



Näslund Medical AB
% Tomas Näslund
VP Supply Chain
Åvägen 40 B
14 130 Huddinge
SWEDEN

January 6, 2022

Re: K213053

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: September 17, 2021
Received: September 22, 2021

Dear Tomas Näslund:

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

Indications for Use

510(k) Number (if known)

K213053

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.

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I. SUBMITTER

Submitter's name: Naslund Medical AB
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Contact Person: Tomas Näslund
Date Prepared: September 17, 2021

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, K201117

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 Gold Anchor™ Introducer ("Introducer") is delivered pre-loaded with the Gold Anchor™ marker inside. It comes in a blister single pack, sterilized, ready for use. The Introducer is used to transfer the marker over into a 22 gauge endoscopic ultrasound aspiration needle ("22G EUS Needle").

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 (K201117):

- 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 (K201117) except that the marker, in the case of the subject device, comes preloaded in an Introducer while, in the case of the predicate device (K201117), the marker comes preloaded in a needle used to implant the marker in soft tissue.

VII. PERFORMANCE DATA

Non-clinical performance bench testing and simulated use testing were completed to evaluate the design of the Gold Anchor Introducer for transferring the marker over into 22G EUS Needles.

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 will, however, make it easier to transfer the Gold Anchor marker over into a 22G EUS Needle. Thus, the subject device is as safe, as effective, and performs as well as or better than the predicate device.