K983517

Record processed under FOIA Request #2016-6414; Released by CDRH on 08-29-2016.

NOV 12 1998

RAM SCIENTIFIC, INC.

P.O. Box 586, Needham, MA 02194 Phone: 800/535-6734 781/433-0766 Fax: 781/433-0767

# 510(k) SUMMARY

June 5, 1998

**Submitter:** RAM Scientific, Inc.
P.O. Box 586
Needham, Massachusetts 02194
Phone (781) 433-0766
Fax (781) 433-0767

**Contact Person:** Monique Muri
RAM Scientific, Inc.
Phone (781) 433-0766
Fax (781) 433-0767

**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.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-6414; Released by CDRH on 08-29-2016.

## 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 |



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-6414; Released by CDRH on 08-29-2016.

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 12 1998

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

Re: K983517
Trade Name: SAFE-T-FILL® Capillary Blood Collection System
Regulatory Class: II
Product Code: JKA
Dated: October 7, 1998
Received: October 7, 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.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-6414; Released by CDRH on 08-29-2016.



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

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-6414; Released by CDRH on 08-29-2016.



**510(k) Number (if known):** K983517

**Device Name:** _____

# Indications For Use:

## STATEMENT OF INDICATIONS FOR USAGE

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 testing.

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

**Concurrence of CDRH, Office of Device Evaluation (ODE)**

(Division Sign-Off)
Division of Clinical Lab...
510(k) Number K983517

**Prescription Use** ✓
(Per 21 CFR 801.109)

OR

**Over-The-Counter Use** ____

(Optional Format 1-2-96)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-6414; Released by CDRH on 08-29-2016.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 12 1998

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

Re: K983517
Trade Name: SAFE-T-FILL® Capillary Blood Collection System
Regulatory Class: II
Product Code: JKA
Dated: October 7, 1998
Received: October 7, 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.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-6414; Released by CDRH on 08-29-2016.



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

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-6414; Released by CDRH on 08-29-2016.



**510(k) Number (if known):** K983517

**Device Name:** _____

# Indications For Use:

## STATEMENT OF INDICATIONS FOR USAGE

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 testing.

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

**Concurrence of CDRH, Office of Device Evaluation (ODE)**

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K983517

**Prescription Use** ✓
(Per 21 CFR 801.109)

OR

**Over-The-Counter Use** ____

(Optional Format 1-2-96)



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-6414; Released by CDRH on 08-29-2016.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food And Drug Administration

Memorandum

From: Reviewer(s) - Name(s) M. Tsai

Subject: 510(k) Number K983517

To: The Record - It is my recommendation that the subject 510(k) Notification:

- ☐ Refused to accept.
- ☐ Requires additional information (other than refuse to accept).
- ☐ Accepted for review _____.
- ☑ Is substantially equivalent to marketed devices.
- ☐ NOT substantially equivalent to marketed devices.
  - De Novo Classification Candidate? ☐ YES ☐ NO
- ☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.)

| | | |
|---|---|---|
| Is this device subject to Postmarket Surveillance? | ☐ YES | ☑ NO |
| Is this device subject to the Tracking Regulation? | ☐ YES | ☑ NO |
| Was clinical data necessary to support the review of this 510(k)? | ☐ YES | ☑ NO |
| Is this a prescription device? | ☑ YES | ☐ NO |
| Was this 510(k) reviewed by a Third Party? | ☐ YES | ☑ NO |
| Special 510(k)? | ☐ YES | ☑ NO |
| Abbreviated 510(k)? | ☐ YES | ☑ NO |

This 510(k) contains:

Truthful and Accurate Statement ☐ Requested ☑ Enclosed
(required for originals received 3-14-95 and after)

☑ A 510(k) summary OR ☐ A 510(k) statement

☐ The required certification and summary for class III devices

☐ The indication for use form (required for originals received 1-1-96 and after)

☐ Material of Biological Origin ☑ YES ☐ NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

