K083093
p1/3

Cheetah Medical
Cheetah Medical, Inc
2828 SW Corbett Avenue, Suite 214-C
Portland, Oregon 97201
USA

DEC 15 2008

510(k) Summary

Submitter: Cheetah Medical, Inc.
2828 SW Corbett Avenue, Suite 214-C
Portland, Oregon 97201

Contact Person:
Rhona Shanker
Regulatory Consultant to
Cheetah Medical, Inc.
Ph: (301) 251-9570
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Device: Trade Name:
Cheetah Reliant
Common/Usual Name
Portable, non-invasive Cardiac Output monitoring device
Non-invasive blood pressure monitor
Classification Name:
21 CFR 870.2770/DSB – Impedance plethysmograph
21 CFR 870.1130/DXN – Non-invasive blood pressure monitor

Predicate Devices:
K072662 – Cheetah Reliant
K010164 – GE Medical Systems ICG Module
K081590 – Ya Horng Arm Type Digital Blood Pressure Monitor

Device Description:
The Cheetah Reliant with NIPB functionality is a modification of the Cheetah Reliant device cleared under K072662. The significant modification discussed in this 510(k) submission is the addition of a Non Invasive Blood Pressure (NIBP) module to the system which involved updating the user interface to allow operating the NIBP module and for displaying the results and saving them within the device's database.

The NIBP Module is the Advantage mini OEM BP™ module (Model 2 Mini), manufactured by SunTech Medical Inc. (Morrisville, NC, USA). The **ADVANTAGE** mini OEM BP™ Module Series is an oscillometric OEM blood pressure system. The module is controlled via software commands issued from a host system through an asynchronous serial data port (factory configurable to Logic Level or RS-232). All Module operations must be

K083093
p 2/3

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initiated by the Host system (Reliant). The module is designed to take blood pressure measurements (systolic, diastolic, and heart rate) on demand. After each blood pressure measurement, the Module discards the previous blood pressure results.

Indications for Use:

The Cheetah Reliant with NIBP functionality is a portable, non-invasive Cardiac Output monitoring device that monitors and displays a patient' Cardiac Output (CO) in Ltr/Min with a non-invasive blood pressure function that non-invasively measures and displays blood pressure (diastolic, systolic, and mean) and heart rate. In addition, the device measures and displays associated hemodynamic parameters based on calculations of measurements already incorporated into the Cheetah Reliant. These parameters are: Cardiac Index (CI), Ventricular Ejection Time (VET), Total Peripheral Resistance Index (TPRI), Stroke Volume Index (SVI), Stroke Volume Variation (SVV), Cardiac Power (CP), Cardiac Power Index (CPI), electrical impedance of the chest cavity (Z0) and Thoracic Fluid Content (TFC). The Cheetah Reliant with NIBP functionality is intended for use within hospitals and other healthcare facilities (e.g., outpatient clinics) that provide patient care.

The original indications for use for the Cheetah Reliant stated the Cheetah Reliant is a portable, non-invasive Cardiac Output monitoring device based on bio-impedance Cardiography. The Cheetah Reliant system is intended to monitor and display a patient's Cardiac Output in units of Ltr/min.

The revised "indications for use" includes the NIBP functionality and has been revised to identify the hemodynamic parameters displayed by the unit that were measured by the original Reliant and that are based on calculations of those measurements. The statement has also been revised to indicate where the device may be used. This additional information is consistent with the indications for use statement for the GE Medical Systems ICG Module cleared under K010164.

Comparison to Predicates

Like the original Cheetah Reliant, the Cheetah Reliant with NIBP functionality is a portable, non-invasive Cardiac Output measurement system that measures cardiac output by employing an electrical bio-impedance based measurement technique. This technology is substantially equivalent to the GE Medical Systems ICG module that measures and processes a patient's hemodynamic parameters using non-invasive bioimpedance technology. The NIBP function of the Cheetah Reliant is substantially equivalent to the Ya Horng Arm Type Digital Blood Pressure Monitor in that both devices use the oscillometric method to determine systolic and diastolic blood pressures and pulse rate (heart rate). Further, the NIBP function meets the requirements of ANSI/AAMI SP10:2002.

K083093
p3/3

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Test Summary:

The following tests were conducted to verify performance:

Non-clinical

Compliance with ANSI/AAMI SP10:2002
Software verification and validation
Electrical Safety
EMC

Clinical

Clinical testing was performed that verified conformance with the clinical requirements ANSI/AAMI SP10:2002 for adult subjects.

Conclusion:

The Cheetah Reliant with NIBP functionality is substantially equivalent to the identified predicate devices as it has the same indications for use, incorporates the same fundamental scientific technologies as the predicates, and testing demonstrates that its performance is substantially equivalent. As such, the Cheetah Reliant with NIBP functionality is safe and effective for use as described in the indications for use statement.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Cheetah Medical, Inc.
Ms. Rhona Shanker
Regulatory Consultant to Cheetah Medical, Inc.
2828 SW Corbett Avenue, Suite 214-C
Portland, Oregon 97201

Re: K083093
Trade/Device Name: Cheetah Reliant
Regulation Number: 21 CFR 870.2770 and 21 CFR 870.1130
Regulation Name: Impedance Plethysmograph and Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DSB and DXN
Dated: October 17, 2008
Received: October 17, 2008

Dear Ms. Shanker:

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), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K083093

INDICATIONS FOR USE

510(k) Number (if known): K083093

Device Name: **Cheetah Reliant**

Indications for Use:

The Cheetah Reliant with NIBP functionality is a portable, non-invasive Cardiac Output monitoring device that monitors and displays a patient' Cardiac Output (CO) in Ltr/Min with a non-invasive blood pressure function that non-invasively measures and displays blood pressure (diastolic, systolic, and mean) and heart rate. In addition, the device measures and displays associated hemodynamic parameters based on calculations of measurements already incorporated into the Cheetah Reliant. These parameters are: Cardiac Index (CI), Ventricular Ejection Time (VET), Total Peripheral Resistance Index (TPRI), Stroke Volume Index (SVI), Stroke Volume Variation (SVV), Cardiac Power (CP), Cardiac Power Index (CPI), electrical impedance of the chest cavity (Z0) and Thoracic Fluid Content (TFC). The Cheetah Reliant with NIBP functionality is intended for use within hospitals and other healthcare facilities (e.g., outpatient clinics) that provide patient care.

Prescription Use __√__ (Per 21 C.F.R. 801 Subpart D)	OR	Over-The-Counter Use___ (Optional Format Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vachon

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K083093