K993843

JAN 11 2000

SUMMARY OF 510 (k) SAFETY AND EFFECTIVENESS INFORMATION

This summary of 510 (k) safety and effectiveness information is being submitted in accordance with the requirement of SMDA 1990 and 21 CFR 807.92.

MDI RF Test reagents (P/N: RFKi-G) are intended for the semi-quantitative determination of IgM antibodies to *IgG* in human serum. The principal diagnostic value of this test is detection of autoantibodies, which are used as an aid in patients with rheumatoid diseases.

The Micro Detect, Inc. *RF* reagent (**MDI RF Test)** is intended to be used as a manual procedure. The reagents are supplied as a micro plate coated with specific antigens and Controls, Wash Buffer, Sample Diluent, Conjugate, Substrate, and Stop Solution.

The patient results obtained using the **MDI RF Test** is substantially equivalent to those obtained by using predicate assays:

Relative Sensitivity:	95.2%
Relative Specificity:	100 %

Precision (%CV): 1.9 –5.15(Inter) and 1.44 – 3.62(Intra)

Stability: One year at 2-8°C. The stability of the **MDI RF Test** Kit for the detection of IgM antibodies to *IgG* was found to be one year at 2-8°C. This was predicted from studies done under stress condition (47.5°C). Real time stability has only been monitored for ten weeks at 2-8°C.

The Micro plate ELISA formats is a commonly used format for the detection of many entities of clinical interest, including autoimmune diseases.

The **MDI RF Test** system is shown to be safe and effective and provide results, which are substantially equivalent to those, obtained by predicate products.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 11 2000

Mehdi Alem, Ph.D.
President
Micro Detect, Inc.
2852 Walnut Avenue
Suite H-1
Tustin, California 92780

Re: K993843
Trade Name: MDI RF Test
Regulatory Class: II
Product Code: DHR
Dated: December 17, 1999
Received: December 21, 1999

Dear Dr. Alem:

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 (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

K993843/A1

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510(k) Number (if known): k993843

Device Name: MDI RF Test

Indications For Use:

The **MDI RF Test** is a semi quantitative Enzyme Immunoassay (EIA) Kit for the detection of IgM antibodies against human IgG (RF) in human serum. The test is intended as an aid in the diagnosis of rheumatoid arthritis. FOR *IN VITRO* DIAGNOSTIC USE ONLY.

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26 Nov 99 07 25

FDA/CDRH/ODE/DMC

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Peter E. Maheni

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K993843

Prescription Use ✓
(Per 21 CFR 801,109)

OR

Over-The-Counter Use___

(Optional Format 1-2 -96)