☐ No Confidentiality ☐ Confidentiality for 90 days ☐ Continued Confidentiality exceeding 90 days

Predicate Product Code with class: JKA/85; 862.1675 Class II

Additional Product Code(s) with panel (optional):

Review (Branch Chief) TCM3 (Branch Code) 11/6-98 (Date)

Final Review: (Division Director) 11/10/98 (Date)

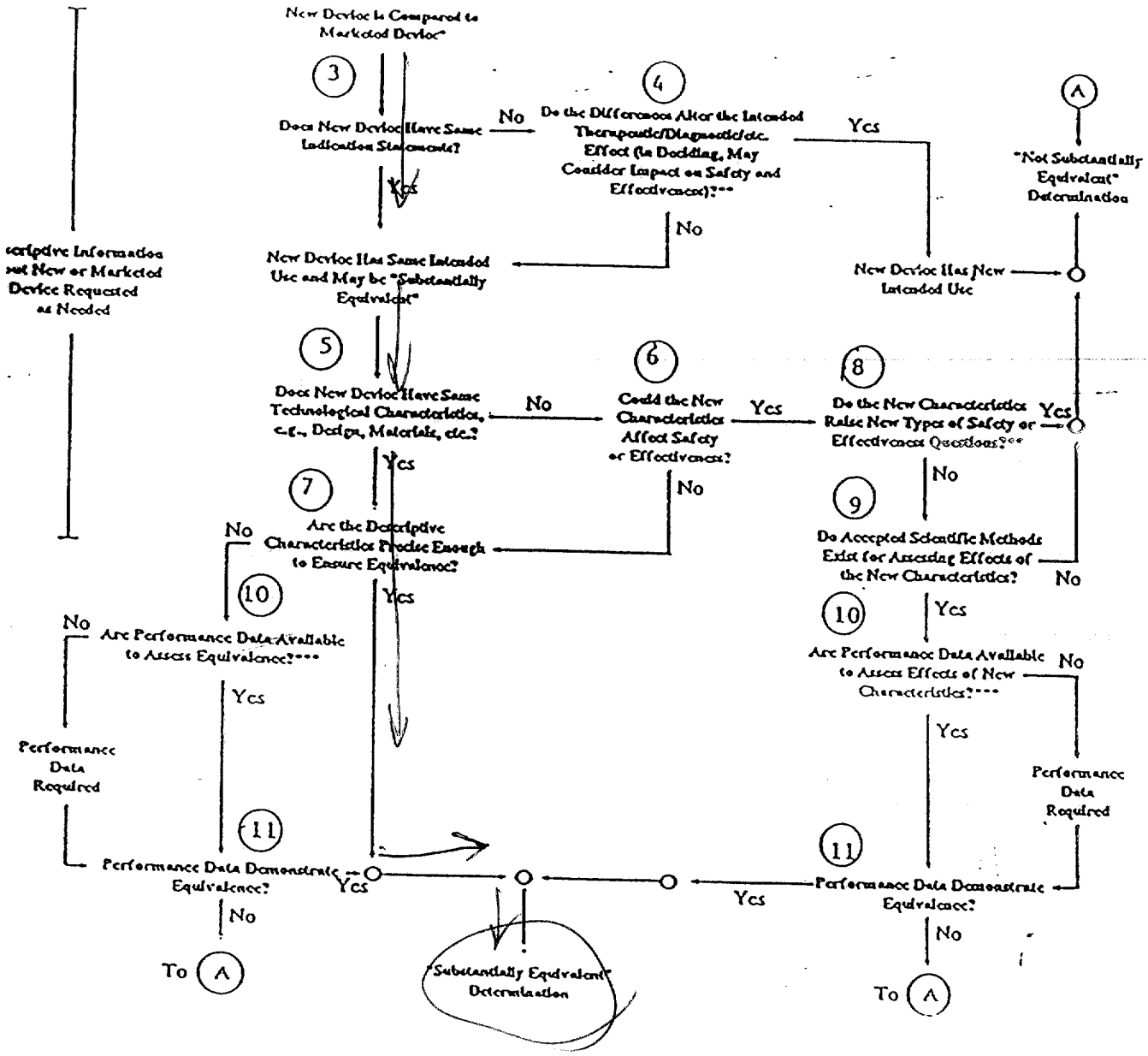
Rev. 11/10/98

Questions? Contact FOIA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Revised:6/2//98

Records processed under FOIA Request #2016-6414; Released by CDRH on 08-29-2016.

