DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

June 21, 2016

NASLUND MEDICAL Ab
Tomas Naslund
Head of Supply Chain
Vassvagen 21
Huddinge, 14139 SE

Re: K160209
Trade/Device Name: Gold Anchor
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical Charged-Particle Radiation Therapy System
Regulatory Class: Class II
Product Code: IYE
Dated: January 25, 2016
Received: January 28, 2016

Dear Tomas Naslund:

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.

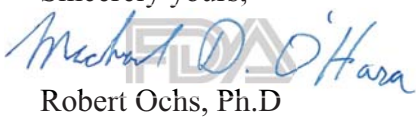
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,



For

Robert Ochs, Ph.D
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160209

Device Name
Gold Anchor

Indications for Use *(Describe)*
The Gold Anchor marker is indicated for use to radiographically mark soft tissue for future therapeutic procedures.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K160209

5. 510(k) Summary

Department of Health and Human Services
Centre of Device and Radiological Health
Office of Device Evaluation
Traditional 510(k) section

510(k) Summary of safety and effectiveness Information as required by section 807.92(c)

I. SUBMITTER OF 510(k):

Company name:	Naslund Medical AB
Address:	Vassvagen 21
	141 39 Huddinge
	Sweden
Phone:	+46 732 620 717
Fax:	+46 850 900 381
Correspondent:	Tomas Naslund

II. DEVICE

Name of Device:	Gold Anchor™
Common or Usual Name:	Fiducial marker
Classification Name:	Accelerator, Linear, Medical
Regulatory Class:	II
Product Code:	IYE

III. PREDICATE DEVICE

The predicate devices are:

1. Gold Anchor (K091645)
2. VisiCoil Marker (K070305)

IV. DEVICE DESCRIPTION

The Gold Anchor™ Marker is a fiducial gold marker intended to be implanted within the body, either temporarily or permanently, to create identifying marks that can be seen on radiographic film or digital images. The marker is formed as a wire with cutouts and used to locate and delineate a tumor, lesion, or other site of interest. The marker comes pre-loaded in 25G, 22G and 20G needles delivered sterile and ready for use. Sterilization is achieved by E-Beam Radiation. This is a single-use device. The device is a passive implant.

V. INDICATIONS FOR USE

The Indications for Use statement for the subject device is identical to that of its predicate device Gold Anchor (K091645):

- The Gold Anchor marker is indicated for use to radiographically mark soft tissue for future therapeutic procedures.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

At a high level, the subject device and the predicate device Gold Anchor (K091645) are based on the following same technological characteristics:

- Device delivered sterilized using Electron Beam Radiation.
- Device delivered pre-loaded in 25G or 22G needles.
- Use of a needle to reach the target tissue.
- Use of a stylet to deploy the fiducial gold marker to mark the soft tissue.
- Use of a material that lubricates the inside of the needle.
- Use of a marker with a unique and patented design (wire with cutouts).

The following technological differences exist between the subject device and the predicate device Gold Anchor (K091645):

- The subject device is also available pre-loaded in a 20G needle.
- The 25G needle of the predicate device was 120 mm long. The 25G needle of the subject device is 150 mm long.
- The material used to lubricate the inside of the needle of the subject device is Nusil Med-360 unrestricted silicone oil.
- The fiducial marker in the subject device contains a small amount of pure iron (0.5% of mass) mixed with the pure gold as an alloy to enhance the visibility of the marker on MRI.
- The predicate device only came with a Ø 0.28 mm marker. The subject device comes with either a Ø 0.40 mm marker or a Ø 0.28 mm marker.

Comparison to the predicate device VisiCoil Marker (K070305):

- The subject device is available pre-loaded in a 20G needle. The predicate device is available pre-loaded in thicker 17G, 18G, or 19G needles.

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination:

Tests were conducted in accordance with FDA's guidance document, "Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment Guidance for Industry and Food and Drug Administration Staff" and the following ASTM standards:

- ASTM F2052-15 Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment.
- ASTM F2182–11a Standard Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants During Magnetic Resonance Imaging
- ASTM F2119-07(2013) Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants.

Because of the minor amount of translational attraction (1-degree deflection angle) and no torque (qualitatively determined) at 3-Tesla, it was deemed unnecessary to conduct a quantitative evaluation of torque according to ASTM F2213-2006 (2011), Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment.

A biocompatibility evaluation has been performed based on a chemical characterization risk assessment in accordance with ISO 10993-17 and ISO 10993-18.