DEC 22 1998

K984462

BIO-RAD

Bio-Rad Laboratories

Diagnostics Group
9500 Jeronimo Road
Irvine, California 92618-2017
Telephone: (949) 598-1200

510(k) Summary

Submitter

Bio-Rad Laboratories
9500 Jeronimo Road
Irvine, CA
(949)598-1285
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Contact Person

Elizabeth Platt

Date of Summary Preparation

December 14, 1998

Device (Trade & Common Name)

Liquichek ENA Control, EIA Screen

Classification Name

Class II, 82LLL
CFR 866.5100: Extractable Antinuclear Antibody, Antigen and Control.

Devices to Which Substantial Equivalence is Claimed

Helix Enzyme Immunoassay Antinuclear Antibody Screening Test Kit
Helix Diagnostics
West Sacrament, California
K954723

Statement of Intended Use

Liquichek ENA Control, EIA Screen is intended for use as an unassayed quality control to monitor enzyme immunoassay procedures for the screening of extractable nuclear antigen (ENA) autoantibodies.

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Description of the Device

Liquichek ENA Control, EIA Screen is prepared from human serum with added preservatives and stabilizers. This product is provided in liquid form for convenience.
This product contains 0.1% sodium azide as a preservative.

Statement of How Technological Characteristics Compare to Substantial Equivalent Device

A table is provided below comparing the similarities between the Bio-Rad Liquichek ENA Control, EIA Screen and the device to which substantial equivalence is claimed.

	Helix Enzyme Immunoassay Antinuclear Antibody Screening Test Kit	Bio-Rad Liquichek ENAControl, EIA Screen
Intended Use	A qualitative enzyme immunoassay (EIA) for screening the presence of antinuclear antibodies (ANAs) in human serum as an aid in the diagnosis of certain systemic rheumatic diseases.	An unassayed quality control serum for monitoring enzyme immunoassay procedures for the screening of extractable nuclear antigen (ENA) autoantibodies.
Form	Liquid	Liquid
Matrix	Human Serum	Human Serum
Levels	Negative, Positive, Cutoff	Negative, Positive, High Positive
Storage	2-8°C	2-8°C
Analytes	Total ANAs against: DNA (dsDNA, nDNA) Histones SS-A/Ro SS-B/La Sm SmRNP Scl-70 Jo-1 Centrometric antigens Sera positive for Immunofluorescent (IFA) Hep-2 ANAs	ENA
Open Vial Claim	Shelf life	30 Days at 2-8°C

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 22 1998

Ms. Elizabeth Platt
Staff Regulatory Affairs Representative
BIO-RAD LABORATORIES
9500 Jeronimo Road
Irvine, CA 92618-2017

Re: K984462
Trade Name: Liquichek ENA Control, EIA Screen
Regulatory Class: II
Product Code: LLL
Dated: December 14, 1998
Received: December 16, 1998

Dear Ms. Platt:

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.

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

510(k) Number: K984462

Device Name: Liquichek ENA Control, EIA Screen

Indications for Use:

Liquichek ENA Control, EIA Screen is intended for use as an unassayed quality control to monitor enzyme immunoassay procedures for the screening of extractable nuclear antigen (ENA) autoantibodies.

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

(Concurrence of CDRH, Office of Device Evaluation)

Peter E Madsen

(Division Sign-Off)
Division of Clinical Laboratory Devices K984462
510(k) Number

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Prescription Use _____ OR Over-The Counter Use _____