# 510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS (DETAILED)




510(k) submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

* Data may be in the 510(k), other 510(k)s, the Center's classification files, or the literature.

5

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-6414; Released by CDRH on 08-29-2016.

# Internal Administrative Form

| | YES | NO |
|---|---|---|
| 1. Did the firm request expedited review? | | ✓ |
| 2. Did we grant expedited review? | | ✓ |
| 3. Have you verified that the Document is labeled Class III for GMP purposes? | | |
| 4. If, not, has POS been notified? | | |
| 5. Is the product a device? | ✓ | |
| 6. Is the device exempt from 510(k) by regulation or policy? | | ✓ |
| 7. Is the device subject to review by CDRH? | ✓ | |
| 8. Are you aware that this device has been the subject of a previous NSE decision? | | ✓ |
| 9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)? | | |
| 10. Are you aware of the submitter being the subject of an integrity investigation? | | ✓ |
| 11. If, yes, consult the ODE Integrity Officer. | | |
| 12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N0332, September 10, 1991. | | |



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-6414; Released by CDRH on 08-29-2016.

# Screening Checklist
# For all Premarket Notification 510(k) Submissions

**Device Name:** K983517

**Submitter (Company):** BAM

| Items which should be included *(circle missing & needed information)* | SPECIAL YES | SPECIAL NO | ABBREVIATED YES | ABBREVIATED NO | TRADITIONAL YES | TRADITIONAL NO | ✓ IF ITEM IS NEEDED AND IS MISSING |
|---|---|---|---|---|---|---|---|
| **1. Cover Letter clearly identifies Submission as:** | | | | | | | |
| a) "Special 510(k): Device Modification" | | | | | ✓ | | |
| b) "Abbreviated 510(k)" | GO TO #2,4 | | GO TO #3,4,5 | | GO TO #4,5 | | |
| c) Traditional 510(k) | | | | | | | |
| **2. "SPECIALS" - ONLY FOR MODIFICATIONS TO MANUFACTURER'S OWN CLASS II, III OR RESERVED CLASS I DEVICE** | | | | | | | |
| a) Name & 510(k) number of legally marketed (unmodified) predicate device | | | | | | | |
| b) ***STATEMENT - INTENDED USE AND INDICATIONS FOR USE OF MODIFIED DEVICE AS DESCRIBED IN ITS LABELING HAVE NOT CHANGED**** | | | * If no - STOP not a special | | | | |
| c) ***STATEMENT - FUNDAMENTAL SCIENTIFIC TECHNOLOGY OF THE MODIFIED DEVICE HAS NOT CHANGED**** | | | * If no - STOP not a special | | | | |
| d) Design Control Activities Summary | | | | | | | |
| i) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis | | | | | | | |
| ii) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied | | | | | | | |
| iii) A declaration of conformity with design controls. The declaration of conformity should include: | | | | | | | |
| 1) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met | | | | | | | |
| 2) A statement signed by the individual responsible, that manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review. | | | | | | | |

1

Records processed under FOIA Request #2016-6414; Released by CDRH on 08-29-2016.

