

July 31, 1997

VIDCO MDP2000

510k SUMMARY

510k number: K972880

Submitter: VIDCO, Inc.
6175 SW 112th Avenue
Beaverton, OR 97008

Contact: Bradley A. Cohen
Phone: (503) 641-1804
FAX: (503) 641-1806

Device Name/Common Name: MDP2000 Medical Data Processor/Remote Display & Central Display

The MDP2000 is intended for use in conjunction with patient monitoring equipment. The MDP2000 is *not* patient connected. It accepts analog and/or digital physiological information from patient monitoring equipment and processes these signals to provide outputs to:

- *Color monitors for display of information*
- *Chart recorders or printers for hardcopy records*
- *Media for storage*
- *Other devices to share information*

The MDP2000 is substantially equivalent to current and previously marketed VIDCO products:

VIDCO model 580CD (K926162)
VIDCO model 620CSR (K932894)
VIDCO model 580CDR (K934093)
VIDCO model 516YT (K926219)
VIDCO model 520 (K926298)

The MDP2000 has no new questions of safety or effectiveness as it is performing essentially the same functions as the predicate devices. For the same rationale, no new hazards arise when comparing the MDP2000 to the predicate devices.

Technical characteristics of the MDP2000 are similar to the predicate devices. Primary differences include: Reduced physical size, improved display resolution capabilities (aesthetics), and improved user interface to simplify operation.

The MDP2000 has been tested to and conforms with UL2601, the domestic standard of IEC 601-1, as a Class I Type B device. Testing has been conducted by Intertek Testing Services (formerly Inchcape, Inc.), an NRTL (nationally recognized test laboratory), and Notified Body in the European Union. The MDP2000 is ETL listed indicating conformance to UL2601. The predicate devices, except 516YT and 520, were Underwriters Laboratory Listed under the now obsolete UL544.

The MDP2000 has been tested to and conforms to the requirements of EN60601-1-2 (IEC 601-1-2), Collateral Standard for Electromagnetic Compatibility. The testing was conducted by Northwest EMC which is an FCC, NIST, and NVLAP recognized testing facility in the United States and accepted and accredited internationally by agencies such as TÜV and NEMKO. The EMC performance of the MDP2000 exceeds the predicate devices.

Validation performed consists of bench testing of specifications as called out in the Engineering Instrument Specification that is an integral part of the Device Master Record. All tests were completed successfully and the MDP2000 meets it's specified performance including those related to ANSI/AAMI EC13 (1992) Heart Rate Meters & Alarms. The MDP2000 performance results are equivalent to or better than the predicate devices.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 22 1997

Mr. Bradley A. Cohen
VIDCO, Inc.
6175 SW 112th Avenue
Beaverton, Oregon 97008

Re: K972880
MDP2000 Medical Data Processor
Regulatory Class: II (two)
Product Code: 74 MSX
Dated: July 31, 1997
Received: August 5, 1997

Dear Mr. Cohen:

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 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.

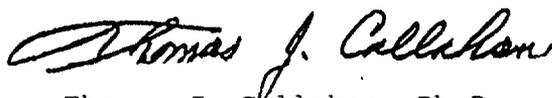
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

Page 2 - Mr. Bradley A. Cohen

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) 594-4648. 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/dsmamain.html>".

Sincerely yours,



Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INTENDED USE STATEMENT

510k number: K972880

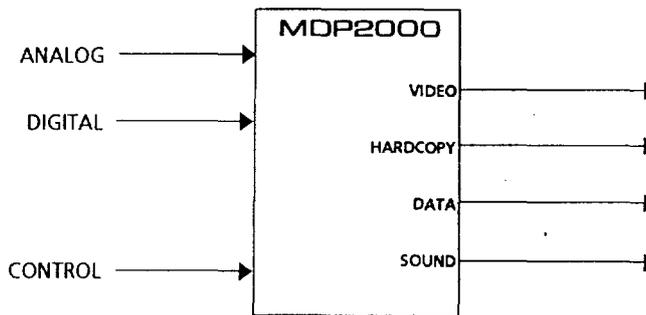
Device Name: MDP2000 Medical Data Processor

The MDP2000 is intended for use in conjunction with patient monitoring equipment. The MDP2000 is **not** patient connected. It accepts analog and/or digital physiological information from patient monitoring equipment and processes these signals to provide outputs to:

- Color monitors for local and remote display of information
- Chart recorders or printers for hardcopy records
- Media for storage
- Other devices to share information

Examples of areas where the MDP2000 is used include ICU, CCU, PACU, Emergency, Telemetry, Step-down and other areas where patient's physiological information are to be observed at one or more locations. Typical information displayed includes ECG and blood pressure waveforms and numeric values such as heart rate and systolic, mean, and diastolic pressure. *This device acts as the Central monitor station, it permits from one (1) to sixteen (16) bedside monitor(s) to be connected simultaneously.*

Block Diagram



Arth. A. Ciarkowski
(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K972880

Prescription Use x
(Per 21 CFR 801.109)