K040307

1/1

AUG 1 2 2004

SECTION 9

510(k) SUMMARY STATEMENT

February 6, 2004

Applicant:	Hanson Medical, Inc. PO Box 1160, Kingston, Washington, 98346 Tel: 800.771-2215 Fax: 360.297-1998
Contact Representative:	John Harrison, PhD Medical Devices Associates, International Tel/Fax: 805.961-9334) Email: joli@west.net

Proprietary Name:	**"HANSON SCAR ADE"**
Classification Name:	Elastomer, Silicone, for Scar Management
Common Name:	Silicone gel for hypertrophic and keloid scar management
Classification:	Class I

HANSON SCAR ADE is a topical gel made from silicones. HANSON SCAR ADE is intended OTC for use in management of existing and new hypertrophic and keloid scarring resulting from burns, trauma, surgery, laser abrasion, chemical peels and other trauma.

This product is offered non-sterile. For convenience it is packaged in half ounce and one ounce plastic tubes. Each tube will have Directions for Use, and Cautions.

HANSON SCAR ADE is indicated for use to aid associated erythema or discoloration of scars. HANSON SCAR ADE is applied to the scar in a thin coat and excess is wiped away with a tissue. HANSON SCAR ADE is to be used on healed scars, in the case of surgery typically after 10 days from surgery. **The product is not to be used on open wounds. Discontinue use if any infection is suspected, and obtain professional health care assistance.**

Hanson Medical **HANSON SCAR ADE** is substantially equivalent to Kelo-Cote topical gel (Advanced Bio-Technologies).

John Harrison, PhD (Consultant)
Tel/Fax: 805-961-9334 Email: joli@west.net

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 2 2004

Mr. Erik Hanson
Vice President
Hanson Medical, Inc.
P.O. Box 1160
Kingston, Washington 98346

Re: K040307
Trade/Device Name: Hanson Scar Ade
Regulatory Class: Unclassified
Product Code: MDA
Dated: July 27, 2004
Received: July 27, 2004

Dear Mr. Hanson:

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) 594-4659. 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,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K040307

Device Name: HANSON SCAR ADE

Indications For Use: HANSON SCAR ADE is indicated for the topical management of keloid and hypertrophic scars

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____x___ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

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

510(k) Number K040307