



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

Cianna Medical, Inc.
% Mr. Gary Mocnik
V.P. Regulatory Affairs and Quality Systems
6 Journey, Suite 125
ALISO VIEJO CA 92656

December 20, 2016

Re: K161507

Trade/Device Name: SAVI Scout Reflector and SAVI Scout System
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable Clip
Regulatory Class: Class II
Product Code: PBY
Dated: May 25, 2016
Received: June 1, 2016

Dear Mr. Mocnik,

This letter corrects our substantially equivalent letter of July 29, 2016.

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" (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 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,

A handwritten signature in blue ink that reads "Michael D. O'Hara". The signature is written over a large, faint, grey watermark of the letters "FDA".

For

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

Enclosure

Indications for Use

510(k) Number (if known)

K161507

Device Name

SAVI Scout Reflector and SAVI Scout System

Indications for Use (Describe)

The SAVI Scout Reflector is intended to be placed percutaneously in the breast to temporarily mark (<30days) a lumpectomy site intended for surgical removal. Using imaging guidance (such as ultrasound or radiography) or aided by non-imaging guidance (SAVI Scout System) the SAVI Scout Reflector is located and surgically removed with the target tissue. The SAVI Scout System is intended only for the non-imaging detection and localization of the SAVI Scout Reflector that has been implanted in a lumpectomy site intended for surgical removal.

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.

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