K991473

NOV 23 1999

APPENDIX H

510(k) SUMMARY
i2a Corporation
SIRSCAN

This 510(k) summary of safety and effectiveness for SIRSCAN is submitted in accordance with the requirements of SMDA and follows Office of Device Evaluation guidance concerning the organization and content of a 510(k) summary.

Applicant:	i2a Corporation (Intelligence Artificielle Applications)
Address:	Parc de la Méditerranée BP 42 34470 PEROLS Cedex FRANCE
Contact Person:	Mr. Jean-Philippe Duverge, Managing Director
Telephone:	011-33-467-504-800
Preparation Date:	June 1998
Device Trade Name:	SIRSCAN™
Common Name:	Automatic Zone Reader
Classification Name:	Automated Zone Reader (see 21 C.F.R. § 866.2850) Product Code: KZK
Device Description:	SIRSCAN is an automatic reader of petri dishes that is used to manage overall susceptibility tests. The SIRSCAN is an automated susceptibility reader and interpretation system. It consists of two components: (1) The SIRSCAN automated zone reader device is a video-camera image analysis computer-based system to read susceptibility test data from NCCLS M2-A6 Kirby-Bauer disk-diffusion test plates for the following organisms: enterobacteriacae; staphylococci, (except coagulase negative staphylococci with weak growth); and non-fermenting gram negative bacilli (except strains with weak growth). Other susceptibility tests on solid medium are read with the electronic caliper, and the results of susceptibility tests in other media can be keyed in manually.

(2) The SIRSCAN data management system compiles data from the NCCLS agar disk diffusion test. It prints, files and produces integrated results reports, regularly or on request, to be used by clinicians, bacteriologists and epidemiologists. Its expert system feature offers consistency checks for validation of tests and results.

In addition, the SIRSCAN data management system: interprets zones; calculates MICs; provides quality control and epidemiology and infection control; identifies and eliminates duplicates; compares patient histories; classifies and monitors resistance phenotypes; monitors multi-resistant organisms; detects and monitors nosocomial infections; and prepares epidemiological statistics.

SIRSCAN can be connected to any laboratory management system, and to some micro-dilution systems (*e.g.*, Vitek™, Microscan™).

Intended Use:

SIRSCAN is intended for the management of overall susceptibility tests for the following organisms: Enterobacteriacae, staphylococci (expert coagulase negative staphylococci with weak growth), and non-fermenting gram negative bacilli (except strains with weak growth).

Performance Data:

Medeiros, A. And Crellin, J., *Evaluation of the SIRSCAN Automated Zone Reader in a Clinical Microbioloby Laboratory*, Brown University (1998). See Appendix C.

CONCLUSIONS:

Based on the foregoing and other information in this application, i2a Corporation believes that the performance data provide reasonable assurance of the safety and effectiveness of SIRSCAN for its proposed indications for use. Further, SIRSCAN is substantially equivalent to the claimed predicates under conditions of intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 23 1999

Intelligence Artificielle Applications (i2a) Corp.
Mr. Marc J. Scheineson, Esq.
c/o Reed Smith Shaw & McClay
1301 K Street, N.W.
Suite 1100 – East Tower
Washington, D.C. 20005-3317

Re: K991473
Trade Name: SIRSCAN™
Regulatory Class: II
Product Code: KZK
Dated: September 27, 1999
Received: September 28, 1999

Dear Mr. Scheineson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS 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,

Steven Gutman

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

Enclosure

APPENDIX C

LABELING/INDICATIONS FOR USE

Application Number (if known): K991473

Device Name: SIRSCAN

Indications For Use:

The SIRSCAN automated zone reader device is a video-camera image analysis computer-based system to read susceptibility test data from NCCLS M2-A6 Kirby-Bauer disk-diffusion test plates for the following organisms: enterobacteriacae; staphylococci, (except coagulase negative staphylococci with weak growth); and non-fermenting gram negative bacilli (except strains with weak growth). Other susceptibility tests on solid medium are read with the electronic caliper, and the results of susceptibility tests in other media can be keyed in manually.

The SIRSCAN data management system compiles data from the NCCLS agar disk diffusion test. It prints, files and produces integrated results reports, regularly or on request, to be used by clinicians, bacteriologists and epidemiologists. Its expert system feature offers consistency checks for validation of tests and results.

In addition, the SIRSCAN data management system: interprets zones; calculates MICs; provides quality control and epidemiology and infection control; identifies and eliminates duplicates; compares patient histories; classifies and monitors resistance phenotypes; monitors multi-resistant organisms; detects and monitors nosocomial infections; and prepares epidemiological statistics.

SIRSCAN can be connected to any laboratory management system, as well as to some micro-dilution systems (*e.g.*, Vitek™, Microscan™).

* * *

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the-Counter Use _____
(Per 21 C.F.R. 801.109)

Woody Dubois
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K991473