APR 2 1 2003

K030809

ATTACHMENT 7

510k SUMMARY STATEMENT

March 5, 2003

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

Proprietary Name:	Hanson Medical Gluteal Implant
Common Name:	Silicone Carving Block
Classification Name:	Elastomer, Silicone Block

Hanson Medical Gluteal Implants are intended for augmentation, or as reconstruction to minimize muscular defects. The Hanson Gluteal Implant is carvable, allowing the physician to adapt the device shape to individual patient contours. They are manufactured using heat cured, medical grade, two part, liquid silicone system (LSR), silicones that meet FDA requirements for replacement of Dow's discontinued medical grade silicone analogues.

Hanson Gluteal Implants are substantially equivalent to itself (Hanson Medical Silicone Carving Block), and to the Gluteal Implants made by AART, Inc and Silimed LLC. Hanson Gluteal Implants employ the same materials, methods of manufacture, and are identical in dimension and very similar in others, to these predicate devices.

Hanson Gluteal Implants will be offered non-sterile. The implants will be packaged in autoclavable peel pouches labeled with a detachable traceability tab for patient record files. Autoclave sterilization details are provided in the package insert. The implants are finally boxed with package insert materials and labeled for shelving and shipping traceability.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 21 2003

Hanson Medical, Inc.
c/o John Harrison, Ph.D.
Medical Devices Associates, International
5662 Calle Real, #331
Goleta, California 93117

Re: K030809
Trade Name: Hanson Medical Gluteal Implant
Regulation Number: 21 CFR 874.3620
Regulation Name: Ear, Nose, and Throat Synthetic Polymer Material
Regulatory Class: II
Product Code: MIB
Dated: March 5, 2003
Received: March 13, 2003

Dear Dr. Harrison:

We have reviewed your Section 510(k) premarket 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) 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

510k NUMBER: K030809

DEVICE NAME: Hanson Medical Gluteal Implant

INDICATIONS FOR USE:

The Hanson Medical Gluteal Implant (Silicone Carving Block) is for augmentation and reconstructive surgery. The Hanson Gluteal Implant will be carvable, allowing the physician to customize the device shape for muscular defects.

(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)

Miriam C. Provost

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

510(k) Number K030809