1 510(k) Summary

Date of Summary Preparation: November 25, 2003

1.2 Submitter:

Ms. Gitte Brinkmann
DakoCytomation Denmark A/S.
Produktionsvej 42
DK-2600 Glostrup
Denmark

1.3 Trade Name: DakoCytomation Beta-2-Microglobulin Kit.

1.4 Classification Name, Product Code, Class, Classification Reference:

Classification Name	Product Code	Class	21CFR §
System, Test, Beta-2-Microglobulin Immunological	JZG	II	866.5630

1.5 Standards/Special Controls:

None

1.6 Indications for Use:

For in vitro diagnostic use.
DakoCytomation Beta-2-Microglobulin Kit is intended for the quantitative determination of beta-2-microglobulin in human serum and plasma by rate nephelometry on IMMAGE® Immunochemistry Systems. Measurement of beta-2-microglobulin aids in the diagnosis of patients with active rheumatoid arthritis and kidney disease.

1.7 Device Description:

DakoCytomation Beta-2-Microglobulin Kit is an in vitro diagnostic assay device for the quantitative determination of human beta-2-microglobulin. Beta-2-microglobulin (B2M), a low molecular weight polypeptide of 11,800 daltons, is the light chain component of the major histocompatibility antigen (HLA). B2M is present on the membrane surface of all cells that express major histocompatibility antigens and it is normally present in the circulation as a result of cell membrane turnover.

The Beta-2-Microglobulin device is similar in design, materials and intended use to other 510(k) cleared devices, which are in commercial distribution.

1.8 Substantially Equivalent Commercially Available Devices:

The Beta-2-Microglobulin device is substantially equivalent to the predicate device described herein with respect to indications for use, device design, materials, and method of manufacture:
IMx B2 Microglobulin – K890421

The predicate device is commercially available and a marketed Class II device indicated for use for the quantitative measurement of beta-2-microglobulin in human serum, plasma or urine.

1.9 Substantial Equivalence Comparison:

Beta-2-Microglobulin is similar to commercially available device with respect to intended use, material, design and operational principles as follows:

Table 1

Similarities

Feature	**New device DakoCytomation Beta-2-Microglobulin Kit**	**Predicate device IMx B2 Microglobulin**
Intended Use	Quantitative determination of beta-2-microglobulin in human serum and plasma by rate nephelometry on IMMAGE® Immunochemistry Systems. Measurement of beta-2-microglobulin aids in the diagnosis of patients with active rheumatoid arthritis and kidney disease.	Quantitative measurement of beta-2-microglobulin in human serum, plasma or urine to be used as an aid in the management of patients with renal dysfunction or rheumatoid arthritis
Sample Type	Serum, plasma	Serum, plasma, urine

Feature	New device DakoCytomation Beta-2-Microglobulin Kit	Predicate device IMx B2 Microglobulin
Interfering Substances	Hemoglobin concentrations up to 1000 mg/dL, bilirubin (conjugated) up to 60 mg/dL and triglyceride up to 1500 mg/dL do not significantly interfere with the assay. No significant interference is defined as recovery within ±10% at β2M > 6 mg/L or within ± 0.6 mg/L at β2M ≤ 6 mg/L.	Hemoglobin concentrations up to 1000 mg/dL, bilirubin (conjugated) up to 41.9 mg/dL and triglyceride up to 1023 mg/dL do not significantly interfere with the assay
Specificity	b-2-microglobulin	b-2-microglobulin
Reagents/Calibrators/Controls	Liquid stable	Liquid stable

Differences

Feature	DakoCytomation Beta-2-Microglobulin Kit	IMx B2 Microglobulin
Instrument Required	Beckman Coulter IMMAGE	Abbott IMx
Antibody	Polyclonal	Monoclonal
Sample type	Serum, plasma	Serum , plasma and urine
Reaction Test Principle	Nephelometry	MEIA
Assay Type	Homogenous Immunoassay	Heterogenous Immunoassay
Lower Detection Limit (Serum)	0.3 mg/L	0.05 mg/L
Assay Range (Serum)	0.3 to 20 mg/L	0 to 40 mg/L

Indications and Contraindications:

Relative indications and contraindications for DakoCytomation Beta-2-Microglobulin Kit and commercially available devices for similar intended uses are the same.

1.11 Conclusion:

In accordance with the Federal Food, Drug and Cosmetic Act and 21 CFR Part 807, and based on the information provided in this pre-market notification, DakoCytomation concludes that the new device, DakoCytomation Beta-2-Microglobulin Kit, is safe, effective and substantially equivalent to the predicate device as described herein.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 2 2 2004

Ms. Gitte Brinkmann
QA Professional
DakoCytomation Denmark A/S
Produktionsvej 42
DK-2600Glostrup
Denmark
CVR N0. 33 21 13 17

Re: k032692
Trade/Device Name: DakoCytomation Beta-2-Microglobulin Kit
Regulation Number: 21 CFR 866.5630
Regulation Name: Beta-2-microglobulin immunological test system
Regulatory Class: Class II
Product Code: JZG
Dated: November 25, 2003
Received: November 28, 2003

Dear Ms. Brinkmann:

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 (301) 594-3084. 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/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman, M.D.

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K032692

Statement of Indication for Use

Device Name: DakoCytomation Beta-2-Microglobulin Kit

Indications for Use:

For in vitro diagnostic use.

DakoCytomation Beta-2-Microglobulin Kit is intended for the quantitative determination of beta-2-microglobulin in human serum and plasma by rate nephelometry on IMMAGE® Immunochemistry Systems. Measurement of beta-2-microglobulin aids in the diagnosis of patients with active rheumatoid arthritis and kidney disease.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

A P Reeves

(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K032692

Prescription Use ✓ OR Over-The-Counter Use __