DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Hanson Medical, Inc.
% Mr. Gerald Hanson
P.O. Box 1160
Kingston, Washington 98346

JUN 30 2010

Re: K090803
Trade/Device Name: Hanson Medical Facial Implants
Regulation Number: 21 CFR 878.3550
Regulation Name: Polytetrafluoroethylene with carbon fibers composite implant material
Regulatory Class: II
Product Code: FWP, ESR, LZK
Dated: June 24, 2010
Received: June 28, 2010

Dear Ms. 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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

Enclosure

K050805

TAB D

INTENDED USE FORM

510(k) Number K 973573 Silicone Nasal Implant
K 973574 Silicone Malar Implant
K 973575 Silicone Chin Implant

Device Name: Hanson Medical Facial Implants

Indications for use:

Silicone Nasal Implant – For the augmentation or reconstruction of the nasal contour

Silicone Malar Implant – For the augmentation or reconstruction of the malar contour

Silicone Chin Implant – For the augmentation or reconstruction of the chin contour

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign Off
Division of General and Restorative Devices
510(k) numbers K973573, K973574, K973575

Prescription Use ✓

Optional Format 1-2-96

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K050805