFR 878.4025
Product code: MDA

Indications for Use

Kelo-Cote Spray is a topical silicone spray intended for the management of old and new hypertrophic and keloid scarring on scars resulting from burns, general surgical procedures and trauma wounds.

Substantial Equivalence

ABT believes Kelo-Cote Spray is substantially equivalent to legally marketed products: ABT's Kelo-Cote Topical Gel (K002488) and the Curad Spray Bandage (K022645).

The ABT Kelo-Coat Topical Gel provides a substantial equivalence basis for the intended use and components of Kelo-Coat Spray. The Curad Spray Bandage provides a substantial equivalence basis for the method of application of Kelo-Cote Spray.

Device description

Kelo-Cote Spray is a lightweight, self-drying silicone gel spray for the treatment of scars. Upon drying, the silicone gel layer forms a film for the management of scars.

The components of Kelo-Cote Spray include fumed silica and silicone elastomer, liquid, and gum. It is provided in a can with a spray nozzle for application purposes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 14 2006

Advanced Bio-Technologies, Inc.
c/o Drug & Device Development Corp.
Mr. Steven Chernoff
P.O. Box 3515
Redmond, Washington 98073-3515

Re: K053481
Trade/Device Name: Kelo-Cote Spray
Regulation Number: 21 CFR 878.4025
Regulation Name: Silicone sheeting
Regulatory Class: I
Product Code: MDA
Dated: March 7, 2006
Received: March 8, 2006

Dear Mr. Chernoff:

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,

for Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use Statement

510(k) Number (if known): K053481

Device Name: Kelo-Cote Spray

Indication for Use:

Kelo-Cote Spray is a topical silicone spray intended for the management of old and new hypertrophic and keloid scarring on scars resulting from burns, general surgical procedures and trauma wounds.

Prescription Use____ AND/OR Over-the-counter Use ___X___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K053481