



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 2 2002

Millar Instruments, Inc.
c/o Ms. Monica R. Montanez
Manager, Regulatory Affairs/Quality Assurance
6001-A Gulf Freeway
Houston, TX 77023

Re: K013205
Trade Name: Pressure Control Unit PCU-2000
Regulation Number: 21 CFR 870.2060
Regulation Name: Transducer Signal Amplifier and Conditioner
Regulatory Class: Class II (two)
Product Code: DRQ
Dated: April 8, 2002
Received: April 9, 2002

Dear Ms. Montanez:

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,



Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 2

Indications for Use Statement

510(k)
Number
(if known)

K013205

Device Name

Millar PCU-2000

Indications
for Use

The PCU-2000 Pressure Control Unit is a two-channel electrically isolated amplifier that is intended for use with Millar Mikro-Tip Pressure Catheters that have the standard medical sensitivity of 5 microvolts per mmHg of applied pressure and per volt of bridge excitation. The PCU-2000 provides an electrical interface between a physiological pressure transducer and a data acquisition module or medical monitor. It is intended for use in monitoring diagnostic pressures, such as noninvasive or invasive blood pressures, intracranial pressures, gastrointestinal pressures, esophageal pressures, urinary tract pressures, intrauterine pressures, intraocular pressures and other physiological pressures with similar ranges. It is intended for use in critical care areas in a hospital and in diagnostic centers in hospitals or medical clinics. It is intended for use by trained clinicians or research personnel.

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)

Over-The-Counter Use



(Division Sign-Off)
Division of Cardiovascular
and Respiratory Devices

510(k) Number

K013205