RAM
SCIENTIFIC, INC.
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K981973

SEP 3 1998

510(k) SUMMARY

June 5, 1998

Submitter: RAM Scientific, Inc.
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Contact Person: Monique Muri
RAM Scientific, Inc.
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Trade Name: SAFE-T-FILL® Capillary Blood Collection System

Common Name: Capillary blood collection system

Classification Name: Blood Specimen Collection Device

Predicate Device: StatSampler® (K896206); CapiJect® Capillary Blood Collection System (K833475); and Microtainer® Tube with EDTA and Microgard™ Closure (K931368).

Description: The SAFE-T-FILL® Capillary Blood Collection System is a collection device used to draw capillary blood from the finger or heelstick. It is a non-invasive device. SAFE-T-FILL® is a 100 % plastic preassembled system made up of 4 components. A capillary end-to-end tube, a colored sleeve which holds the capillary, a microtube, and a cap. The sleeve and cap come in different colors which identify the general type of additive or anticoagulant that is contained within the microtube. Blood is collected into the capillary tube and allowed to flow into the microtube. The tube is capped, mixed and then processed by the user organization.

Intended Use: The SAFE-T-FILL® Capillary Blood Collection System is indicated for the drawing of blood via capillary action from a finger or heelstick to be placed in a microtube for the purposes of obtaining a blood sample for testing.

Summary of Similarities and Differences of Predicate Devices

Characteristic	SAFE-T-FILL®	StatSampler®	CapiJect®	Microtainer®
Combination capillary tube and microtube.	Yes	Yes	No	No
Available with different additives or anticoagulants	Yes	Yes	Yes	Yes
All Components Plastic	Yes	No	Yes	Yes
Used to collect, Anticoagulate and Store Skin Puncture Blood Specimens	Yes	Yes	Yes	Yes
Similar Hematological Determinations	Yes	Yes	Yes	Yes
Fill Lines	125µl, 150 µl, & 200 µl	100µl & 200µl	250µl, 500µl & 625µl	500 µl
Preassembled	Yes	No	Yes	Yes
Sterile	No	No	No	No

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

SEP 3 1998

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ram Scientific
C/O Mr. Geoffrey M. Levitt
Venable, Baetjer, Howard
& Ceviletti, LLP
1201 New York Avenue, N.W., Suite 1000
Washington, D.C. 20005-3917

Re: K981973/S1
Trade Name: SAFE-T-FILL® Capillary Blood Collection System
Regulatory Class: II
Product Code: JKA
Dated: July 31, 1998
Received: July 31, 1998

Dear Mr. Levitt:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

The SAFE-T-FILL® Capillary Blood Collection System is indicated for the drawing of blood via capillary action from a finger or heelstick to be placed in a microtube for the purposes of obtaining a blood sample for diagnostic hematology testing.

Peter E. Maxim

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K981973

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