

SUMMARY OF SAFETY AND EFFECTIVENESS**ALARIS Medical Systems, Inc.
MEDLEY SpO₂ Module, Model 8210**

SUBMITTER'S NAME: ALARIS Medical Systems, Inc.
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CONTACT PERSON: Renée L. Fluet
Principal Regulatory Affairs Specialist

DATE PREPARED: August 9, 2002

DEVICE NAME: **Proprietary Name**
MEDLEY SpO₂ Module, Model 8210
SpO₂ Sensors and Cables

Common Name
Pulse Oximeter and Sensor
Transducer & Electrode Cables

Classification Name
Oximeter, DQA (870.2700)
Cable, Transducer and Electrode, DSA (870.2900)

PREDICATE DEVICES: MEDLEY SpO₂ Module, Model 8220, K010966
Nellcor OxiMax Pulse Oximetry System, K012891

DEVICE DESCRIPTION

The MEDLEY SpO₂ Module, Model 8210, is essentially the same as the previously cleared device (MEDLEY SpO₂ Module, Model 8220). The MEDLEY SpO₂ Module (Models 8220 and 8210) and accessories is a device capable of non-invasively monitoring functional oxygen saturation of arterial hemoglobin and pulse rate. The system consists of an SpO₂ Module, a Programming Module, connecting cable, and oximetry sensors.

SUMMARY OF SAFETY AND EFFECTIVENESS

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The MEDLEY Programming Module (PM) and SpO₂ Module snap together. The Nellcor board contains all of the pulse oximetry algorithms used to measure saturation and pulse rate. The patient cable and oximetry sensors, manufactured by Nellcor, work in combination with the MEDLEY SpO₂ Module to utilize Nellcor's technology to measure functional oxygen saturation and pulse rate. See **Section 5** for a detailed device description and comparison.

SUBSTANTIAL EQUIVALENCE

The MEDLEY SpO₂ Module, Model 8210 is similar to the predicate devices (MEDLEY SpO₂ Module, Model 8220, K010966, and the Nellcor OxiMax Pulse Oximetry System, K012891) in that they have the same intended use, operating principles, technological design, incorporate similar materials and manufacturing processes. The changes as described in this Special 510(k) pose no new issues of safety or efficacy. The MEDLEY SpO₂ Module, Model 8210 described in this submission, in our opinion, is substantially equivalent to the predicate devices. See **Section 6** for substantial equivalence details and a comparison table.

INTENDED USE

The MEDLEY SpO₂ Module and accessories are intended for continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO₂) and pulse rate (measured by an SpO₂ sensor) for adult, pediatric, and neonatal patients in hospitals and hospital-type facilities. This is the same intended use as previously cleared for the MEDLEY SpO₂ Module, Model 8220, K010966. A separate Indications for Use statement is provided in **Attachment B**.

SUMMARY OF SAFETY AND EFFECTIVENESS**Page 3 of 3****TECHNOLOGY**

The MEDLEY SpO₂ Module, Model 8210, as described in this Special 510(k) Premarket Notification, and the MEDLEY SpO₂ Module, Model 8220 (K010966) are similar devices. The pulse oximeter systems have the same intended use, principle of operation, technology, and functionality. In addition, the MEDLEY SpO₂ Module, Model 8210 (with Nellcor technology) and the MEDLEY SpO₂ Module, Model 8220 (with Masimo technology) have a similar method of operation and utilize similar accessories. The minor differences as identified in this submission do not alter the fundamental technology of the predicate device.

SYSTEM AND SOFTWARE PERFORMANCE

The performance information provided demonstrates that the MEDLEY SpO₂ Module, Model 8210 and accessories perform as intended and within the required specifications to demonstrate the safety and effectiveness of the device. All required verification testing for the MEDLEY SpO₂ Module, Model 8210 (Nellcor) has been completed. Design verification testing including software V&V is complete, acceptable and design output matches design input. See **Section 8** for detailed system and software performance information.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 11 2002

Ms. Renee L. Fluet
Principal Regulatory Affairs Specialist
Alaris Medical Systems, Incorporated
10221 Wateridge Circle
San Diego, California 92121

Re: K022677
Trade/Device Name: MEDLEY SpO₂ Module and Accessories
Regulation Number: 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: August 9, 2002
Received: August 12, 2002

Dear Ms. Fluet:

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.

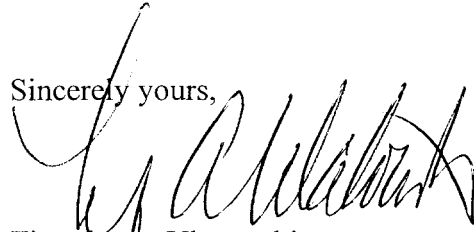
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html>

Sincerely yours,



Timothy A. Ulatowski
Director

Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment B



MEDLEY SpO₂ Module, Model 8210

Indications for Use

510(k) Number: K022677 (To Be Assigned By FDA)

Device Trade Name: **MEDLEY SpO₂ Module**

Indications For Use: The MEDLEY SpO₂ Module and accessories are indicated for the continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO₂) and pulse rate. It is intended for use with neonatal, pediatric, and adult patients during both no motion and motion conditions, and for patients who are either well or poorly perfused, in hospitals and hospital-type facilities.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use OR Over-The-Counter Use
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K022677