SPECIAL 510(K)
510(k) Summary
For the Medos Medizintechnik AG
Medos Hilite 2800 & 2400 LT Oxygenators

FEB 18 2014

I. SUBMITTER/510(k) HOLDER:

Medos Medizintechnik AG
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Head of Regulatory Affairs: Heiko Frerichs
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II. CONTACT PERSON

Leann Christman
Novalung, Inc.
3526 West Liberty Rd., Suite 100
Ann Arbor, MI 48103
Telephone: (734) 995-9089 ext. 232
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Email: leann.christman@Novalung.com

III. DEVICE NAME

Proprietary Trade Name: Medos Hilite 2800 & 2400 LT Oxygenators
Common/Usual Name: Blood Oxygenator

IV. DEVICE CLASS:

Class II

V. CLASSIFICATION NAME AND CITATION:

Classification Name: Oxygenator, Cardiopulmonary Bypass
Classification regulation: Sec. 870.4350

VI. PRODUCT CODES:

DTZ

VII. PREDICATE DEVICES

K090450, Medos Hilite 2800 & 2400 LT Oxygenators

VIII. PRODUCT DESCRIPTION

The Medos Hilite 2800 & 2400 LT Oxygenators consist of a hollow fiber membrane oxygenator and extracorporeal heat exchanger. The Medos Hilite 2800 hollow fiber membrane consists of a polypropylene gas permeable mat. The Medos Hilite 2400 LT hollow fiber membrane consists of a polymethylpentene plasma tight mat. The unique mat design increases the interaction between blood and gas, creating a highly efficient blood oxygenator. The heat exchanger consists of a polyester non-porous hollow fiber configured heat exchanger as the primary element to affect heat exchange. This element is encased by a polycarbonate housing, which directs the blood around the outside of the fibers while water flows through the inner lumen of the fibers and therefore effects heat exchange while minimizing priming volume.

The device allows for trapping and removal of air. Oxygenated blood is delivered to the patient through the tubing and appropriate cannula. Blood flow is driven by a roller pump or centrifugal pump connected through the tubing. The Medos Hilite 2800 and 2400 LT Oxygenators may be purchased separately or pre-connected with tubing and other components of an extracorporeal circuit.

IX. INDICATIONS OF USE

The Medos Hilite 2800 & 2400 LT Oxygenators are indicated for use in procedures requiring the extracorporeal oxygenation of and carbon dioxide removal from human blood. It is designed to operate at a blood flow rate of 0.5 to 2.8 liters per minute for the Hilite 2800 and 0.5 to 2.4 liters per minute for the Hilite 2400 LT for periods of up to six (6.0) hours.

X. TECHNOLOGICAL CHARACTERISITICS AND SUBSTANTIAL EQUIVALENCE

The Medos Hilite 2800 & 2400 LT Oxygenators are identical to the predicate device in terms of intended use, indications for use, levels of attachment, fundamental scientific technology, materials and surgical technique. Based on the information provided herein, the subject Medos Hilite 2800 & 2400 LT Oxygenators have been demonstrated to be substantially equivalent to the previously cleared Medos Hilite 2800 & 2400 LT Oxygenators (K090450). Please refer to the Table 9-1 for a comparison of the predicate and subject Medos Hilite 2800 & 2400 LT Oxygenators regarding substantial equivalence.

XI. PERFORMANCE TESTING

The Medos Hilite 2800 & 2400 LT Oxygenators have been subjected to extensive safety, performance, and validations prior to release. Final testing for the systems includes various performance tests designed to ensure that the device meets all of its functional requirements and performance specifications. Safety tests have further been performed to ensure the device complies with applicable industry and safety standards. The following tests were performed due to the change in potting material:

- Blood Pathway Integrity
- Heat Exchanger Fluid Pathway Integrity
- Chemical analysis
    - Macroplast CR 3502 / CR 4100, EO sterilized
    - Hilite 7000, PUR Macroplast CR3505/CR4605
    - Hilite 7000 LT, PUR Macroplast CR3505/CR4605

  - Hilite 7000, PUR Macroplast CR3505/CR4100
- Evaluation of Biological Safety – toxicology
  - Macroplast CR 3502 / CR 4100, PUR posting material for hollow fibers of oxygenators
- Cytotoxicity, L 929-Proliferation
  - Macroplast CR 3502 / CR 4100, EO sterilized
- Hemolysis (elution method)
  - Macroplast CR 3502 / CR 4100, EO sterilized
- Cytotoxicity
- Sensitization
- Intracutaneous Reactivity
- Acute Systemic Toxicity
- Pyrogen
- Hemocompatibility

XII. SUMMARY AND CONCLUSIONS

Medos Medizintechnik AG makes the claim that the Medos Hilite 2800 & 2400 LT Oxygenators are substantially equivalent to the cited predicate in terms of intended use, indications for use, fundamental technology, design characteristics, generic materials of construction, and operational characteristics. As shown in Table 9-1 and the discussion above, the differences between the Medos Hilite 2800 & 2400 LT Oxygenators and cited predicate are minor and raise no new issues of safety or effectiveness. The Medos Hilite 2800 & 2400 LT Oxygenators meet design specifications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

February 18, 2014

Medos Medizintechnik AG
c/o Leann Christman
Novalung, Inc.
3526 West Liberty, Suite 100
Ann Arbor, Mich. 48103

Re: K140177
Trade/Device Name: Medos hilite 2800 & 2400 LT Hollow Fiber Oxygenators
Regulation Number: 21 CFR 870.4350
Regulation Name: Cardiopulmonary Bypass Oxygenator
Regulatory Class: Class II
Product Code: DTZ, DTR
Dated: January 22, 2014
Received: January 24, 2014

Dear Ms. Christman:

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 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/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known) K140177

Device Name: Medos hilite 2800 & 2400 LT Oxygenators

Indications for use:

The Medos hilite 2800 & 2400 LT Hollow Fiber Oxygenators are indicated for use in procedures requiring the extracorporeal oxygenation of and carbon dioxide removal from human blood. It is designed to operate at a blood flow rate of 0.5 to 2.8 liters per minute for the hilite 2800 and 0.5 to 2.4 liters per minute for the hilite 2400 LT for periods of up to six (6.0) hours.

Prescription Device:
Federal Law (US) restricts this device to sale by or on the order of a physician.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: **Yes** OR Over-The-Counter Use: No