



DEC 23 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Joel C. Kent
Manager, Quality and Regulatory Affairs
Datex Engstrom, Inc.
3 Highwood Drive
Tewksbury, MA 01876

Re: K983366
TRIP Tonometry Catheter, 16F (with stopcock) and
TRIP Tonometry Catheter, 16F
(with integral sampling line and biofilter)
Dated: September 21, 1998
Received: September 24, 1998
Regulatory Class: II
21 CFR 876.5980/Procode: 78 KNT
21 CFR 868.1400/Procode: 73 CCK
21 CFR 868.1700/Procode: 73 CBR

Dear Mr. Kent:

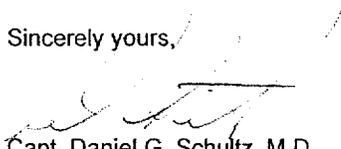
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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) 594-4613. 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" (21 CFR 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,


Capt. Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K983366

Device Name: TRIP Tonometry Catheter, 16 F (with stopcock) and
TRIP Tonometry Catheter, 16 F (with integral sampling line and biofilter

Indications For Use:

The Trip® Tonometry Catheter, 16 F (with stopcock)

The Trip Tonometry Catheter, 16 F (with stopcock) is used for the determination of regional PCO₂ (PrCO₂) and intramucosal pH (pHi) of the gastric mucosal tissue.

This catheter is also used as a gastrointestinal tract access device for connecting the Tonocap™ monitor. The sampling line and biofilter (which are separate from the device) serve as a means of connecting the catheter to the Tonocap™ monitor and as a transducer protector to prevent patient cross-contamination and to prevent monitor damage, respectively. Since it incorporates a vented gastric sump, the catheter is also used for feeding and/or decompression or aspiration of the contents of the stomach.

The device is indicated for use in surgical/operating room patients, intensive care unit patients, emergency/trauma patients and hospital patients with suspected mesenteric ischemia

The Trip® Tonometry Catheter, 16 F (with biofilter and sampling line)

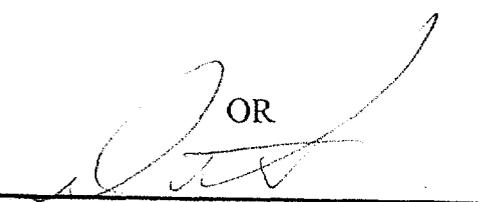
The Trip Tonometry Catheter, 16 F (with biofilter and sampling line) is used for the determination of regional PCO₂ (PrCO₂) and intramucosal pH (pHi) of the gastric mucosal tissue when used as a gastrointestinal tract access device for connecting the Tonocap™ monitor. The sampling line and biofilter serve as a means of connecting the catheter to the Tonocap™ monitor and as a transducer protector to prevent patient cross-contamination and to prevent monitor damage, respectively. Since it incorporates a vented gastric sump, the catheter is also used for feeding and/or decompression or aspiration of the contents of the stomach.

The device is indicated for use in surgical/operating room patients, intensive care unit patients, emergency/trauma patients and hospital patients with suspected mesenteric ischemia

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR


Over-The-Counter Use

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K983366