K063783

APR 27 2007

8.0 510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 C.F.R. §807.92.

1. The submitter of this premarket notification is:

   Philips Medical Systems

   This summary was prepared on 15 December, 2006.

The name of this device is the:
Philips Reusable SpO_2 Sensors M1191T, M1192T, & M1193T;
Philips SpO_2 Reusable Clip Sensor M1196T;
Philips Disposable SpO_2 Sensor M1131A;
Philips Disposable SpO_2 Sensors M1132A & M1133A.
Classification names are as follows:

Device Panel	Classification	ProCode	Description
Anesthesiology 73	§870.2700, II	DQA	Oximeter

2. The new device is substantially equivalent to previously cleared Philips devices Philips Reusable SpO_2 Sensors M1191T, M1192T, & M1193T marketed pursuant to K032979; Philips SpO_2 Reusable Clip Sensor M1196T pursuant to K062605; Philips Disposable SpO_2 Sensor M1131A pursuant to K042306; as well as Philips Disposable SpO_2 Sensors M1132A & M1133A pursuant to K052377.

3. The modification involves a labeling change to add compatibility of the subject sensors with three existing non-Philips monitors; Nellcor's N-20 PA Portable Pulse Oximeter, Nellcor's NPB-40 Handheld Pulse Oximeter & Critikon's Dinamap Pro 400 V1.

4. The new device has the same Indications for Use as the legally marketed predicate device.

   The Philips reusable and disposable SpO_2 Sensors are intended for non-invasive measurement of oxygen saturation (SpO2) and pulse rate.

   Philips Reusable SpO_2 Sensors M1191T, M1192T, and M1193T:
   M1191T is indicated for adult patients, M1192T is indicated for pediatric patients, and M1193T is indicated for neonatal patients.

   Philips SpO_2 Reusable Clip Sensor Model M1196T:
   M1196A and M1196T are indicated for patients > 40 kg (typically adult patients).

   Philips Disposable SpO_2 Sensor M1131A:
   M1131A is indicated for adult patients/pediatric patients

   Philips Disposable SpO_2 Sensors M1132A and M1133A:
   M1132A is indicated for infant patients, and M1133A for adult/infant/neonatal patients.

5. The new device has the same technological characteristics as the legally marketed predicate device.

6. Verification, validation, and testing activities establish the performance, functionality, and reliability characteristics of the new device with respect to the predicate. Testing involved system level tests, integration tests, environmental tests, and safety testing from hazard analysis. Pass/Fail criteria were based on the specifications cleared for the predicate device and test results showed substantial equivalence. The results demonstrate that the pulse oximetry sensors functionality meets all reliability requirements and performance claims.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Philips Medical Systems, Incorporated
Mr. Tapan D. Shah
Regulatory Affairs
Cardiac and Monitoring Systems
3000 Minuteman Road
Andover, Massachusetts 01810

APR 27 2007

Re: K063783
Trade/Device Name: Philips Reusable SpO_2 Sensors M1191T, M1192T, and M1193T
Philips SpO_2 Reusable Clip Sensor Model M1196T, Philips Disposable SpO_2 Sensor M1131A, Philips Disposable SpO_2 Sensors M1132A and M1133A
Regulation Number: 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: Undated
Received: April 11, 2007

Dear Mr. Shah:

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.

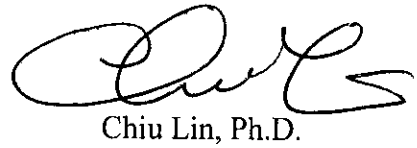
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name(s): 1). Philips Reusable SpO_2 Sensors M1191T, M1192T, and M1193T
2). Philips SpO_2 Reusable Clip Sensor Model M1196T
3). Philips Disposable SpO_2 Sensor M1131A
4). Philips Disposable SpO_2 Sensors M1132A and M1133A

Indications for Use:

The Philips reusable and disposable SpO_2 Sensors are intended for non-invasive measurement of oxygen saturation (SpO_2) and pulse rate.

Philips Reusable SpO_2 Sensors M1191T, M1192T, and M1193T
M1191T is indicated for adult patients, M1192T is indicated for pediatric patients, and M1193T is indicated for neonatal patients.

Philips SpO_2 Reusable Clip Sensors Models M1196T
M1196T is indicated for patients > 40 kg (typically adult patients)

Philips Disposable SpO_2 Sensor M1131A
M1131A is indicated for adult patients/pediatric patients

Philips Disposable SpO_2 Sensors M1132A and M1133A
M1132A is indicated for infant patients, and M1133A for adult/infant/neonatal patients.

Prescription Use __yes_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use __No___ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices
510(k) Number: K063783