NOV - 1 1999

K993034

## Pre-market Notification [510 (k)] Summary

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| **Summary prepared on:** | Sept. 8, 1999 |
| **Submitted by:** | MeDiCa |
| **Address:** | 336 Encinitas Blvd., Suite 200<br>Encinitas, California 92024 |
| **Telephone:** | (760) 634- 5440 |
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| **Registration number:** | 2021875 |
| **Contact person:** | Rhodora Chapoco |
| **Contact Title:** | Lab Manager |
| **Device Name:** | Indirect Immunofluorescence Anti-Endomysial Antibody Test Kit |
| **Common Name:** | Indirect Immunofluorescence Anti-Endomysial Antibody Test Kit |
| **Trade Name:** | MeDiCa Indirect Immunofluorescence (IIF) Anti- Endomysial Antibody (AEmA) Test Kit |
| **Product Code:** | MVM |
| **CFR Section:** | 866.5660 |
| **Device Class:** | II |
| **Classification Panel:** | Immunology/ Microbiology |
| **Predicate Device:** | Scimedx Anti- Endomysial IgA (EMA) Test System |

## Pre-market Notification [510 (k)] Summary (continuation)

**Description of Device:** MeDiCa Indirect Immunofluorescence (IIF) Anti- Endomysial Antibody Test Kit is used for the qualitative and semi-quantitative detection of IgA class endomysial autoantibodies (AEmA) in human serum as an aid in the diagnosis of Celiac Disease and other related disorders such as Dermatitis Herpetiformis.

In general, MeDiCa and Scimedx Anti- Endomysial Antibody Test Kits have the following similarities:

a) intended use
b) methodology- indirect immunofluorescence method
c) test kit composition
d) type of substrate

Results of performance evaluation show that MeDiCa IIF Anti-Endomysial Antibody Test Kit matches Scimedx test kit, the predicate device on:

a) specificity
b) sensitivity
c) reproducibility
d) reactivity

MeDiCa and Scimedx test kits differ in the following features:

a) volume of conjugate and controls provided by MeDiCa is about 50-65% less than Scimedx test kit. During evaluation, it was demonstrated that the amount of conjugate and controls provided by MeDiCa are sufficient. The kit was designed with this volume of reagents, in order for the end user not to overfill the wells of the slides with controls and/ or reagents. Applying enough reagents prevents cross contamination of adjacent wells.

b) presentation of substrate on slide wells. Both MeDiCa and Scimedx provide the same type of substrate. The only difference is that MeDiCa monkey esophagus distal substrate sections are cut sequentially from one and the same block. They are deposited individually one after another and oriented the same way in all wells of each slide. The sections for Scimedx are cut from four different blocks at the same time, resulting in different orientation of sections from well to well. The advantage of sequential sectioning from a single block is the ease in interpretation of fluorescent patterns. This also contributes to better reproducibility and comparability of test results.

In summary, MeDiCa IIF Anti- Endomysial Antibody Test Kit, described and summarized in this 510 (k) notification submission, in our opinion, is substantially equivalent to the predicate device, Scimedx Anti-Endomysial (IgA) Test System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV - 1 1999

Ms. Rhodora Chapoco
Lab Manager
MeDiCa Medical Diagnostics, California
336 Encinitas Boulevard
Suite 200
Encinitas, California 92024

Re: K993034
Trade Name: Indirect Immunofluorescence Anti-Endomysial Antibody Test Kit
Regulatory Class: II
Product Code: MVM
Dated: September 8, 1999
Received: September 9, 1999

Dear Ms. Chapoco:

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

## Indication for Use Statement

**510(k) Number (if known):** ~~not known~~ K993034

**Device Name:** MeDiCa Indirect Immunofluorescence (IIF) Anti- Endomysial Antibody (AEmA) Test Kit

**Indications For Use:**

MeDiCa Indirect Immunofluorescence (IIF) Anti- Endomysial Antibody Test Kit is used for the qualitative and semi- quantitative detection of IgA class endomysial autoantibodies (AEmA) in human serum as an aid in the diagnosis of Celiac Disease and other related disorders such as Dermatitis Herpetiformis.

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

**Concurrence of CDRH, Office of Device Evaluation (ODE)**

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K993034

**Prescription Use** ✓ (Per 21 CFR 801.109)

**Over the Counter Use** _____