

APR 30 1998

510(k) SUMMARY
K973335

Date: August 28, 1997

Sponsor: Zenyx Scientific Ltd.
Broadoak Business Centre
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Contact: Paul W. McWalter

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Proprietary Names: Quatro SP Sample Processing Systems
Quatro Concerto Software

Classification Name: Automated Pipetting and Diluting System

Common Name: Robotic Sample Processor

Predicate Device: Novapath SP Advanced Liquid Handling System, which is the Quatro SP 200D, manufactured under OEM arrangement for Bio-Rad Laboratories. The Novapath included a microplate reader with computer interface. This sample processing system was cleared for US marketing on March 9, 1990 under reference number K900775. The differences in the Quatro 200D and other SP Series models involve workstation capacity for handling tubes and microplates, physical dimensions, keypad control option, and bar code reader option. All Quatro SP models are identical to the Novapath in principles of operation, intended use, power requirements and consumption, and most functional and technical specifications.

Device Description: Quatro SP Series Sample Processing Systems are bench top, four probe, automated pipettor/dilutors of various sizes (capacities) which are programmed via keypad or personal computer. Optional system components include bar code readers, sample racks for tubes or microplates, workstations, and a washing module. Another option, Concerto software, allows control of the processor from a personal computer and extension of programming capabilities via menu-driven commands. The Quatro SP Series Sample Processing Systems use either stainless steel or teflon coated probe tips. The systems are supplied for generic liquid handling application and must be customized to each user's *in vitro* test specifications. Training is provided for users who wish to perform their own programming. When

Zenyx supplies customized software with the sample processing system, a user validation guide is included.

Intended Use: Liquid handling and sample preparation for *in vitro* diagnostic testing in the clinical laboratory.

Performance Data: Each instrument is tested for accuracy and precision. A gravimetric test must yield +/- 1% at 10 μ l. Overall CV must be less than 1% under a standard protocol. These results are reported on Instrument Test Certificates which are issued with each system. Carryover of liquids is variable and is influenced by type of probe tip, assay setting, sample processor model, and the nature of samples tested. Zenyx liquid handling experts can assist customers in minimizing carryover, if it is a concern. Each user must validate that the unit has been programmed to local test specifications and that the accuracy, precision and carryover are satisfactory for each test protocol.

Conclusion: Approximately 450 Quatro SP series sample processing systems have been placed successfully in 25 countries over the past decade. An estimated one million clinical assays are performed annually, with approximately 10% of these performed in the US.



Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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Mr. Paul McWalter
Regulatory Affairs Manager
Zenyx Scientific Ltd
Barnes Hospital
Cheadle Cheshire SK8 2NY
United Kingdom

RE: K973335
Trade Name: Quatro SP Series Robotic Sample Processing
Systems, Models 200-499, Sample Transport Unit/Automated
Security Module and Quatro Concerto Software
Regulatory Class: I Product Code: JQW
Dated: April 9, 1998 Received: April 16, 1998

Dear Mr. McWalter:

We have reviewed your Section 510(k) notification of intent to market the devices referenced above and we have determined the devices are substantially equivalent (for the indications for use stated in the enclosure) to 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). 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.

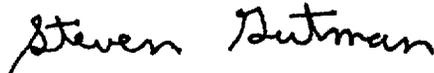
If your devices are classified (see above) into either class II (Special Controls) or class III (Premarket Approval), they may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770)488-7655.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive style with a large initial 'S' and 'G'.

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Indications for Use Statement

510(k) Number: K973335

Device Name: Quatro SP Series Robotic Sample Processing Systems, Models 200 - 499, inclusive
Sample Transport Unit or Automated Sample Security Module
Quatro Concerto Software

Indications for Use:

The Quatro SP Series Robotic Sample Processing Systems and their accessories are provided as generic liquid handling systems which must be customized and validated for each user environment, according to *in vitro* diagnostic test instructions and requirements. The customization can be accomplished by users or can be provided, to customer specifications, by Zenyx authorized representatives.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Clara Mwa

(Division Sign-Off)

Division of Clinical Laboratory Devices

510(k) Number K973335

Prescription Use (Per 21 CFR 801.109)

OR

Over-The-Counter Use