→ → → CONTINUE TO SECTION 4 ← ← ←

| | SPECIALS | | ABBREVIATED | | TRADITIONAL | | ✓ IF ITEM IS NEEDED AND IS MISSING |
|---|---|---|---|---|---|---|---|
| | YES | NO | YES | NO | YES | NO | |
| **3. ABBREVIATED 510(K): SPECIAL CONTROLS/CONFORMANCE TO RECOGNIZED STANDARDS** | | | | | | | |
| a) For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type | | | | | | | |
| b) If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach. | | | | | | | |
| c) For a submission, which relies on a recognized standard, a declaration of conformity to the standard. The declaration should include the following: | | | | | | | |
| i) An identification of the applicable recognized consensus standards that were met | | | | | | | |
| ii) A specification, for each consensus standard, that all requirements were met, except for inapplicable requirements or deviations noted below | | | | | | | |
| iii) An identification, for each consensus standard, of any way(s) in which the standard may have been adapted for application to the device under review, e.g., an identification of an alternative series of tests that were performed | | | | | | | |
| iv) An identification, for each consensus standard, of any requirements that were not applicable to the device | | | | | | | |
| v) A specification of any deviations from each applicable standard that were applied | | | | | | | |
| vi) A specification of the differences that may exist, if any, between the tested device and the device to be marketed and a justification of the test results in these areas of difference | | | | | | | |
| vii) Name/address of test laboratory/certification body involved in determining the conformance of the device with applicable consensus standards and a reference to any accreditations for those organizations | | | | | | | |
| d) Data/information to address issues not covered by guidance documents, special controls, and/or recognized standards | | | | | | | |

8

→ → → CONTINUE TO SECTION 4 ← ← ←

Records processed under FOIA Request #2016-6414; Released by CDRH on 08-29-2016.

| 4. GENERAL INFORMATION: REQUIRED IN ALL 510(K) SUBMISSIONS | SPECIALS | | ABBREVIATED | | TRADITIONAL | | ✓ IF ITEM IS NEEDED AND IS MISSING |
|---|---|---|---|---|---|---|---|
| | YES | NO | YES | NO | YES | NO | |
| a) trade name, classification name, establishment registration number, address of manufacturer. device class | | | | | ✓ | | |
| b) OR a statement that the device is not yet classified | FDA - may be a classification request; see coordinator | | | | | | |
| c) identification of legally marketed equivalent device | NA | | | | ✓ | | |
| d) compliance with Section 514 - performance standards | NA | | | | | | |
| e) address of manufacturer | | | | | ✓ | | |
| f) Truthful and Accurate Statement | | | | | ✓ | | |
| g) Indications for Use enclosure | | | | | ✓ | | |
| h) SMDA Summary or Statement *(FOR ALL DEVICE CLASSES)* | | | | | ✓ | | |
| i) Class III Certification & Summary *(FOR ALL CLASS III DEVICES)* | | | | | | | |
| j) Description of device (or modification) including diagrams, engineering drawings, photographs, service manuals | | | | | ✓ | | |
| k) Proposed Labeling: | | | | | | | |
| i) package labeling (user info) | | | | | ✓ | | |
| ii) statement of intended use | | | | | ✓ | | |
| iii) advertisements or promotional materials | | | | | ✓ | | |
| l) MRI compatibility (if claimed) | | | | | | | |
| m) Comparison Information (similarities and differences) to named legally marketed equivalent device (table preferred) should include: | | | | | ✓ | | |
| i) labeling | | | | | ✓ | | |
| ii) intended use | | | | | ✓ | | |
| iii) physical characteristics | | | | | ✓ | | |
| iv) anatomical sites of use | | | | | | | |
| v) performance (bench, animal, clinical) testing | NA | | | | | | |
| vi) safety characteristics | NA | | | | ✓ | | |
| n) If kit, kit certification | | | | | | | |

| 5. Additional Considerations: (may be covered by Design Controls) | | | | | | | |
|---|---|---|---|---|---|---|---|
| a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation: | | | | | | | |
| i) component & material | | | | | | | |
| ii) identify patient-contacting materials | | | | | | | |
| iii) biocompatibility of final sterilized product | | | | | | | |
| b) Sterilization and expiration dating information: | | | | | | | |
| i) sterilization method | | | | | | | |
| ii) SAL | | | | | | | |
| iii) packaging | | | | | | | |
| iv) specify pyrogen free | | | | | | | |
| v) ETO residues | | | | | | | |
| vi) radiation dose | | | | | | | |
| c) Software validation & verification: | | | | | | | |
| i) hazard analysis | | | | | | | |
| ii) level of concern | | | | | | | |
| iii) development documentation | | | | | | | |
| iv) certification | | | | | | | |

