K041690

FEB 11 2005

February 4, 2005

TAB H

REVISED 510(K) SUMMARY STATEMENT

The Monarch Nasal Implant by Hanson Medical, Inc., is substantially equivalent to the Medpore Nasal Strut, Nasal Dorsum, Nasal Batten, and the Gortex Guided Tissue Regeneration Device.

The Monarch Nasal Implant is a Class II Device.

The Intended use of the Monarch Nasal Implant is to augment or cosmetically change the shape of the nose. It can be used to widen the narrow nose and straighten the nasal dorsum.

Labeling and packaging will be similar to the predicate device with an outer carton and a double peel pouch inside with appropriate labels. The product will be sold sterile. Sterilization methods are validated to a Sterilization Assurance Level of 10 to the minus sixth. Accelerated Aging testing is used to establish the 3-year expiration date of the packaging as per ISO 10993.

Physical and Chemical properties are reflected in the files at FDA on ePTFE and Medical Grade Titanium Alloys. Certification is Grade 1 Titanium ASTM F-67. The Titanium is malleable or shapeable however the Titanium Nickel Alloy (Nitinol) is only minimally shapeable.

The ePTFE component has a high temperature tolerance. It is a waxy white cloth-like material with various degrees of porosity and high tear and tensile strength. The percentage of elongation is low. Both of these components have demonstrated a good degree of biocompatibility over thirty years. The pore size of the ePTFE is 25 to 30 microns and is available in various thicknesses from .003 to .010 inches.

Sizes and configurations – The Monarch Nasal Implant is available in 48mm and 44mm lengths in an elliptical shape .6cm wide at the center and 1cm wide at the ends. The margin of the ePTFE covering is 1.5mm to 2mm around the edges.

The Monarch Nasal Implant may be inserted via three approaches: Transcutaneous External Technique, Intranasal or Intercartilaginous Approach and The Open Technique.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 11 2005

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

Re: K041690
Trade/Device Name: Monarch Nasal Implant
Regulation Number: 21 CFR 878.3680
Regulation Name: Nose prosthesis
Regulatory Class: II
Product Code: FZE
Dated: January 19, 2005
Received: January 19, 2005

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 (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/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson

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): K041690

Device Name: Monarch Nasal Implant
Indications For Use:

For the Augmentation or cosmetic alteration of the nasal shape or contour by straightening the nasal dorsum or widening the narrow nose.

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)

for Mark N Milhern

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

510(k) Number K041690