

SEP - 5 2003

510(k) Summary

1. Name: Quinton Inc
2. Address: 3303 Monte Villa Parkway
Bothell, WA 98021-8906
3. Phone number: (425) 402-2255
4. Fax number: (425) 402-2017
5. Contact: Karen Browne
6. Summary prepared: 06/21/2003
7. Proprietary name: Pyramis ECG Management System
8. Common name: Electrocardiograph
9. Classification name: § 870.2340 Electrocardiograph (Accessory)
10. The Pyramis ECG Management System is substantially equivalent to the Quinton Synergy Cardiology Information System, CIS (K964784)

11. Description.

The Pyramis system is a personal computer based, comprehensive data management tool, with multi-tasking capabilities for receiving, editing, retrieving, and printing of ECG, Stress and Holter reports. The Pyramis system uses a transactional client/server database model with database transactional backup logging. User interface tools include bar coding, batch processing, on-screen diagnostic quality waveform viewing, customized header format, dynamic record retrieval and automated Quality Assurance reports on demand. Records can be accessed upon demand and transmitted remotely. The Pyramis system also uses industry standard protocols for communication so it can interface with the hospital's information system.

The Pyramis system can be comprised of two functional components; the client application (user interface), and a suite of server applications that serve to acquire the ECG, Stress and Holter records, store them in a database and print/fax/email and export (distribute) those selected records.

12. Intended use:

The Pyramis ECG Management System is an ECG data management and information system. Its primary function is to store records of biologic origin such as ECG, Stress and Holter records received from those respective recording devices in a database and subsequently allow the user to select, view, edit, print/fax/email and export (distribute) those records.

13. Technological comparison.

Both devices are based on personal computer (PC) platforms. Both the Pyramis ECG Management System and the Synergy Cardiology Information System, receive, view, edit and transmit ECG records. Neither device modifies the original waveform as provided by the ECG recording device. The transmission of records includes email and faxing of stored ECG waveforms and reports. The Pyramis ECG Management System can also receive, view, edit, print and transmit Stress and Holter records as well. The Pyramis system can calculate multiple QTc metrics, based upon the data provided by the ECG record. The metric provided is not an interpretation of data, but the result of a selected QTc formula - the interval between the Q and T, ECG waveforms.

Both systems provide information for qualified clinicians responsible for the diagnosis and treatment of patients (adult and pediatric) with heart disease.

Both systems can be comprised of two functional components; the client application (user interface), and a suite of server applications that serve to acquire, store, retrieve and transmit the ECG records; with the proposed device having the additional capability of acquiring, storing, retrieving and transmitting Stress or Holter records.

The differences in the hardware platforms and off the shelf software used to operate the proposed device are considered to be improvements in the "state of the art" as compared to the predicate device, and offer no affect to the safety or efficacy of the product.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 5 2003

Quinton, Inc.
c/o Ms. Karen Browne
Director, Quality Assurance and
Regulatory Affairs
3303 Monte Villa Parkway
Bothell, WA 98021-8906

Re: K032038
Trade Name: Pyramis ECG Management System
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable diagnostic computer
Regulatory Class: Class II (two)
Product Code: DQK
Dated: June 30, 2003
Received: July 1, 2003

Dear Ms. Browne:

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.

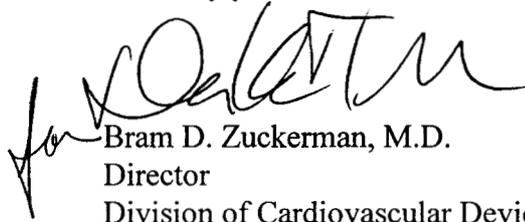
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

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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 Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman". The signature is written in a cursive style with a large initial "B" and "Z".

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

Enclosure

510(k) Number (if known): K032038

Device Name: Pyramis ECG Management System

Indications For Use:

- The system may be used to store, retrieve, edit and report records of biologic origin such as ECG, exercise stress and Holter tests.
- The system can receive tests from a variety of devices. Data is then available through onscreen display, printer, email, fax, HIS (Hospital Information System) results reporting interface or via customized database queries.
- Users may view and edit interpretative statements and measurements through the onscreen display.
- The system can calculate multiple QTc metrics based upon acquired ECG data.
- The system does not modify the original ECG waveform information, nor does it provide an automated ECG interpretive analysis of the data.
- The system is designed to provide information for qualified clinicians responsible for the diagnosis and treatment of patients (adult and pediatric) with heart disease.
- The system is designed for use in a clinical setting by physicians, nurses, clinical technicians, medical records personnel and medical record transcriptionists.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____



(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K032038