***Items shaded under "NO" are necessary for that type of submission. Circled items and items with checks in the "Needed & Missing" column must be submitted before acceptance of the document.***

**Passed Screening** _____**Yes**_____**No**
**Date:** 10-13-98

**Reviewer:** Joan McClain-Bennett
**Concurrence by Review Branch:** _____

9

Records processed under FOIA Request #2016-6414; Released by CDRH on 08-29-2016.

# Review Memorandum

**Document #:** K983517

**Reviewer:** Miin-Rong Tsai 11/6/98

**Applicant :** Ram Scientific, Inc.
P.O.Box 586
Needham, MA 02194
**Contact:** Monique Muri
(781)433-0766
Geoffrey M. Levitt
(202) 962-4923

**Device Propriety Name:** SAFE-T-FILL® Capillary Blood Collection System

**Device Classification Name:** Blood Specimen Collection Device
(Tubes, Vials, Systems, Serum Separators, Blood Collection)
21 CFR 862.1675; Class II; JKA/75

1. **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 diagnostic testing.

2. **Device Description :**

The SAFE-T-FILL® Capillary Blood Collection System is a non-sterile, single-use disposable system. The system is composed of a capillary end-to-end tube, a color-coded sleeve which hold the capillary. Both capillary tube and sleeve are attached to a microtube with a color-code plastic cap. Blood is collected into the capillary tube and allowed to flow into the microtube. There are fifteen products which are listed on page III-1. The tube capacities are 125 ul,150 ul, or 200 ul. The system is available with the following additives:

| | | |
|---|---|---|
| Hematology | Liquid EDTA | non-gel |
| Serum | Clotting activator | non-gel/gel |
| Plasma | Lithium heparin | non-gel/gel |
| Glucose | Sodium fluoride | non-gel |
| Serum Bilirubin | Clotting activator | non-gel/gel |

10

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-6414; Released by CDRH on 08-29-2016.

(b)(4) Confidential and Proprietary Information

[redacted]

The submission includes a stability summary for the product (Section V). The sponsor stated that the product quality was checked by FDA Baltimore Distract personnel. Shelf-life for each collection tube within the product line has been established by verification of service life.

3. **Predicate Device:**
   Becton Dickinson Microtainer® tube with EDTA and Microgard™ closure
   StatSpin StatSampler for "finger-stick" collection
   Terun Medical CapiJect Capillary Blood Collection System

4. **Similarities to the Predicate:**

   The SAFE-T-FILL® Capillary Blood Collection System and the predicate device have the same intended use and are available with anticoagulants or various additives.

5. **Differences from the Predicate:**

   The SAFE-T-FILL® Capillary Blood Collection System, StatSampler, and Capiject Capillary Blood Collection System are the combination of capillary tube and microtube. Becton Dickinson Microtainer® does not contain capillary tube.

6. **Soft-Ware Description:** N/A

7. **Sterilization:** The device is provided as no sterile

8. **Clinical Evaluation:**

(b)(4) Confidential and Proprietary Information

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-6414; Released by CDRH on 08-29-2016.

9. **Performance Characteristic:**

(b)(4) Confidential and Proprietary Information

[redacted]

10. **Device Labeling :**

The proposed device package insert, primary carton label, and accessories label are provided in the submission (Section VI). The proposed labeling include information on instructions for use, product description, intended use, procedure, limitations, caution, shelf life, storage, specimen collection and handling, and general instruction.

