

K973464  
Oct. 22, 1997

**SECTION 3**  
**quantex RF plus - 510(k) SUMMARY**  
**(Summary of Safety and Effectiveness)**

**Submitted by:**

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**Contact Persons:**

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**Summary Prepared:**

September 11, 1997

**Name of the device:**

quantex RF plus (latex, buffer, standard, control)

**Classification name(s):**

866.5775 Rheumatoid factor immunological test systems Class II  
82DHR System, test, rheumatoid factor

**Identification of predicate device(s):**

quantex RF plus (latex, buffer, standard, control) K896271

**Description of the device/intended use(s):**

Biokit's quantex RF plus (latex, buffer, standard, control) is an *in vitro* diagnostic product for use with automated instrumentation in the quantitative determination of human rheumatoid factors in serum by turbidimetric immunoassay and is intended as an aid in the diagnosis of Rheumatoid Arthritis.

**Statement of how the Technological Characteristics of the Device compare to the Predicate device:**

The new quantex RF plus (latex, buffer, standard, control) is a modified version of the predicate quantex RF plus (latex, buffer, standard, control) with an analysis range extended from 0-100 IU/mL to 0-200 IU/mL. It is substantially equivalent in performance, intended use, safety and effectiveness to the predicate device as supported by the performance data and labeling.

**Summary of Performance Data:**

In three different method comparison studies comparing the new quantex RF plus to the predicate, the correlation (*r*) on the Monarch (n=152) was 0.992, on the Hitachi (n=175) was 0.995 and on the Cobas Mira (n=261) was 0.990. Results from a precision study on a Monarch that accessed three serum samples with different levels of rheumatoid factors over multiple runs support package insert claims of within run CVs of < 3% and between run CVs of < 5%.



Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Carol Marble  
Regulatory Affairs Engineer  
Instrumentation Laboratory Company  
113 Hartwell Avenue  
Lexington, MA 02173

OCT 22 1997

Re: K973464  
Trade Name: quantex RF plus (layex, buffer, standard, control)  
Regulatory Class: II  
Product Code: DHR  
Dated: September 11, 1997  
Received: September 12, 1997

Dear Ms. Marble:

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 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.

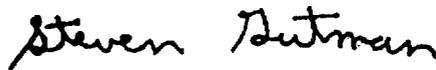
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirement, 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 I. Gutman, M.D., M.B.A.  
Director  
Division of Clinical  
Laboratory Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure



## Indications for Use Statement

510(k) Number (if known): K973464

Device Name: quantex RF plus (latex, buffer, standard, control)

### Indications for Use:

quantex RF plus (latex, buffer, standard, control) is an *in vitro* diagnostic test for use with automated instrumentation in the quantitative determination of human rheumatoid factors in serum by turbidimetric immunoassay and is intended as an aid in the diagnosis of rheumatoid arthritis.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Peter E. Malin

(Division Sign-Off)

Division of Clinical Laboratory Devices

510(k) Number

K973464

Prescription Use   
(Per 21 CFR 801.019)

OR

Over-The-Counter Use