K093981
p1/3

C N G A
M E D I C A L
Seeing Beyond Imagination

JUL 22 2010

510(K) SUMMARY FOR CNOGA MEDICAL'S TENSORTIP™ – NON-INVASIVE HEMODYNAMIC BLOOD PRESSURE MONITOR

DATE PREPARED: JULY 10, 2010

1. 510(K) OWNER NAME

Cnoga Medical ACAL
North Industrial Park, Ha-Ilan 83 St., Or Akiva, Israel
Tel: +972 4 6361080, Fax: +972 4 6361321, E mail: yosef@cnoga.com
(**Mailing address:** POB 79, Zichron Yaacov, 30900, Israel).

Contact person name: Dr. Yosef Segman, Cnoga Medical's CEO.
Telephone: 972-4-6361080 ext. 105, *E-mail:* yosef@cnoga.com

Submitter: Ms. Tali Hazan – R.A Consultant
Telephone: 972-50-5292304, *Fax:* 972-151-508963806,
E-mail: tali.hazan@012.net.il

2. DEVICE NAME

Common/Usual Name: Non-Invasive Measurement Chamber.
Proprietary/Trade name: TensorTip™ – Non-invasive Hemodynamic Blood Pressure Monitor
Classification: Cnoga Medical's TensorTip- Non-invasive Hemodynamic Blood Pressure Monitor has been classified as **Class II** devices under the following classification names:

Classification Name	Product Code	21 CFR Ref.	Panel
System, measurement, blood-pressure, non-invasive	DXN	870.1130	Cardiovascular
Impedance plethysmograph	DSB	870.2770	Cardiovascular

C N G A
M E D I C A L
Seeing Beyond Imagination

3. PREDICATE DEVICES

Cnoga Medical's TensorTip device is substantially equivalent to the following Predicates:

3.1 A&D Engineering's *A&D Medical Ua-767pbt Digital Blood Pressure Monitor* (non-invasive), cleared under 510(k) number **K043217**.

3.2 Finapres Medical Systems' *Finometer Noninvasive Hemodynamic Monitor,* cleared under 510(k) number **K023723.**

3.3 Finapress Medical Systems' *Portapress Ambulatory Continuous noninvasive blood pressure monitor,* cleared under 510(k) number **K023338.**

4. DEVICE DESCRIPTION

The *TensorTip - Non-invasive Hemodynamic Blood Pressure Monitor* measurement chamber is designed to measure spot-check of heartbeat and blood pressure trending levels by simply inserting the finger into the device "chamber".

It contains a dedicated finger compartment having soft gel on the upper compartment lead door suiting the finger to be placed inside. The device incorporates LEDs (Light Emitting Diode); a sensor array enables to sense the spectrum from near UV to near IR and a rechargeable battery for power supply. The device has large display for displaying temporal Pulse Per Minute (PPM) and Systolic and Diastolic Blood Pressure trending. In addition it shows the capillary blood waveform and the blood pressure variation during the measurement period. It is utilizing software that collects and presents the measured data.
Body contact materials were evaluated for biocompatibility with accordance to *FDA's Memorandum – #G95 1, May 1, 1995* and *ISO 10993-1:2003 - Biological evaluation of medical devices – Part 1: Evaluation and testing* with acceptable results.

K093981
p3/3

C N O G A
M E D I C A L
Seeing Beyond Imagination

5. INTENDED USE

The TensorTip - Non-invasive blood pressure trending device is a small, lightweight, handheld, device intended for measuring and display of Blood Pressure trending (systolic and diastolic) and spot-check of Peripheral pulse rate (PPR) and Peripheral pulse wave (PPW). Measurement is performing on capillary finger tip tissue (other than the thumb). The ring finger is the recommended site. The results of each measurement are stored in the system memory.
The device is intended for use in the home environment.
It is intended to be used by any person aged above 18 years old.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

Cnoga Medical's *TensorTip-Non-invasive Hemodynamic Blood Pressure Monitor* device combines two features (Pulse rate spot-check and blood pressure trending) into one device. Both features are substantially equivalent to the predicate devices already commercially available in the market, as identified in this 510(k) summary, section 3. These predicate devices have the same intended use and share a similar technology as our TensorTip device.
Certain differences in the technology utilized for the TensorTip did not raise new safety and effectiveness questions and found to be substantial equivalence for the device intended use.

7. PERFORMANCE DATA

Cnoga Medical's *TensorTip* spot-check pulse rate and non-invasive blood pressure trending device has been successfully tested with bench, human and safety testing to support the determination of substantial equivalence with predicate devices. Safety and EMC tests were conducted with accordance to EN 60601-1 and EN/IEC 60601-1-2 standards. Clinical validation has met the requirement of ISO 81060-2 standard.

Tests results are supporting all labeling claims and substantial equivalency.

8. CONCLUSIONS

The evaluation of our device performances demonstrates that it is as safe and as effective as predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

JUL 22 2010

Cnoga Medical, Ltd.
c/o Ms. Tali Hazan
Regulatory Affairs Advisor for Medical Devices
Ramot Naftali
M.P. Upper Galilee
ISRAEL 13830

Re: K093981
Trade/Device Name: TensorTip – Noninvasive Hemodynamic Blood Pressure Monitor
Regulatory Number: 21 CFR 870.1130
Regulation Name: Non-invasive Blood Pressure Measurement System
Regulatory Class: II (two)
Product Code: 74 DXN
Dated: June 12, 2010
Received: June 16, 2010

Dear Ms. Hazan:

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.

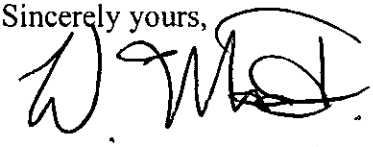
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 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" (21CFR 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

K093981

CNOGA
MEDICAL
Seeing Beyond Imagination

Indications for Use

510(k) Number (if known): K093981

Device Name: TensorTip – Non-invasive Hemodynamic Blood Pressure Monitor

Indications for Use:

The TensorTip - Non-invasive Hemodynamic blood pressure monitor trending device is a small, lightweight, handheld, device intended for measuring and display of Blood Pressure trending (systolic and diastolic) and spot-check of Peripheral pulse rate (PPR) and Peripheral pulse wave (PPW). Measurement is performing on capillary finger tip tissue (other than the thumb). The ring finger is the recommended site. The results of each measurement are stored in the system memory.
The device is intended for use in the home environment.
It is intended to be used by any person aged above 18 years old.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1

(Posted November 13, 2003)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K093981