Naslünd Medical AB
℅ Tomas Naslünd
VP Supply Chain
Avägen 40 B
14 130 Huddinge, Stockholm
SWEDEN

June 11, 2020

Re: K201117
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: April 21, 2020
Received: April 27, 2020

Dear Tomas Naslünd:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201117

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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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."

5. 510(k) Summary

I. SUBMITTER K201117

Submitter's name:	Naslund Medical AB
Address:	Åvägen 40 B 141 30 Huddinge Sweden
Phone:	+46 732 620 717
Fax:	+46 850 900 381
Contact Person:	Tomas Naslund
Date Prepared:	April 21, 2020

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

Predicate device:	Gold Anchor, K160209

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:

- 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

The subject device is identical with the predicate device except that the iron content of our patented marker material has increased in order to further enhance the visibility on MRI.

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 (Reapproved 2013) Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants.
- ASTM F2213-17, Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment.

A biocompatibility evaluation was conducted in accordance with the FDA guidance document "Use of International Standard ISO-*10993,* "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process*"* June 16, 2016, and International Standard ISO 10993-1 "Biological Evaluation of *Medical Devices – Part 1: Evaluation and* Testing Within a Risk Management Process", as recognized by FDA. The evaluation was based on a chemical characterization risk assessment in accordance with ISO 10993-17 and ISO 10993-18.

VIII. Conclusion

The changes between the predicate device and the new device do not affect the intended use in terms of safety and effectiveness. The subject device can, however, be better visualized on MRI. Thus, the subject device is as safe, as effective, and performs as well as or better than the predicate device.