APR 7 2000

K993414

Prucka Engineering, Inc.

Advanced Technology for Cardiology

Section C - 510(k) Summary

October 8, 1999

A. Contact Information:

Matthew W. Prucka
Prucka Engineering, Inc.
13000 Executive Drive
Sugar Land, TX 77478

Phone: (281) 275-5011
Fax: (281) 275-5001

B. Device names:

Trade Name: Prucka Engineering, Inc. CardioLab EP System
Common Name: Electrophysiology lab system
Classification Names: Electrocardiograph
Biopotential Amplifier and Signal Conditioner
Programmable Diagnostic Computer
Blood Pressure Computer

C. Substantial equivalence is claimed to the following devices:

Quinton EP System (K971570)
EP Medsystem EP System (K935186)
Biosense Carto System (K954395)

D. Description of device:

The CardioLab EP System is a microprocessor based data acquisition system used during electrophysiology procedures to accquire ECG, intracardiac, pressure, and digital data from other devices such as RF generators and fluoro video systems. The ECG, intracardiac and pressure data are acquired by an amplifier that is connected to the patient by third-party

devices such as ECG leadwires and catheters. The amplifier filters, amplifies, digitizes and transmits the data to the computer. The computer stores the data on optical disks, displays the data on the video monitors, allows the user to perform basic signal measurements, and prints out waveforms on a laser printer or continuous paper recorder. The software has three major functions: data acquisition and display, data storage, and reporting of data. The system is able to acquire signal data in the presence of pacing pulses. In addition to signal waveform display and basic caliper-type measurement, the system allows the user to create isopotential and isochronal activation maps of waveform timing information. The system can also be used to accept video input from a fluoroscopy system for either single frame capture or full motion video display. The system can also acquire data from an RF generator via standard computer RS-232 serial port. The CardioLab EP system does not control the delivery of energy, administer drugs, perform any life-supporting or life-sustaining functions, or analyze physiological data or other data acquired during an EP procedure. It does not transmit alarms or arrhythmias, and does not have arrhythmia detection capabilities.

E. Intended use of device:

The intended use of the Prucka Engineering, Inc. CardioLab EP 4.2 System is to acquire, filter, digitize, amplify, display, and record electrical signals obtained during electrophysiological studies and related procedures conducted in an electrophysiological laboratory. Signal types acquired include ECG signals, direct cardiac signals, and pressure recordings. Physiological parameters such as diastolic, systolic, and mean blood pressure, heart rate, and cycle length may be derived from the signal data, displayed and recorded. The system allows the user to monitor the acquisition of data, review the data, store the data, perform elementary caliper-type measurements of the data, and generate reports on the data. Additionally, the system may acquire, amplify, display, and record data received from other medical devices typically used during these procedures, such as imaging devices and RF generators.

F. Summary of the technological characteristics of the CardioLab EP System compared to the predicate devices:

Technological characteristics of the Prucka Engineering, Inc. CardioLab EP System are the same as predicate devices with the following exceptions:

Comparison Table Reference*	Summary of differences
2	Amplifier leakage current data not available for Biosense Carto System
3	Amplifier input channel types data not available for Biosense Carto System
4	Amplifier output channel types data not available for Biosense Carto System

