EXHIBIT 5

JUN 11 1999

CAPINTEC, INC.

K982448

510(k) SUMMARY

Submission Date: July 13, 1998

Pursuant to the requirements of Section 510(k) of the Food, Drug, and Cosmetic Act, notification is made by Capintec, Inc. on behalf of MedSet to manufacture and market an ambulatory electrocardiogram with analysis algorithm.

Medset is located at the following site:

Medset Medizintechnik GmbH
Postfach 800 103
D-21001
Hamburg, Germany

Tel: 49-40-725-822-0
FAX: 49-40-725-822-11

510(k) Contact:
Mary Anne Dell
Capintec, Inc.
540 Alpha Drive
Pittsburgh, PA 15238

Tel: 412-963-1988
FAX: 412-963-0610

Classification Name:	Holter
Classification Number:	74MLO (870.2800) or DSH
Common or Usual Name:	Electrocardiograph, Ambulatory, with analysis algorithm
Proprietary Name:	Cardiolight Ambulatory Cardiac Monitor
Establishment Registration Number:	N/A
Regulatory Class:	II

Description: The MedSet Cardiolight System is a real time ambulatory ECG recording and analysis system for a recording period of up to 24 hours. The stored data is

transferred to a PC for graphical display of the results as an aid to the medical diagnosis of heart disease by a trained cardiologist.

Substantial equivalence: The Medset Cardiolight ambulatory ECG recording and analysis system is substantially equivalent to the Medicomp EpiCardia System which was found to be substantially equivalent under 510(k) number K830013A.

Intended Use: The MedSet Cardiolight system is intended to be used by trained ECG technicians with analysis and interpretation by cardiologists for the measurement and analysis of electrocardiogram signals on ambulatory patients as an aid to the diagnosis of heart disease.

Test Results: The accuracy of the automatic ECG analysis was tested using many recorded and manually edited ECG data sets. Among these were the standard data of the American Hearts Association (AHA). Comparing the AHA-annotations to the results of the automatic analysis gives the following results from 150 000 events:

	Sensitivity	**Specifity**	**Pos.predictive accuracy**
Normal	99%	99%	92%
VES	91%	95%	99%

Clinical validation protocol was performed at the University of Ulm Medical Clinic on 150 patients. In addition, the Cariolight ECG System has been in commercial use in Europe for several years and has log term data for clinical use. The conclusion of the validation testing was that "the quality of the automatic analysis of the Cardiolight system corresponds to those of other commercial long term ECG devices."

Conclusion: The MedSet Cariolight Ambulatory ECG System functions as intended and is substantially equivalent in performance and intended use to the EpiCardia Ambulatory ECG System. The MedSet system provides improved performance specifications and better data manipulation compared to its predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 11 1999

Ms. Mary Anne Dell
Capintec, Inc.
540 Alpha Drive
Pittsburgh, PA 15238

Re: K982448
Cardiolight ECG Monitor, including FMC Recorder, PC Interface Card, and Associated Software
Regulatory Class: II (two)
Product Code: 74 DSH
Dated: Undated
Received: April 30, 1999

Dear Ms. Dell:

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

Sincerely yours,

Thomas J. Callahan

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

Enclosure

EXHIBIT 4

K982448

INTENDED USE STATEMENT

The MedSet Cardiolight system is intended to be used by trained ECG technicians with analysis and interpretation by cardiologists for the measurement and analysis of electrocardiogram signals on ambulatory patients as an aid to the diagnosis of heart disease.

Prescription Use ✓

Wolf Sapunlen MD for
(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number _____