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BECKMAN

JUN 27 1997

K971602

Summary of Safety & Effectiveness
Array® Systems Rheumatoid Factor (RF_{MPE}) Reagent

1.0 Submitted By:

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2.0 Date Submitted:

30 April 1997

3.0 Device Name(s):

3.1 Proprietary Names

Array® Systems Rheumatoid Factor (RF_{MPE}) Reagent

3.2 Classification Names

Rheumatoid factor immunological test system(21 CFR 866.5775)

4.0 Predicate Device(s):

IMMAGE™ Immunochemistry System Rheumatoid Factor (RF) Reagent
K963048

5.0 Description:

The Array Systems Rheumatoid Factor (RF_{MPE}) Reagent is designed for optimal performance on Beckman's Array® Systems. It is intended for use in the quantitative determination of human rheumatoid factor concentrations in human serum samples.

6.0 Intended Use:

The Array® Systems Rheumatoid Factor (RF_{MPE}) reagent, when used in conjunction with the Beckman Array System and Beckman Calibrator 5 Plus, is intended for quantitative determination of human rheumatoid factor by rate nephelometry.

7.0 Comparison to Predicate(s):

The following table shows similarities and differences between the predicates identified in Section 4.0 of this summary.

Reagent	Aspect/Characteristic	Comments
SIMILARITIES		
Array Systems RF_{MPE} Reagent	Intended use	Same as IMMAGE System RF Reagent
	Nephelometric principle	
	Latex coated particles	
	Shelf-life of 24 months (stored at 2-8°C)	
	Calibrator (Beckman Calibrator 5 Plus)	
DIFFERENCES		
Array Systems RF_{MPE} Reagent	Angle of measurement	The Array System measures at a 70° angle while the IMMAGE System measures at a 90° angle
Array Systems RF_{MPE} Reagent	Initial analytic range	The initial analytic range for Array is 20 to 600 IU/mL while the IMMAGE System is 20 to 800.
Array Systems RF_{MPE} Reagent	Reaction temperature	The Array Systems measure at 26.7°C while the IMMAGE System measures at 37°C.

8.0 Summary of Performance Data:

The data in the Premarket Notification on safety and effectiveness supports a finding of substantial equivalence to chemistry test systems already in commercial distribution. Equivalence is demonstrated through method comparison, stability, and imprecision experiments that relate results obtained from the Array RF_{MPE} Reagent to the IMMAGE System RF Reagent.

Method Comparison Study Results
Array RF_{MPE} Reagent vs. IMMAGE RF Reagent

Analyte	Slope	Intercept	r	Predicate
RF	0.957	1.86	0.972	IMMAGE RF

Stability Study Results

Reagent	Product Claim
Array (RF_{MPE})	24 months shelf-life 30 day calibration stability

Estimated Array RF_{MPE} Reagent Imprecision

Sample	Mean (IU/mL)	S.D. (IU/mL)	%C.V.	N
Within-Run Imprecision				
Level 1	30.2	1.07	3.56	160
Level 2	313	8.71	2.78	160
Level 3	564	15.2	2.69	160
Total Imprecision				
Level 1	30.2	1.56	5.16	160
Level 2	313	10.4	3.32	160
Level 3	564	17.9	3.17	160

This summary of safety and effectiveness is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and the implementing regulation 21 CFR 807.92.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Annette Hellie
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JUN 27 1997

Re: K971602
Trade Name: Array® Systems Rheumatoid Factor(RF_{MPE}) Reagent
Regulatory Class: II
Product Code: DHR
Dated: April 30, 1997
Received: May 01, 1997

Dear Ms. Hellie:

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 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,

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): K971602

Device Name: **Array® Systems Rheumatoid Factor (RF_{MPE}) Reagent**

Indications for Use:

The Array® Systems Rheumatoid Factor (RF_{MPE}) reagent, when used in conjunction with the Beckman Array System and Beckman Calibrator 5 Plus, is intended for quantitative determination of human rheumatoid factor by rate nephelometry.

Rheumatoid factor immunological test system(21 CFR 866.5775)

(a) Identification. A rheumatoid factor immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the rheumatoid factor (antibodies to immunoglobulins) in serum, other body fluids, and tissues. Measurement of rheumatoid factor may aid in the diagnosis of rheumatoid arthritis.

(b) Classification. Class II (performance standards).

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Peter E Maker

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number _____

Prescription Use ✓ OR Over-the-Counter Use _____
(per 21 CFR 801.109)