# 510(k) Summary

JAN 1 1 2013

This is a 510(k) filing for a new product, the SPECBOARD JR. K123414

The SPECBOARD JR product is substantially equivalent to the SPECBOARD product (510(k) K891090, decision 04/07/1989), the difference being in size. The SPECBOARD JR is smaller than the SPECBOARD.

1. Submission Date: October/31/2012
2. Submitter Name: MacBrud Corporation, Submitter Address: 14021 SW 143 Court, Unit 6, Miami, Florida 33186, Submitter Phone: (305) 3781958, Submitter FAX: (305) 3781954
3. Establishment Registration Number: 1052243
4. Common Name of Device: Specimen Transport and Identification
5. Trade Name & Model Number: SPECBOARD JR model 222
6. Classification Name and Class: System, X-Ray, Mammographic, IZH
7. Regulation Number: 892.1710
8. Reason for the 510(k) – New Device. The SPECBOARD JR product is substantially equivalent to the SPECBOARD product (510(k) K891090, decision 04/07/1989), the difference being in size. The SPECBOARD JR is smaller than the SPECBOARD. Newer X-ray devise used in the operating room are more compact and require less energy than previous x-ray machines. The SPECBOARD JR uses the same design elements and packages them into a smaller package to allow for the use in these newer smaller portable x-ray machines.
9. Identification of Substantially Equivalent Product: SPECBOARD (510(k) K891090, decision 04/07/1989
10. The SPECBOARD is a medical device that allows for accurate localization of suspect lesions in breast tissue. The SPECBOARD JR is comprised of a foam core base coupled with a tape hinge along one edge to a thick cardboard cover. On the base foam core piece there is a centrally located piece of absorbent blotter paper. Along two joining edges of the blotter are two radio-opaque nickel stencils, one marked with alpha characters and the other with numerical characters. The SPECBOARD JR is used in the operating room where the surgeon will remove a suspect portion of the breast tissue and place it on the blotter portion of the SPECBOARD JR. The cover is then closed, sandwiching the breast specimen between the cover and the base. The cover is then secured with the Velcro latch and an x-ray is taken of the specimen inside the SPECBOARD JR. The resulting x-ray image will show the perpendicular stencils along the border of the blotter paper and the specimen on the blotter paper. Any lesions will show up within the specimen and the pathologist then has a reference of where to cut into the specimen to withdrawal a piece for analysis. The SPECBOARD predicate product has been in worldwide use since 1989 and is a couple of inches larger than the SPECBOARD JR. The same materials are used in both products. The SPECBOARD JR is expected to have the same safety record as the predicate SPECBOARD product, no failures or adverse reports.
11. Indications for Use: SPECBOARD JR is intended to be used as an accessory to a mammographic x-ray system. The SPECBOARD JR is used to contain the mammographic specimen from the patient when transported to the x-ray device and then accompany the x-ray image to the pathology laboratory.

**Decision Summary for Web Posting**

Decision Summary, K123414

This 510(k) was reviewed under OIR's Pilot Triage Program. This program represents an internal workload management tool intended to reduce internal FDA review resources for 510(k) applications that are of good quality upon receipt by FDA.

The information in the 510(k) is complete and supports a substantial equivalence (SE) determination. Please refer to the applicant's 510(k) summary for a summary of the information that supports this SE determination.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

January 11, 2013

Mr. Todd Lary
President
MacBrud Corporation - Medical Division
14021 SW 143 Court, Unit 6
MIAMI FL 33186

Re: K123414
Trade/Device Name: SPECBOARD JR
Regulation Number: 21 CFR 892.1710
Regulation Name: Mammographic x-ray system
Regulatory Class: II
Product Code: IZH
Dated: November 1, 2012
Received: December 20, 2012

Dear Mr. Lary:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. 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 Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Sean M. Boyd -S for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K123414

Device name: SPECBOARD JR

Indications for Use: SPECBOARD JR is intended to be used as an accessory to a mammographic x-ray system. The SPECBOARD JR is used to contain the mammographic specimen from the patient when transported to the x-ray device and then accompany the x-ray image to the pathology laboratory.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

Sean M. Boyd -S

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostic and Radiological Health

510(k) K123414