



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

Hermes Medical Solutions AB  
% Joakim Arwidson  
Quality Manager  
Skeppsbron 44  
11130 Stockholm  
SWEDEN

July 19, 2017

Re: K163687  
Trade/Device Name: OLINDA/EXM v2.0  
Regulation Number: 21 CFR 892.1100  
Regulation Name: Scintillation (Gamma) Camera  
Regulatory Class: Class I  
Product Code: IYX  
Dated: July 5, 2017  
Received: July 7, 2017

Dear Joakim Arwidson:

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,

A handwritten signature in blue ink that reads "Michael D. O'Hara". The signature is written over a large, light blue, semi-transparent watermark of the letters "FDA". To the right of the signature, the word "For" is printed in a small, black, sans-serif font.

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)  
K163687

Device Name  
OLINDA/EXM v2.0

### Indications for Use (Describe)

The intended use of OLINDA/EXM is to provide estimates (deterministic) of absorbed radiation dose at the whole organ level as a result of administering any radionuclide and to calculate effective whole-body dose. This is dependent on input data regarding bio distribution being supplied to the application.

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.\***

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## 510 (k) SUMMARY

### A. Submitted by:

- **Submitters name and address:**  
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- **Contact person**  
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Quality Manager  
Hermes Medical Solutions AB  
Skeppsbron 44  
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Sweden
  
- **Registration number**  
9710645

### B. Preparation date:

2016-11-23

### C. Proprietary/Trade name, Common name, Classification name:

- **Proprietary/Trade name**  
OLINDA/EXM® v2.0
  
- **Common name**  
Scintillation (gamma) camera.
  
- **Classification name**  
Scintillation (gamma) camera, Class I, 21CFR892.1100.

### D. Legally marketed device (predicate device):

Following legally marketed device has been used for comparison.

- OLINDA/EXM® v1.1 (K033960)

### E. Description of the device that is subject of this premarket notification:

The OLINDA/EXM® v2.0 is a modification of OLINDA/EXM® v1.1 (K033960) and includes new human models and nuclides. OLINDA/EXM® 2.0 employs a new set of decay data recommended by the International Commission on Radiological Protection (ICRP). OLINDA/EXM® 2.0 introduces a new series of anthropomorphic human body models (phantoms), so new values of Specific Absorbed Fractions (SAF),  $\phi_i$  (T←S) were generated. These phantoms were based on updated values of the mass of the target region ( $m_T$ ) recommended by the ICRP.

The base product design of OLINDA/EXM<sup>®</sup> v2.0 is the same as for the OLINDA/EXM<sup>®</sup> v1.1 (K033960).

**F. Intended use:**

The intended use of OLINDA/EXM is to provide estimates (deterministic) of absorbed radiation dose at the whole organ level as a result of administering any radionuclide and to calculate effective whole-body dose. This is dependent on input data regarding bio distribution being supplied to the application.

**G. Technological characteristics:**

The proposed device OLINDA/EXM<sup>®</sup> v2.0 has the same technological characteristics as the original device OLINDA EXM<sup>®</sup> v1.1 and the same indication for use.

**H. Testing:**

The tests for verification and validation followed Hermes Medical Solutions AB design controlled procedures. The Risk analysis was completed and risk control implemented to mitigate identified hazards. The testing results supports that all the software specifications have met the acceptance criteria.

**I. Substantially Equivalent/Conclusions:**

The proposed device OLINDA/EXM<sup>®</sup> v2.0 and the predicate devices OLINDA/EXM<sup>®</sup> v1.1 (K033960) have the same indication for use.

The proposed device will use similar technology and fundamental concepts and operation are also the same, as described in the 510(k) submission.

Comparisons were made between OLINDA/EXM<sup>®</sup> v2.0 and OLINDA/EXM<sup>®</sup> v1.1 (K033960). The results showed a good compliance.

In summary, the OLINDA/EXM<sup>®</sup> v2.0 described in this submission is in our opinion substantially equivalent to the predicate device.