I. 510(k) Summary

JAN 2 8 2005

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

The assigned 510 (k) number is: K043264

(A) (1) Submitter's name: Denka Seiken Co., Ltd.

Submitter's address: 3-4-2, Nihonbashi kayabacho,
Chuo-ku
Tokyo, Japan 103-0025

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Contact Person: Mr. Toshimi Matsunaga
Manager
Pharmaceutical Affairs

Contact Person's telephone number: +81-250- 42-7222

Date Summary Prepared: November 22, 2004

(2) Trade or proprietary device name: LDL-EX SEIKEN Assay Kit
Common or usual name: Homogeneous assay for low-density lipoprotein cholesterol
Classification Name: Low-density lipoprotein cholesterol test
Panel: Clinical Chemistry
Class: I
Product Code: MRR

(3) Legally marketed predicate device: N-Geneous LDL Cholesterol Reagent [Genzyme Corp.] (K971573)

(4) Subject device description:

The LDL-EX SEIKEN Assay Kit is an in vitro diagnostic test for the quantitative determination of low-density lipoprotein cholesterol (LDL-C) in human serum and heparinized- or EDTA-plasma on automated chemistry analyzers. The LDL-EX SEIKEN Assay Kit is a homogeneous method for directly measuring LDL-C levels in serum and plasma without the need for any off-line pretreatment or centrifugation steps.

(5) Subject device intended use:

The LDL-EX SEIKEN Assay Kit is an *in vitro* diagnostic test for the quantitative determination of low-density lipoprotein cholesterol (LDL-C) in human serum and heparinized- or EDTA-plasma on automated chemistry analyzers.

(6) Performance data:

The LDL-EX SEIKEN Assay Kit and the predicate device, N-Geneous LDL Cholesterol Reagent [Genzyme Corp.] have only relatively minor differences in that the differences do not affect the performance, safety or effectiveness of the measurement.

Comparative performance studies, when conducted on 100 donor samples, yielded a high correlation coefficient upon comparison of the LDL-EX SEIKEN Assay Kit and the N-Geneous LDL Cholesterol Reagent. The correlation coefficient $r = 0.994$; slope = 0.982, y intercept = -1.83.

Precision studies were conducted using the LDL-EX SEIKEN Assay Kit. Within run and between day studies were performed using three levels of control material for each. In both studies, the LDL-EX SEIKEN Assay Kit showed very similar CVs as shown in the kit insert of the predicate device.

These findings serve to demonstrate that the performance of the LDL-EX SEIKEN Assay Kit is substantially equivalent to the predicate device, N-Geneous LDL Cholesterol Reagent [Genzyme Corp.].

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 26 2005

Mr. Toshimi Matsunaga
Manager, Pharmaceutical Affairs
Denka Seiken Co., Ltd.
1-2-2, Minamihoncho, Gosen City
Niigata, Japan 959-1695

Re: k043264
Trade/Device Name: LDL-EX SEIKEN Assay Kit
Regulation Number: 21 CFR 862.1475
Regulation Name: Lipoprotein test system
Regulatory Class: Class I
Product Code: MRR
Dated: November 22, 2004
Received: December 14, 2004

Dear Mr. Matsunaga:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (240)276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Jean M. Cooper MS, DVM

Jean M. Cooper, MS, D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

C. Indications for use of the Device

510(k) Number): K043264

Device Name: LDL-EX SEIKEN Assay Kit

Indications for Use:

The LDL-EX SEIKEN Assay Kit is an *in vitro* diagnostic test for the quantitative determination of low-density lipoprotein cholesterol (LDL-C) in human serum and heparinized- or EDTA-plasma. Lipoprotein measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus, atherosclerosis and various liver and renal diseases). The device is intended to be used on automated chemistry analyzers in clinical laboratories.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol C Benson

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K043264