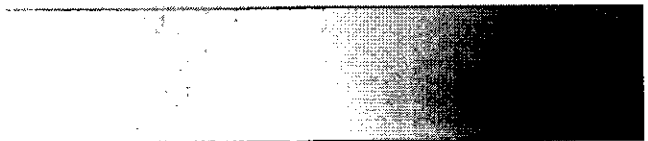




Cheetah Medical

Cheetah Medical, Inc
2828 SW Corbett Avenue
Portland, Oregon 97201
USA



SECTION 5: 510(k) Summary

K101487

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

JUL - 2 2010

Contact Person:

Rhona Shanker
Regulatory Consultant to
Cheetah Medical, Inc.
Z & B Enterprises, Inc.
North Potomac, MD 20878
Ph: (301) 251-9570
Fax: (301) 251-9571

Date Prepared: May 27, 2010

Device Information

Trade name: Cheetah **NICOM System**

Classification Name: Pre-Programmable Diagnostic Computer, 21 CFR 870.1435,
Product code: DXG;
Electrocardiograph electrode, 21 CFR 870.2360, Product Code
DRX

Devices to which substantial equivalence is claimed:

510(k) number	Trade or propriety name	Submitter
K071631	NICOM electrodes	Cheetah-Medical Inc.
K083093	Cheetah Reliant	Cheetah Medical Inc.



Cheetah Medical, Inc
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Portland, Oregon 97201
USA



Device Description:

The Cheetah Reliant non-invasive CO monitor (NICOM) is a portable, non-invasive, Cardiac Output detector system. The NICOM system measures the Cardiac Output by employing the electrical bio-impedance measurement technique. Electrical bio-impedance is the characteristic impedance of a volume of tissue and fluid. In the case of Cardiac Output measurements, the relevant tissue includes the heart and the immediate surrounding volume of the thorax. The relevant fluid is blood.

Cheetah Medical's alternative NICOM Sensor is a double electrode sticker. Within each sticker, one electrode is used to inject the a high frequency sine wave into the body, while the resulting voltage is measured at the adjacent electrode. An array of such electrodes is placed at specific areas of the thorax, the impedance to the current flow calculated, and finally the electrical bio-reactance waveform constructed.

Indication 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). 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) 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 alternative NICOM Sensors are disposable electrodes used in conjunction with the Cheetah Medical NICOM signal processing product line.

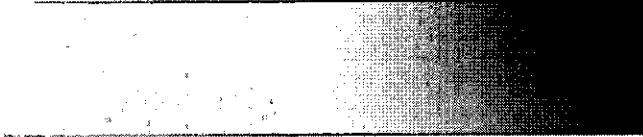
Brief Description of Non-Clinical Testing

The electrodes were tested for and meet the requirements in the following documents:

PAGE 2 OF 3
~~XXXX~~



Cheetah Medical, Inc
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 Portland, Oregon 97201
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AAMI/ANSI EC12:2000/(R)2005, 3 rd edition	Disposables ECG Electrodes
AAMI/ANSI EC53:1995 ECG	Cables and Lead Wires
AAMI/ANSI EC53:1998 ECG	Cables and Lead Wires
IEC 60601-1: 1988 +A1 1991+A2 1995 § -56.3(c)	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance: - Connectors
ASTM F640	Radio Opacity degree
AAMI/ANSI EC12-4.3	Biological Response
ISO 10993-1	Biological evaluation of medical devices Part 1: Evaluation and testing
ISO 10993-5	Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity.
USP AGAR diffusion method	
ISO 10993-10	Biological evaluation of medical devices Part 10: Tests for irritation and delayed-type hypersensitivity

Brief Description of Clinical Testing

The alternative NICOM Electrodes were tested on 15 patients who underwent cardiac output evaluation at Cheetah-Medical Ltd. with the alternative NICOM sensors and the NICOM electrodes cleared for use with the Reliant System.

The data demonstrated that the alternative NICOM Sensors are substantially equivalent to the NICOM electrodes cleared for use with the Reliant System.

Conclusion

The alternative NICOM Sensors manufactured by INTEGRAL PROCESS / Conflans Sainte Honorine, France for Cheetah Medical were extensively tested (bench and clinical) and shown to be substantially equivalent to the NICOM electrodes cleared under K071631 and with K082093.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

~~JUL -2-2010~~

Cheetah Medical, Inc.
c/o Ms. Rhona Shanker
Regulatory Consultant
Z&B Enterprises, Inc.
12154 Darnestown Road
Gaithersburg, MD 20878

Re: K101487
Trade/Device Name: Cheetah NICOM System.
Regulation Number: 21 CFR 870.1435
Regulation Name: Pre-programmable diagnostic computer
Regulatory Class: Class II (two)
Product Code: DXG
Dated: May 27, 2010
Received: May 28, 2010

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 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

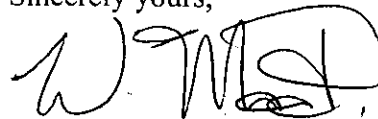
Page 2 – Ms. Rhona Shanker

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



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

Enclosure

SECTION 4: Indications for Use

510(k) Number: K101487

Device Name: Cheetah NICOM System

Indications for Use:

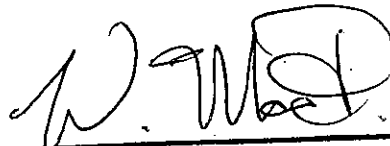
The Cheetah Reliant with NIBP functionality is a portable, non-invasive Cardiac Output monitoring device that monitors and displays a patient's Cardiac Output (CO) in Ltr/Min with a non-invasive blood pressure function that non-invasively measures and displays blood pressure (diastolic, systolic, and mean). 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) 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 alternative NICOM Sensors are disposable electrodes used in conjunction with the Cheetah Medical NICOM signal processing product line.

Prescription Use AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number _____