In the original submission, the proposed device labeling does not include the required statement "For In Vitro Diagnostic Use". The proposed promotional material states that the subject product is "also appropriate for lead testing. There is no performance data provided for lead testing. The sponsor was informed to provide performance data for lead testing or delete this claim. In the amendment, the sponsor agreed to revise the labeling to include the required statement, "For In Vitro Diagnostic Use" and delete "also appropriate for lead testing" from the promotional material.

The proposed device labeling is adequate.

11. **Additional Comments:**

- A 510(k) Summary of Safety and Effectiveness, Truthful and Accuracy Statement, and Statement of Indications for Use are enclosed.
- The device is not life-supporting or sustaining, implanted, sterile or for home use.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-6414; Released by CDRH on 08-29-2016.

## 12. Substantially Equivalence & Recommendation:

The SAFE-T-FILL® Capillary Blood Collection System and the predicate device have the same intended use and are available with anticoagulants or various additives. The SAFE-T-FILL® Capillary Blood Collection System is the combination of capillary tube and microtube. Becton Dickinson Microtainer® does not contain capillary tube. The performance characteristic and data indicate that assay results from specimens collected with the subject device are not statistically or clinically different from those collected with the predicate.

Based on this information, the SAFE-T-FILL® Capillary Blood Collection System is substantially equivalent (SE) to device regulated under 21 CFR 862.1675; JKA /Class II;, Blood Specimen Collection Device (Tubes, Vials, Systems, Serum Separators, Blood Collection)



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-6414; Released by CDRH on 08-29-2016.

# Memorandum

Date: Oct. 23, 1998
From: Miin-Rong Tsai, & Ann Hawthotne
Subject: Teleconference with Sponsor, K983517, SAFE-T-FILL® Capillary Blood Collection System
To: The Record
Contact: Monique Muri (800) 535-6734
Geoffrey M. Levitt (202) 962-4923

Per telephone conference, I faxed the following deficiencies to Mr. Levitt for response.

(b)(4) Confidential and Proprietary Information

[redacted]

The sponsor amended the 510(k) and provided information to adequately address the deficiencies listed above.

4

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-6414; Released by CDRH on 08-29-2016.

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

October 08, 1998

RAM SCIENTIFIC
C/O VENABLE,BAETJER,HOWARD & CIVILE
1201 NEW YORK AVENUE N.W.
SUITE 1000
WASHINGTON, DC 20005
ATTN: GEOFFREY LEVITT

510(k) Number: K983517
Received: 07-OCT-1998
Product: SAFE-T-FILL CAPILLARY BLOOD COLLECTION SYSTEM

The Center for Devices and Radiological Health (CDRH), Office of Device Evaluation (ODE), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

On January 1, 1996, FDA began requiring that all 510(k) submitters provide on a separate page and clearly marked "Indication For Use" the indication for use of their device. If you have not included this information on a separate page in your submission, please complete the attached and amend your 510(k) as soon as possible. Also if you have not included your 510(k) Summary or 510(k) Statement, or your Truthful and Accurate Statement, please do so as soon as possible. There may be other regulations or requirements affecting your device such as Postmarket Surveillance (Section 522 (a) (1) of the Act) and the Device Tracking regulation (21 CFR Part 821). Please contact the Division of Small Manufacturers Assistance at the number below for more information.

With regard to the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88) which became effective September 1, 1992, the Center for Disease Control (CDC) and Prevention is currently handling complexity category/assignments concurrent with FDA's 510(k) review. To determine if your device requires a CLIA complexity categorization, contact CDC at (770)488-7655.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the Document Mail Center will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations, we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official. Any telefaxed material must be followed by a hard copy to the Document Mail Center (HFZ-401).

15

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-6414; Released by CDRH on 08-29-2016.

