K993656

MAR 15 2000

Premarket Notification 510(k) Summary
As required by section 807.92
Datex-Ohmeda Tonometry Module, M-TONO

GENERAL COMPANY INFORMATION as required by 807.92(a)(1)

COMPANY NAME/ADDRESS/PHONE/FAX:

Datex-Ohmeda, Inc.
3 Highwood Drive
Tewksbury, MA 01876
Tel: 978-640-0460
Fax: 978-640-0469

NAME OF CONTACT:

Mr. Joel Kent
FDA Official Correspondent

DATE:

October 28, 1999

DEVICE NAME as required by 807.92(a)(2)

TRADE NAME:

Datex-Ohmeda Tonometry Module, M-TONO

COMMON NAME:

Regional Capnometer

CLASSIFICATION NAME:

Analyzer, Gas, Carbon-Dioxide, Gaseous-phase (per 21CFR 868.1400)

NAME OF LEGALLY MARKETED DEVICE FOR WHICH A CLAIM OF SUBSTANTIAL EQUIVALENCE IS MADE as required by 807.92(a)(3)

The Datex-Ohmeda Tonometry Module, M-TONO is substantially equivalent to the legally marketed (predicate) Tonocap™ Monitor (K962638).

Datex-Ohmeda, Inc.
Three Highwood Drive
Tewksbury, MA 01876
www.datex-ohmeda.com

Telephone: 800-635-6099
978-640-0460
Facsimile: 978-640-0469

DEVICE DESCRIPTION as required by 807.92(a)(4)

The Datex-Ohmeda Tonometry Module, M-TONO (later referred to as M-TONO) is a module used to monitor gastrointestinal PCO2. The user interface has been implemented in the main software of the AS/3 and CS/3 monitoring systems.

The Datex-Ohmeda Tonometry Module, M-TONO is intended to be used with a Datex-Ohmeda Modular monitoring systems for gastrointestinal tonometry measurements.

The Datex-Ohmeda Tonometry Module, M-TONO is indicated for monitoring gastrointestinal CO2 (PgCO2) and calculation of various gastrointestinal tonometry parameters when used with a Datex-Ohmeda monitoring system.
It is indicated for use in hospital patients.

This device is indicated for use by qualified medical personnel only.

M-TONO is a single-width plug-in parameter module including the tonometry measurement module for a modular monitoring system. This module is designed for use in the following Datex-Ohmeda modular monitors; AS/3 Anesthesia Monitor, AS/3 Compact Monitor, CS/3 Compact Monitor and CS/3 Critical Care Monitor.

The tonometry module measures the gastrointestinal PCO2 (PgCO2) every 10 minutes utilizing a tonometry catheter placed into the patient's stomach or intestine. Initially the module fills the balloon of the Tonometrics catheter with ambient air, then repeatedly every 10 minutes deflates the balloon, analyzes and displays the PgCO2, and inflates the balloon again.

INTENDED USE as required by 807.92(a)(5)

The Datex-Ohmeda Tonometry Module, M-TONO is intended to be used with a Datex-Ohmeda Modular monitoring systems for gastrointestinal tonometry measurements.

The Datex-Ohmeda Tonometry Module, M-TONO is indicated for monitoring gastrointestinal CO2 (PgCO2) and calculation of various gastrointestinal tonometry parameters when used with a Datex-Ohmeda monitoring system.
It is indicated for use in hospital patients.

SUMMARY OF TECHNOLOGICAL CHARACTERITICS OF DEVICE COMPARED TO THE PREDICATE DEVICE as required by 807.92(a)(6)

The Datex-Ohmeda Tonometry Module, M-TONO is substantially equivalent to the legally marketed (predicate) Tonocap™ Monitor (K962638). Based on the analysis and other documentation included in this 510(k) notification and attachments it is evident that the main features and indications for use of Datex-Ohmeda Tonometry Module, M-TONO is substantially equivalent to the predicate Tonocap™ Monitor (K962638).
The Datex-Ohmeda Tonometry Module, M-TONO and TONOCAP™ monitor (K962638) have the same intended use for gastrointestinal PCO2 monitoring.
The Datex-Ohmeda Tonometry Module, M-TONO and TONOCAP™ monitor (K962638) are indicated for monitoring gastrointestinal PCO2 (PgCO2) and calculation of various gastrointenstinal tonometry parameters. Both are indicated for use in hospital patients.
The Datex-Ohmeda Tonometry Module, M-TONO uses Tonometrics catheters, which have separate 510(k) clearances, similar to those used by the predicate TONOCAP™ monitor (K962638).
The main differences between M-TONO and the predicate is primarily due to fact that M-TONO is a module used in modular system while predicate TONOCAP™ monitor (K962638) is a stand-alone configured monitor. Additionally, airway gas measurement is not made with M-TONO since another module in the AS/3 and CS/3 family already handles this function.
The M-TONO module can also measure higher PgCO2 than the predicate TONOCAP™ monitor (K962638).
The M-TONO module uses a smaller PgCO2 measurement volume than predicate TONOCAP™ monitor (K962638).

It is evident that the Datex-Ohmeda Tonometry Module, M-TONO is substantially equivalent to the predicate TONOCAP™ Monitor (K962638).

The comparison above shows that there are no questions of safety and effectiveness for the Datex-Ohmeda Tonometry Module, M-TONO.

SUMMARY OF NONCLINICAL TESTING FOR THE DEVICE and CONCLUSIONS as required by 807.92(b)(1)(3)

The Datex-Ohmeda Tonometry Module, M-TONO has taken into account general electrical safety requirements in the design.
The following safety standards have been followed:

- IEC 60601-1:1988 + Amendments: A1:1991,A2:1995
- CAN/CSA C22.2 No. 601-1-M90 (1990) + S1 (1994)+Amdt2:1998
- IEC 60601-1-2:1993
- IEC 60601-1-4:1996

The Datex-Ohmeda Tonometry Module, M-TONO complies with the requirements of above mentioned safety standards and is therefore safe and effective for the intended use.
The module has been thoroughly tested including electrical safety, electromagnetic compatibility, mechanical and environmental tolerance, software validation and verification of specifications.

Conclusion:
The summary above shows that there are no questions of safety and effectiveness for the Datex-Ohmeda Tonometry Module, M-TONO as compared to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 15 2000

Mr. Joel C. Kent
FDA Official Correspondent
Manager, Quality and Regulatory Affairs
Datex-Ohmeda, Inc.
Three Highwood Drive
Tewksbury, Massachusetts 01876

Re: K993656
M-TONO Tonometry Module
Dated: February 17, 2000
Received: February 18, 2000
Regulatory Class: II
CFR §868.1400/Procode: 73 CCK

Dear Mr. Kent:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

510(k) Number (if known): K993656

Device Name: Datex-Ohmeda Tonometry Module, M-TONO

Indications For Use:

The Datex-Ohmeda Tonometry Module, M-TONO is indicated for monitoring gastrointestinal CO2 (PgCO2) and calculation of various gastrointestinal tonometry parameters (gastrointestinal - arterial PCO2 difference, gastrointestinal - end-tidal PCO2 difference and intramucosal pH) when used with a Datex-Ohmeda modular monitoring system. It is indicated for use in hospital patients.

This device is indicated for use by qualified medical personnel only.

(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)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K993656