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SEP 25 2007

## 510(k) Summary
## NetGuard Automated Clinician Alert System

This 510(K) Summary is provided in accordance with 21 CFR 807.92.

**Date:** June 29, 2007

**Submitter:**
Datascope Corp.
800 MacArthur Blvd.
Mahwah, NJ 07430
Contact: Kathleen Kramer
Supervisor, Clinical and Regulatory Affairs
Telephone: 201-995-8169
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**Device Trade Name:** NetGuard Automated Clinician Alert System

**Common Name:** Arrhythmia detector and Alarm

**Device Classification:** Arrhythmia detector and Alarm
21 CFR 870.1025, Product code: DSI, Class: II

**Predicate Devices:** Micropaq™ Vital Signs Monitor, Welch Allyn, K021681
Acuity® Central Monitoring Station, Welch Allyn, K052160

**Device description:** The NetGuard Automated Clinician Alert System is an ambulatory ECG patient monitoring system designed to provide clinicians notification of potentially lethal cardiac events in adult patients, within a healthcare facility.

The NetGuard System is a prescription device to be used by licensed clinicians in a healthcare facility. Departments where the device may be used include:

- Post Operative Recovery Room
- Emergency Department
- Medical/Surgical Patient Floors

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**Indications for Use:**

The NetGuard Automated Clinician Alert System is intended for use by licensed clinicians, within a health care facility, to provide notification of life threatening cardiac events in ambulatory adult patients including:

- Asystole
- Ventricular-Fibrillation

NetGuard monitors a patient's ECG and issues an alert whenever these arrhythmias are detected. The NetGuard System also provides notification for high and low heart rates.

**Technological Comparison to Predicate Device:**

The NetGuard System is technically equivalent to Welch Allyn's Acuity Central Monitoring Station (K052160) and Micropaq Vital Signs Monitor (K021681) with respect to technical and performance characteristic including, but not limited to, transmitting frequency, data storage, patient management, data review, measured physiological parameters and alarm management.

**Summary of Performance Testing:**

The NetGuard System has been tested and found to be in compliance with recognized safety, performance and electromagnetic compatibility standards. The FDA guidance Class II Special Controls Guidance Document: Arrhythmia Detector and Alarm (October 28, 2003), was utilized in the planning and conduct of all performance testing.

A risk analysis has been developed to identify potential hazards and document the mitigation of the hazards. The device's software has been validated in accordance with the requirements set forth in the FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 11, 2005).

**Conclusion:**

Based on the above description, technological comparison, performance testing and the supporting documentation it can be concluded that the NetGuard device is safe, effective and substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 25 2007

Datascope Corp.
c/o Ms. Kathleen Kramer
Supervisor, Clinical and Regulatory Affairs
800 MacArthur Blvd.
Mahwah, NJ 07430

Re: K071805
NetGuard Automated Clinician Alert System
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia detector and Alarm
Regulatory Class: Class II (two)
Product Code: DSI
Dated: June 29, 2007
Received: July 2, 2007

Dear Ms. Kramer:

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 Biometric's (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,

M.G. Hillebrenner

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

Enclosure

# Indications for Use

510(k) Number (if known): K071805

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Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

M. A. Hillebrenner

**(Division Sign-Off)**
**Division of Cardiovascular Devices**

**510(k) Number** K071805