You should be familiar with the manual entitled, "Premarket Notification 510(k) Regulatory Requirements for Medical Devices" available from DSMA. If you have other procedural or policy questions, or want information on how to check on the status of your submission (after 90 days from the receipt date), please contact DSMA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address http://www.fda.gov/cdrh/dsmamain.html or me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Staff

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-944 Released by CDRH on 08-29-2016.

# TELECOPY/TELEX COVER SHEET

DATE/TIME PREPARED: _____ DATE OF TRANSMISSION: _____

C NAME: _____ TIME OF TRANSMISSION: _____

FILE NO.: 29457.123204 TELECOPY OPERATOR: _____

☐ **SENSITIVE DOCUMENT ATTACHED:** Verify telecopy number and name of recipient with telephone number _____, prior to transmittal.

**IF TRANSMISSION IS NOT SUCCESSFUL, CONTACT REQUESTOR FOR CURRENT INFORMATION**

_____ **Time Contacted** _____ **Person Contacted** _____ **Caller's Initials**

**VENABLE, BAETJER, HOWARD & CIVILETTI, LLP**
1201 NEW YORK AVE. NW, SUITE 1000
WASHINGTON, D.C. 20005

Telephone # (202) 962-4800 Telecopy # (202) 962-8300

PLEASE TRANSMIT THE ATTACHED TO:

| | NAME | COMPANY | TELECOPIER NUMBER | TELEPHONE NUMBER |
|---|---|---|---|---|
| 1. | Dr. Tsai | FDA | (301) 594-5941/5940 | |
| 2. | | | | |
| 3. | | | | |
| 4. | | | | |
| 5. | | | | |

FROM:

NAME: Geoffrey M. Levitt LOCATION/DEPT./PHONE NUMBER: (202) 962-4923

**IF YOU DO NOT RECEIVE ALL THE PAGES, PLEASE TELEPHONE SENDER AS SOON AS POSSIBLE.**

TOTAL NUMBER OF PAGES: 29 (EXCLUDING COVER PAGE)

## CONFIDENTIALITY NOTICE

**"WARNING: Unauthorized interception of this telephonic communication could be a violation of Federal and State law."**

The documents accompanying this telecopy transmission contain confidential information belonging to the sender which is legally privileged. The information is intended only for the use of the individual or entity named above. If you are not the intended recipient, you are hereby notified that any disclosure, copying, distribution or the taking of any action in reliance on the contents of this telecopied information is strictly prohibited. If you have received this telecopy in error, please immediately notify us by telephone to arrange for return of the original documents to us.

MESSAGE:

17

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-6414; Released by CDRH on 08-29-2016.

VENABLE, BAETJER, HOWARD & CIVILETTI, LLP
*Including professional corporations*

1201 New York Avenue, N.W., Suite 1000
Washington, D.C. 20005-3917
(202) 962-4800, Fax (202) 962-8300

OFFICES IN

WASHINGTON, D.C.
MARYLAND
VIRGINIA

VENABLE
ATTORNEYS AT LAW

Geoffrey M. Levitt
(202) 962-4923

October 30, 1998

Document Mail Center (HFZ-401)
Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
9200 Corporate Blvd.
Rockville, MD 20850

Attention: Dr. Tsai
Ms. Hawthorne

Re: 510(k) Number: K983517

Dear Dr. Tsai and Ms. Hawthorne:

In response to your fax message of October 23, 1998, we hereby submit additional information on behalf of RAM Scientific, Inc. to the above-referenced Premarket Notification Submission (K983517), received by FDA on October 8, 1998.

If you have any questions regarding this submission, please feel free to call me.

Sincerely,

Geoffrey M. Levitt

Geoffrey M. Levitt

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-6414; Released by CDRH on 08-29-2016.

