MAST GROUP LTD
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K062864

510(k) Summary

OCT 1 8 2006

510(k) Owner: Mast Group Ltd.
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Phone: (+44) 151 933 7277
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Contact: Barbara A Lee, Regulatory Affairs Manager
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Date prepared: 22nd September 2006

Name of Device:

- Trade name - MASTALEX™ - MRSA
- Common name - In-vitro-diagnostic kit, rapid slide latex kit for confirmation of Methicillin-resistant *Staphylococcus aureus* (MRSA).
- Classification name – System, test, Genotypic Detection, Resistant markers, Staphylococcus colonies.
  (21 CFR 866.1640, product code MYI)

Equivalence:
The device is identical to MRSA-SCREEN manufactured by Denka Seiken of Japan, 510(k) number K011400. Mast Group Ltd purchases the unlabelled bottled reagents from Denka Seiken and labels and packs them in the Mast livery. A copy of a letter from Denka Seiken is enclosed at Section 12, confirming the relationship.

Description: Rapid slide latex kit for confirmation of Methicillin-resistant *Staphylococcus aureus* (MRSA).
The kit tests for the *mecA* gene coding for methicillin resistance, by detecting its product, PBP2' (penicillin binding protein 2'). Organisms grown on suitable culture medium and believed to be *Staphylococcus aureus*, are emulsified in an extraction reagent, boiled for a set period of time under alkaline conditions, neutralised and centrifuged. A specified volume of supernatant liquid is mixed with a drop of test latex sensitised with a monoclonal antibody directed against PBP2' and control (unsensitised) latex on a test card. The cards are rotated for a defined length of time and examined for agglutination. A positive reaction observed with the test latex only indicates that the organism contains PBP2' and should be reported as a presumptive methicillin-resistant *Staphylococcus aureus* (MRSA).

Registered Office: Mast House, Derby Road, Bootle, Merseyside L20 1EA, United Kingdom.
Registered in England 632512

The kit contains

1. Extraction Reagent 1 (Green Coloured Cap). Ready to use.
   1 x 10ml of 0.1M sodium hydroxide.
2. Extraction Reagent 2 (Yellow Coloured Cap).
   1 x 2.4ml of 0.5M potassium dihydrogen phosphate.
3. Test Latex (Red Coloured Cap). Ready to use.
   1 x 1.2ml of latex particles sensitised with anti-PBP2' monoclonal antibodies.
4. Control Latex (White Coloured Cap). Ready to use. 1 x 1.2ml of unsensitised latex particles.
5. One tin containing 100 single use disposable wooden mixing sticks.
6. 1 pack of 24 four-well reaction cards.
7. Instruction leaflet.

Intended use:

The kit is used in clinical microbiology laboratories on pre-isolated organisms which have already been identified as *Staphylococcus aureus*, for confirmation of MRSA for epidemiological and research purposes. The intended use is identical to the intended use of the predicate device, MRSA-SCREEN manufactured by Denka Seiken of Japan, 510(k) number K011400.

Technological characteristics:

The technological characteristics of the device are identical to those of the predicate device.

Performance data

The determination of substantial equivalence is not based on performance data. No comparisons are necessary because the device reagents are identical to the predicate device. The only difference is that the device is marketed in Mast's packaging.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Barbara A. Lee
Regulatory Affairs Manager
Mast Group Limited
Mast House, Derby Road
Bootle
Merseyside L20 1EA
UK

OCT 1 8 2006

Re: k062864
Trade/Device Name: MASTALEX® - MRSA
Regulation Number: 21 CFR § 866.1640
Regulation Name: Antimicrobial susceptibility test powder
Regulatory Class: II
Product Code: MYI
Dated: September 22, 2006
Received: September 25, 2006

Dear Ms. Lee:

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.

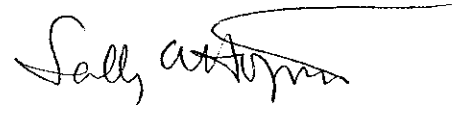
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish 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)276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,



Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) number: not known K062864

Device name : MASTALEX™-MRSA

Indications for use :
A rapid slide latex test for the detection of penicillin binding protein 2' and the confirmation of Methicillin Resistant *Staphylococcus aureus*.

Prescription use?: Yes

Over-the-counter use ? No

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K062864