



Food and Drug Administration
10903 New Hampshire Avenue
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General Equipment for Medical Imaging (Oncovision-Gem Imaging S.A.) August 18, 2016
% Mr. Jose Montes
Quality and Regulatory Affairs Manager
Eduardo Primo Yúfera, nº 3
Valencia, 46012
SPAIN

Re: K162052
Trade/Device Name: Sentinella 102 (models Sentinella 102 and Sentinella 102 Horus)
Regulation Number: 21 CFR 892.1100
Regulation Name: Scintillation (gamma) camera
Regulatory Class: I
Product Code: IYX
Dated: June 27, 2016
Received: July 25, 2016

Dear Mr. Montes:

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

Indications for Use

510(k) Number (if known)

K162052

Device Name

Sentinella 102 (models Sentinella 102 and Sentinella 102 Horus)

Indications for Use (Describe)

Sentinella 102 (models Sentinella 102 and Sentinella 102 Horus) is a mobile gamma camera system which is intended for imaging the distribution of radionuclides in the human body by means of photon detection. The images are intended to be interpreted by qualified personnel.

Sentinella 102 (models Sentinella 102 and Sentinella 102 Horus) may be used intraoperatively if a protective sheath is used.

Sentinella 102 (models Sentinella 102 and Sentinella 102 Horus) may be used at the patient's bedside, or in Emergency Room or Intensive Care Unit.

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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Special 510 (K)
GENERAL EQUIPMENT FOR MEDICAL IMAGING S.A.
SENTINELLA 102 (MODELS SENTINELLA 102 AND
SENTINELLA 102 HORUS)
510(k) Summary



510(k) number:

Owner's name: General Equipment for Medical Imaging, S. A.(Oncovision Gem-Imaging S.A.)

Address: Eduardo Primo Yúfera, 3, 46012, Valencia (Spain)

Phone: + 34 96 372 24 72

Fax number: +34 96 355 65 32

Name of contact person: Jose Montes, Quality and Regulatory Affairs Manager

Date: 06/27/2016

Name of the device: Sentinella 102 / Sentinella 102 Horus

System trade name: Sentinella 102

Common name: Portable Gamma Camera

Classification name: Scintillation Gamma Camera, Class I. 21 CFR § 892.1100 (1990)

Regulatory Class: I

Product Code: IYX

A. LEGALLY MARKETED PREDICATED DEVICES

Product: Sentinella 102

Manufacturer: General Equipment for Medical Imaging, S. A. (Oncovision-GEM Imaging S.A.)

510(k) number: K143156

Substantial Equivalence Date: 11/18/2014

B. DEVICE DESCRIPTION

Sentinella 102 is a currently marketed portable gamma camera system which includes a small gamma camera designed to obtain images from small organs and structures labeled using radionuclides emitting gamma-rays.

The Sentinella system also includes analysis and display equipment, a cart and ergonomic arm, which facilitates the equipment portability and positioning, and accessories.

Due to the difficulty which may involve indentifying the physical location in the body of the patient of the structures observed in the gammagraphy, the model Sentinella 102 Horus incorporates an optical camera that registers the same area that it is being observed by the gamma camera. Both images are coregistered and shown in real time. During this process, the gammagraphy is not reprocessed or modified in any way, so remains unaltered at the end of the process.

C. INDICATIONS FOR USE

Sentinella 102 (models Sentinella 102 and Sentinella 102 Horus) is a mobile gamma camera system which is intended for imaging the distribution of radionuclides in the human body by means of photon detection. The images are intended to be interpreted by qualified personnel.

Sentinella 102 (models Sentinella 102 and Sentinella 102 Horus) may be used intraoperatively if a protective sheath is used.

Sentinella 102 (models Sentinella 102 and Sentinella 102 Horus) may be used at the patient's bedside, or in Emergency Room or Intensive Care Unit.

There are not new indications for use with respect to the previous model certified (K143156), so no new clinical testing has been carried out. The yellow collimator does not modify the indications for use of the equipment.

D. SUBSTANTIAL EQUIVALENCE CLAIM

The present Special 510(k) has been prepared to communicate the new model of collimator for both models of Sentinella 102 (Sentinella 102 and Sentinella 102 Horus).

The new model of collimator has been validated as it is shown in Annex of Section 11.1 Change description summary.

E. BIOCOMPATIBILITY

As a consequence of the new model of collimator for both models of Sentinella 102 (Sentinella 102 and Sentinella 102 Horus), the Biocompatibility Section has not been modified. It is exactly the same as presented in the K143156 Submission.

F. ELECTRICAL SAFETY TESTING

As a consequence of the new model of collimator for both models of Sentinella 102 (Sentinella 102 and Sentinella 102 Horus), Safety Electrical Test Report has not been modified. It is exactly the same as presented in the K143156 Submission.

G. ELECTROMAGNETIC COMPATIBILITY TESTING

As a consequence of the new model of collimator for both models of Sentinella 102 (Sentinella 102 and Sentinella 102 Horus), EMC Test Report has not been modified. It is exactly the same as presented in the K143156 Submission.



H. PERFORMANCE TESTING

Sentinella 102 (models Sentinella 102 and Sentinella 102 Horus) has the same performance specifications than the previous models already certificated by the FDA (predicates). Because of this, no new NEMA performance tests were necessary for the present submission. The previous NEMA test report was carried out using the NEMA NU-1:2007.

I. SOFTWARE TESTING

As a consequence of the new model of collimator for both models of Sentinella 102 (Sentinella 102 and Sentinella 102 Horus), the Software has not been modified. It is exactly the same as presented in the K143156 Submission.

J. CONCLUSION

Based upon a comparison of devices and performance testing results, Sentinella 102 (models Sentinella 102 and Sentinella 102 Horus) is substantially equivalent to the predicate device.