DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Mr. Moritz Hoyer
Quality and Regulatory Affairs Manager
SurgicEye GmbH
Friedenstrasse 18a
81671 Munich, Bavaria
GERMANY

January 25, 2013

Re: K123917
Trade/Device Name: declipseSPECT Viewer
Regulation Number: 21 CFR 892.1320
Regulation Name: Nuclear uptake probe
Regulatory Class: II
Product Code: IZD
Dated: December 14, 2012
Received: December 19, 2012

Dear Mr. Hoyer:

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 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostics and Radiological Health at (301) 796-5450. 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Michael D. O'Hara

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123917

Device Name: declipseSPECT Viewer

Indications for Use:

declipseSPECT Viewer works in conjunction with a nuclear uptake detector capable of measuring the amount of radionuclide taken up by a particular organ or body region. declipseSPECT Viewer is intended to use the said detector and generate images of the distribution of radionuclides in the human body and determine the 3D localization of these radionuclides relative to surgical instruments by means of tracking technologies and image reconstruction techniques. The declipseSPECT Viewer is also intended to be used for hybrid nuclear medicine image viewing in-situ, such as SPECT/CT and PET/CT.

declipseSPECT Viewer may also be used intraoperatively or on pathological specimens if a protective cover is used to cover the nuclear uptake detector. declipseSPECT Viewer may be used at the patient's bedside, or in an Emergency Room or Intensive Care Unit. The scan and operation of the system can be performed by medical staff, including technicians, nurses, physicist and physicians that are trained to use the system.

The generated images can be used also for documentation and reporting. The interpretation and use of the images generated is intended to be done by trained personnel.

declipseSPECT Viewer is compatible currently to following nuclear uptake detectors:

Probe Manufacturer	Probe Model	Probe Handle Model	Energy range of gamma rays
Crystal Photonics:	SG03	Gamma Probe CXS-OP-SZBN	70 – 245 keV
	SG04	Gamma Probe, CXS-OP-SP	70 – 245 keV
		Beta Probe, CXS-OP-SB	27 – 30 keV
RMD	Navigator GPS	Gamma Probe; SP2A14 curved	27 – 245 keV
		Gamma Probe; SP2S14 straight	27 – 245 keV
Eurorad	Europrobe 3	Gamma Probe SOE311	27 – 245 keV

Prescription Use ___ ___ 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 *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostic and Radiological Health

510(k) K123917