APR 14 2006

K060359

This is a Summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of CFR.

The assigned 510(k) Number is:

Company/Contact Person
Hideo G. Noda
Denka Seiken Co., Ltd.
3-4-2 Nihonbashi Kayabacho,
Chuo-ku, Tokyo, Japan 103-0025
Operator Number: 9053049
Establishment Registration Number: 3003871639

Date Prepared: Dec 19, 2005

**Device Name**

**Calibrators**

Trade Name: ARCHITECT® Insulin Calibrators (A-F)

Common Name: Calibrator

Device Classification: 21 CFR 862:1150

Class II

Classification Panel: Clinical Chemistry

Product Code: JIT

**Controls**

Trade Name: ARCHITECT® Insulin Controls (Low, Medium, and High)

Common name: Quality Control Material (Assayed) Single (Specified) analyte

Device Classification: 1 CFR 862:1660

Class I

Classification Panel: Clinical Chemistry

Product Code: JJX

**Legally marketed device to which equivalency is claimed: ADIVA Centaur® and ACS: 180® Insulin**

# Indications for Use

510(k) Number (if known) ~~NA~~ K060359

Device Name: ARCHITECT® Insulin Calibrators and Controls

Indications For Use:

Intended Use and Indications for use

The ARCHITECT® Insulin Calibrators are for the calibration of the ARCHTECT® *i* System when used for the quantitative determination of human insulin in human serum and plasma.

The ARCHITECT® Insulin Controls are for the verification of the accuracy and precision of the ARCHITECT® *i* System when used for the quantitative determination of human insulin in human serum or plasma.

Prescription Use YES (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use NO (21 CFR 801 Subpart C)

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

**Description of the Device**

**Calibrators**

The ARCHITECT® Insulin Calibrators are for the calibration of the ARCHITECT® *i* System when used for the quantitative determination of human insulin in human serum and plasma.

**Controls**

The ARCHITECT® Insulin Controls are for the verification of the accuracy and precision of the ARCHITECT® *i* System when used for the quantitative determination of human insulin in human serum and plasma.

**Comparison of Technological Characteristics:**

The ARCHITECT® Insulin Calibrators (A-F) is substantially equivalent to the ADIVA Centaur® and ACS 180 Insulin Calibrators (K021535).

**Comparison with predicate: Calibrators**

**Similarities**:

| **Calibrator** | **Device** | **Predicate** |
|---|---|---|
| Intended Use | The ARCHITECT® Insulin calibrators are for calibration of the ARCHITECT® *i* System when used for the quantitative determination of human insulin in human serum and plasma. | For in vitro diagnostic use in the calibrating the ADIVA Centaur® or ACS 180® Insulin assays. |
| Methodology | CMIA (Chemiluminescent Microparticle Immunoassay) | Chemiluminescent Microparticle Immunoassay |
| Binding Protein | Insulin | Insulin |
| Assay Protocols | Direct, quantitative immunoassay | Direct, quantitative immunoassay |
| Traceability /Standardization | Relative Light Unit (RLU) matched to Primary Calibrators. The calibrators of the ARCHITECT Insulin are referenced to the World Health Organization (WHO) | Referenced to the World Health Organization (WHO) Insulin 1st[t]. International Reference Preparation, 66/304.<br><br>Assigned values of |

| | | |
|---|---|---|
| | Insulin 1st. International Reference Preparation, 66/304 | calibrators are traceable to this standardization |

**Comparison with predicate: Controls**

The ARCHITECT® Insulin Controls (Low, Medium and High) are substantially equivalent to the Bayer Ligand Plus 1, 2, 3 Controls (K030452).

**Comparison with predicate: Controls**

**Similarities:**

| Controls | **Device** | Predicate |
|---|---|---|
| Intended Use | The ARCHITECT® Insulin Controls are for the verification of the accuracy and precision of the ARCHITECT® *i* System when used for the quantitative determination of human insulin in human serum and plasma. | For the in vitro diagnostic use to monitor the precision and accuracy of immunochemistry and procedures for ADIVA Centaur® and ACS 180® Systems. |
| Methodology | Chemiluminescent Microparticle Immunoassay (CMIA) | Chemiluminescent Microparticle Immunoassay |
| Binding Protein | Insulin | Insulin |
| Assay Protocol | Direct, quantitative immunoassay | Direct, quantitative immunoassay |
| Levels | 3 levels Low, Medium and High: targets: 8, 40, 120 µU/mL. | 3 levels (Ligand 1, 2, 3). |

**Comparison with predicate: Calibrators**

**Differences:**

| **Calibrators** | **Device** | **Predicate** |
|---|---|---|
| Platform | ARCHITECT® *i* System | ADIVA Centaur® or ACS 180® |
| Matrix | Acetate buffer with sodium | Buffered saline with |

| | | |
|---|---|---|
| | azide and preservatives | casein, potassium thiocynate (3.89%), sodium azide and preservatives |
| Calibration Range/Levels | 6 levels: 0, 3, 10, 30, 100, and 300 µU/mL, | High and Low level, per assigned value card |
| Assay Sample Type | Serum and plasma | Serum |

**Comparison with predicate: Controls**

**Differences:**

| **Control** | **Device** | **Predicate** |
|---|---|---|
| Platform | ARCHITECT® *i* System | ADIVA Centaur® or ACS 180® |
| Matrix | Acetate buffer with preservatives | Lypholized, Multi Constituent Controls. Human serum with nonhuman contents added, no preservatives or stabilizers |
| Traceability | Primary Controls | Not given |
| Value Assignment | Relative Light Unit (RLU) matched to Primary Controls. | Adjusted to the level listed in expected values of assay package insert. |
| Assay Sample Type | Serum and plasma | Serum |

**Conclusion:**

As summarized above the ARCHITECT® Insulin Calibrators (A-F) and Controls (Low, Medium, and High) are substantially equivalent to the ADIVA Centaur® and ACS: 180® Insulin Calibrators (K021535) and Bayer Ligand Plus 1, 2, 3 Controls (K030452).

Substantial equivalence for the calibrators has been demonstrated as recommended by the FDA Guidance for Industry "Abbreviated 510(k) Submission for *In Vitro* Calibrators" (issued on: Feb 22, 1999) and for controls as recommended by the FDA Guidance for Industry "Points To Consider Document On Assayed and Unassayed Quality Control Material" (Draft Guidance Released for comment on February 3, 1999).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Toshimi Matsunaga
Denka Seiken Co., Ltd.
1-2-2 Minamihoncho, Gosen-shi
Niigata, Japan 959-1695

APR 14 2006

Re: k060359
Trade/Device Name: ARCHITECT® Insulin Calibrators and Controls
Regulation Number: 21 CFR§862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Code: JIT, JJX
Dated: February 2, 2006
Received: March 2, 2006

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,

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known) ~~NA~~ K060359

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Prescription Use YES AND/OR Over-The-Counter Use NO
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

(Optional) K060359