DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

IQ Corporation
c/o Harold G. Haines, Ph.D.
President
South Florida BioAssociates, Inc.
11511 SW 127th Street
Miami, Florida 33176

SEP 11 2002

Re: k022528
Trade/Device Name: IQ Products Triple-Color Flow Cytometry Reagents
IQ Prep Reagent CD45 FITC/CD4 R-PE/CD3 CyQ
IQ Prep Reagent CD45 FITC/CD8 R-PE/CD3 CyQ
IQ Prep Reagent CD45 FITC/CD19 R-PE/CD3 CyQ
IQ Prep Reagent CD45 FITC/IgG1 R-PE/IgG1 CyQ
Regulation Number: 21 CFR § 864.5220
Regulation Name: Automated differential cell counter
Regulatory Class: II
Product Code: GKZ
Dated: July 2, 2002
Received: July 31, 2002

Dear Dr. Haines:

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 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" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained 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,

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

510(k) Number (if known): K022528

Device Name:

IQ Prep Reagent CD45 FITC/ CD19 R-PE/ CD3 CyQ.

Indications For Use:

IQ Prep Reagent CD45 FITC/ CD19 R-PE/ CD3 CyQ is a triple-color murine monoclonal antibody reagent used to identify and enumerate the percentages of total CD19+ and total CD3+ lymphoctyes in whole blood by flow cytometry.
To monitor for any non-specific staining, the isotypic control IQ Prep Reagent CD45 FITC/ IgG1 R-PE/ IgG1 CyQ may be used.

(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K022528

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR **Over-The-Counter Use**___
(Per CFR 801.109)

510(k) Number (if known): K022528

Device Name:

IQ Prep Reagent CD45 FITC/ CD8 R-PE/ CD3 CyQ

Indications For Use:

IQ Prep Reagent CD45 FITC/ CD8 R-PE/ CD3 CyQ is a triple-color murine monoclonal antibody reagent used to identify and enumerate the percentages of total CD8+, total CD3+, and dual CD3+/CD8+ lymphoctyes in whole blood by flow cytometry.
To monitor for any non-specific staining, the isotypic control IQ Prep Reagent CD45 FITC/ IgG1 R-PE/ IgG1 CyQ may be used.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR **Over-The-Counter Use** ___

510(k) Number (if known): K022528

Device Name:

IQ Prep Reagent CD45 FITC/ CD4 R-PE/ CD3 CyQ

Indications For Use:

IQ Prep Reagent CD45 FITC/ CD4 R-PE/ CD3 CyQ is a triple-color murine monoclonal antibody reagent used to identify and enumerate the percentages of total CD3 positive, total CD4 positive, and dual CD3 positive/CD4 positive lymphoctyes in whole blood by flow cytometry. To monitor for any non-specific staining, the isotypic control IQ Prep Reagent CD45 FITC/ IgG1 R-PE/ IgG1 CyQ is used.

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Prescription Use ✓ OR **Over-The-Counter Use**___
(Per CFR 801.109)

510(k) Number (if known): K022528

Device Name:

IQ Prep Reagent CD45 FITC/IgG1 R-PE/IgG1 CyQ

Indications For Use:

IQ Prep Reagent CD45 FITC/IgG1 R-PE/IgG1 CyQ is a triple-color murine monoclonal antibody reagent used to monitor the level of nonspecific antibody binding in cell surface staining procedures that use the other IQ Prep Reagents. These reagents are comprised of the monoclonal antibody to CD45, that is labeled with the fluorochrome FITC, and two other IgG1 subclass monoclonal antibodies that are conjugated to either PE or CyQ fluorochromes.

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Prescription Use ✓ OR **Over-The-Counter Use**___
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(Optional Format) 1-2-96