6	The amplifier in the CardioLab EP System sends digital data to the computer via fiber optic cable which provides complete electrical isolation between the computer and amplifier unit. The predicate devices use an electrical connection between the amplifier and computer, and electrical isolation is provided by an opto isolator inside the amplifier.
7 and 8	The CardioLab EP System, the Quinton EP System and the EP Medsystems EP System use standard personal computers to control the amplifier and use it as the main data processing unit. The Biosense Carto System uses a Sun workstation computer for these functions.
9	The CardioLab EP System, the Quinton EP System and the EP Medsystems EP System have independently controlled monitors which display real-time data, review information, and images. The Biosense Carto System has only one computer monitor.
10	The CardioLab EP System, the EP Medsystems EP System, and the Biosense Carto System store data on read/write optical media. The Quinton EP System stores data on "write once" media.
12	The CardioLab EP System, the Quinton EP System and the EP Medsystems EP System have the ability to print data on a strip chart recorder. The Biosense Carto System does not have this feature.
13	The CardioLab EP System and the Quinton EP System have input for a third party cardiac stimulator which will connect the stimulator to the intracardiac signal inputs with no control over the function of the third party cardiac stimulator. The EP Medsystems EP System has the same properties, except it controls the function of the external stimulator. Third party stimulator input capability data not available for the Biosense Carto System.
15	The CardioLab EP System, the Quinton EP System and the EP Medsystems EP System have the ability to record from intracardiac signal at the same time a third party cardiac stimulator is pacing to the intracardiac signal. Biosense Carto System data not available with respect to this feature.
16	The CardioLab EP System, the Quinton EP System and the EP Medsystems EP System can connect to third party RF generators using a standard RS-232 serial prot in order to acquire, display, store and print data from the third party RF generators. The Biosense Carto System does not have this feature.
17	The CardioLab EP System, the Quinton EP System and the EP Medsystems EP System have standard video frame grabber board that operates in the personal computer and digitizes standard video images for display on the computer monitor and storage with the patient information. The Biosense Carto System does not have this feature.
18	The CardioLab EP System and the Biosense Carto System have the ability to display waveform timing information in a two dimensional color map that indicates either the isocronal or isopotential timing information. The Quinton EP System and EP Medsystem EP System do not have this feature.

*See corresponding number in comparison table in Section F.

Each technological characteristic of the CardioLab EP System is found in at least one predicate device used in the same type of procedure as the CardioLab EP System is intended to be used in. The technological differences listed above are minor and do not raise new issues of safety and efficacy. The technological characteristics of the CardioLab EP System are substantially equivalent to technological characteristics found in predicate devices.

G. Brief discussion of the nonclinical tests and how their results support a determination of substantial equivalence:

The equipment has been tested and certified to meet the following national and international safety stadards by SEMKO which is an Inchcape Testing Services Company.

IEC 601-1
IEC 601-1-1
IEC 601-1-2
IEC 601-2-27
IEC 601-2-34

The equipment has also been tested by ETL Testing Laboratories with the applicable requirements of the FDA Reviewer Guidance for premarket Notification Submissions, November 1993.

In addition, an in-house validation has been performed on the system with results that meet acceptance criteria, confirming the safety and efficacy of each functional aspect of the system.

These tests conducted by outside laboratories together with system level validation testing conducted in-house provide complete confirmation that the system is safe and effective for its intended use. This demonstrates that the Prucka Engineering, Inc. CardioLab EP 4.2 System has a substantially equivalent level of safety and efficacy as predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 7 2000

Mr. Matthew Prucka
President
Prucka Engineering, Inc.
13000 Executive Drive
Sugar Land, TX 77478

Re: K993414
Prucka Engineering, Inc. CardioLab EP System, Version 4.2
Regulatory Class: II (two)
Product Code: DPS
Dated: February 3, 2000
Received: February 4, 2000

Dear Mr. Prucka:

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) 594-4639. 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,

for James E. Dillard III
Director
Division of Cardiovascular, Respiratory
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K993414

Device Name: CardioLab EP System, Version 4.2

Indications For Use:

The intended use of the Prucka Engineering, Inc. CardioLab EP 4.2 System is to acquire, filter, digitize, amplify, display, and record electrical signals obtained during electrophysiological studies and related procedures conducted in an electrophysiological laboratory. Signal types acquired include ECG signals, direct cardiac signals, and pressure recordings. Physiological parameters such as diastolic, systolic, and mean blood pressure, heart rate, and cycle length may be derived from the signal data, displayed and recorded. The system allows the user to monitor the acquisition of data, review the data, store the data, perform elementary caliper-type measurements of the data, and generate reports on the data. Additionally, the system may acquire, amplify, display, and record data received from other medical devices typically used during these procedures, such as imaging devices and RF generators.

The CardioLab EP system does not control the delivery of energy, administer drugs, perform any life-supporting or life-sustaining functions, or analyze physiological data or other data acquired during an EP procedure. It does not transmit alarms or arrhythmias, and does not have arrhythmia detection capabilities.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Megan Moynihan for Jim Dillard

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K993414

(Optional Format 3-10-98)