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AUG 3 1 2010

510(k) SUMMARY

510(k) Submission: K091539

iQ® 200 Urine Analyzer Body Fluids Module (The addition of Synovial Fluid)

1.	**Submitted by:**	Iris Diagnostics, a Division of IRIS International, Inc. 9172 Eton Avenue Chatsworth, CA 91311 Phone: 818.527-7264 Contact person: David W. Gates Vice-President Quality Assurance and Regulatory Affairs david.gates@proiris.com
2.	**Name of Device:**	Addition of Synovial Fluid Cell Count parameter to iQ® 200 Urine Analyzer Body Fluids Module Common Name: Instrument for performing RBC and nucleated cell (WBC and other as a group) counts in Synovial Fluid. Classification Name: Automated cell counter, 21 CFR 864.5200, Class II device, Product Code GKL
3.	**Predicate Methods:**	Iris Diagnostics believes the addition of synovial fluids to the iQ®200 Urine Analyzer Body Fluids Module is substantially equivalent to the Sysmex® XT-4000i, cleared Mar 30, 2010 under K091313.
4.	**Device Description:**	The iQ®200 Urine Analyzer Body Fluids Module for use with synovial fluid is an additional use for the iQ®200 Urine Analyzer (K022774 – cleared October 21, 2002). It is used by a competent human observer to examine and count red blood cells and nucleated

		cells in synovial fluid and is an added body fluid to the previously cleared iQ®200 Urine Analyzer Body Fluids Module cerebrospinal and serous fluids (K050235 – Cleared March 23, 2005).
5.	**Intended Use:**	The iQ®200 Urine Analyzer Body Fluids Module is an in-vitro diagnostic device used by an appropriately trained laboratory user to examine and count red blood cells and nucleated cells in cerebrospinal fluid, serous fluids and synovial fluid. This module is a capability added to the iQ®200 Urine Analyzer.
6.	**Substantial equivalence - Similarities and Differences:**	Table 1 shows substantial equivalence of the proposed synovial fluid parameter to the cleared predicate.
7.	**Conclusion:**	Clinical trial performance data demonstrated that the Synovial Fluid parameter on the iQ®200 Urine Analyzer Body Fluids Module is substantially equivalent to its predicates.

Table 1: Substantial Equivalence – Similarities and Difference to predicate devices:

Characteristic	iQ200 Urine Analyzer Body Fluid module with Synovial Fluid Parameter	Predicate Device Sysmex® XT-4000i, K091313.
	New Parameter	Similarity/ Differences
Intended Use	The iQ®200 Urine Analyzer Body Fluids Module is an in-vitro diagnostic device used by an appropriately trained laboratory user to examine and count red blood cells and nucleated cells in cerebrospinal fluid, serous fluids and synovial fluid. This module is a capability added to the iQ®200 Urine Analyzer.	The Sysmex®I XT-4000i is a quantitative multi-parameter automated hematology analyzer intended for *in vitro* diagnostic use in screening patient populations found in clinical laboratories. The XT-4000i classifies and enumerates the following parameters for whole blood: WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT, NEU%#, LYMPH%/#, MONO%./#, E0 %/#, BASO%/#, IG%/#, RDW-CV, RDW-SD, MP-V, RETP%/#, IRF, RET-He and has a Body Fluid- mode for body fluids. The Body Fluid mode enumerates the WBC-BF, RBC-BF, MN%/#, PMN%/# and TC-BF# parameters in cerebrospinal fluids (CSF), serous fluids (peritoneal, pleural) and synovial fluids. Serous and Synovial fluids should be collected in K2EDTA to prevent clotting of fluid. The use of anticoagulants with CSF specimens is not required or recommended.
Methodology	Hyaluronidase is added to the specimen, mixed and incubated. Two aliquots from each body fluid specimen sample are prepared. One aliquot is diluted in normal saline to provide a concentration in the linear range of the instrument. The second aliquot is treated with a lysing agent to allow unambiguous identification of WBC and other nucleated cells by eliminating RBC. Particle images are captured and saved electronically as the sample flows past a microscope objective at a high speed, electronically concentrating particles. Particle images are then ordered by size into assigned categories on a video display. A competent human observer may change machine assignments, after which particle	Performs hematology according to the Hydro Dynamic Focusing (DC Detection), flow cytometry method (using a semiconductor laser), and SLS-hemoglobin laser).

	concentrations are recomputed and reported	
Parameters Tested	iQ®200 Urine Analyzer Body Fluids Module with synovial fluid capability enumerates red blood cells and nucleated cells in synovial fluid.	The Body Fluid mode enumerates the WBC-BF, RBC-BF, MN%/#, PMN%/# and TC-BF# parameters in cerebrospinal fluids (CSF), serous fluids (peritoneal, pleural) and synovial fluids.
Specimen Collection	Synovial specimens should be collected using K_2EDTA as an anti-coagulant.	Synovial fluids should be collected in K2EDTA to prevent clotting of fluid.
Reagents / Consumables	**Body Fluids specific consumables:** - Hyaluronidase (not supplied by Iris Diagnostics) - iQ®Body Fluids Control – Two levels - iQ® Body Fluids Lysing Reagent	CELLPACK™ (Diluent), STROMATOLYSER™- FB (Lyse), STROMATOLYSER-4DL™ (Lyse) STROMATOLYSER- 4DS™ (Stain) SULFOLYSER (Lyse) RET-SEARCH II (Diluent) RET-SEARCH (Stain)
Calibrator / Quality Control	- iQ®Calibrator Pack - iQ®Control/Focus Set - iQ®Body Fluids Control – Two levels	c-Check (XE) - 3 Levels Calibrator (X Cal)
Software / Hardware	The iQ®200 Urine Analyzer Body Fluids Module software added Synovial Fluid capability	The XT-4000i performs the same as the XT-2000i and has a Body fluid mode the same as the XE- 5000
Specimen Types	Cerebrospinal fluid, serous fluids and synovial fluid	Whole blood, cerebrospinal fluid, serous fluids and synovial fluid
Performance / Equivalency Data	Data consisting of Accuracy, Precision, Linearity and Carryover was collected to show performance to the manufacturer's specification for the Body Fluid mode. This analysis supports the claim that the synovial capability in the iQ®200 Urine Analyzer Body Fluids Module is substantially equivalent to the predicate.	Data consisting of Accuracy, Precision, Linearity and Carryover was collected to show performance to the manufacturer's specification for the Body Fluid mode. This analysis supports the claim that the XT-4000i Body Fluid mode is substantially equivalent to the XE-5000

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

Iris Diagnostics
c/o Mr. William M. Dougherty
Director, Clinical Evaluations
9172 Eton Avenue
Chatsworth, CA 91311

AUG 3 1 2010

Re: k091539
Trade/Device Name: iQ® 200 Urine Analyzer Body Fluids Module
Regulation Number: 21 CFR 864.5200
Regulation Name: Automated cell counter
Regulatory Class: Class II
Product Code: GKL
Dated: August 17, 2010
Received: August 19, 2010

Dear Mr. Dougherty:

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 class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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/cdrh/industry/support/index.html.

Sincerely yours,

Maria M. Chan

Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

AUG 3 1 2010

510(k) Number (if known): K091539

Device Name: iQ 200 Urine Analyzer Body Fluids Module (Addition of Synovial Fluids)

Indications For Use: The iQ®200 Urine Analyzer Body Fluids Module is an in-vitro diagnostic device used by an appropriately trained laboratory user to examine and count red blood cells and nucleated cells in cerebrospinal fluid, serous fluids and synovial fluid. This module is a capability added to the iQ®200 Urine Analyzer.

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

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K091539