P.O. Box 586, Needham, MA 02494-0004 • 800-535-6734 • 781-433-0766 • FAX: 781-433-0767

# FAX COVER SHEET

**DATE:** October 29, 1998
**TO:** Geoff Levitt
**COMPANY:** Venable
**FROM:** Monique Muri
**RE:** Additional Info
**Number of pages including cover sheet:** 1

**PHONE:** (202)962-4923
**FAX PHONE:** (202)962-8332

Dear Geoff:

(b)(4) Confidential and Proprietary Information

[redacted]

A

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

(b)(4) Confidential and Proprietary Information - Testing

(b)(4) Confidential and Proprietary Information - Testing

(b)(4) Confidential and Proprietary Information - Testing

(b)(4) Confidential and Proprietary Information - Testing

(b)(4) Confidential and Proprietary Information - Testing

(b)(4) Confidential and Proprietary Information - Testing

(b)(4) Confidential and Proprietary Information - Testing

(b)(4) Confidential and Proprietary Information - Testing

(b)(4) Confidential and Proprietary Information - Testing

(b)(4) Confidential and Proprietary Information - Testing

(b)(4) Confidential and Proprietary Information - Testing

(b)(4) Confidential and Proprietary Information - Testing

(b)(4) Confidential and Proprietary Information - Testing

(b)(4) Confidential and Proprietary Information - Testing

(b)(4) Confidential and Proprietary Information - Testing

(b)(4) Confidential and Proprietary Information - Testing

(b)(4) Confidential and Proprietary Information - Testing

(b)(4) Confidential and Proprietary Information - Testing

(b)(4) Confidential and Proprietary Information - Testing

(b)(4) Confidential and Proprietary Information - Testing

(b)(4) Confidential and Proprietary Information - Testing

(b)(4) Confidential and Proprietary Information - Testing

(b)(4) Confidential and Proprietary Information - Testing

(b)(4) Confidential and Proprietary Information - Testing

(b)(4) Confidential and Proprietary Information - Testing

(b)(4) Confidential and Proprietary Information - Testing

(b)(4) Confidential and Proprietary Information - Testing

Records processed under FOIA Request #2016-6414; Released by CDRH on 08-29-2016.

K983517

RAM SCIENTIFIC, INC.
P.O. Box 586, Needham, MA 02194 Phone: 800/535-6734 781/433-0766 Fax: 781/433-0767

FDA/CDRH/OCE/OMC
7 Oct 98 16 31
RECEIVED

October 7, 1998

Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

**Re: 510(k) Notification**

Dear Document Control Clerk:

Pursuant to Section 510(k) of the Federal Food Drug and Cosmetic Act, and 21 C.F.R. §807, Subpart E, we are submitting a premarket notification for the SAFE-T-FILL® Capillary Blood Collection System.

If you have any questions regarding this submission, please call our submission correspondent, Geoffrey M. Levitt, at 202-962-4923.

Sincerely,

Monique Muri
President

SK-37

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-6414; Released by CDRH on 08-29-2016.

# 510(k) SUBMISSION
# SAFE-T-FILL® CAPILLARY BLOOD COLLECTION SYSTEM



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-6414; Released by CDRH on 08-29-2016.

# TABLE OF CONTENTS

I. Premarket Submission Cover Sheet
II. Truthful and Accurate Statement
III. Product Description
IV. Comparative Test Results
V. Stability Summary
VI. Product Labeling
VII. Statement of Indications for Usage
VIII. Statement of Substantial Equivalence
IX. 510(k) Summary



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-6414; Released by CDRH on 08-29-2016.

# PREMARKET SUBMISSION COVER SHEET

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-6414; Released by CDRH on 08-29-2016.

# CDRH SUBMISSION COVER SHEET

Date of Submission: October 7, 1998

FDA Document Number:

## Section A — Type of Submission

| PMA | PMA Supplement | PDP | 510(k) | Meeting |
|---|---|---|---|---|
| ☐ Original submission<br>☐ Modular submission<br>☐ Amendment<br>☐ Report<br>☐ Report Amendment | ☐ Regular<br>☐ Special<br>☐ Panel Track<br>☐ 30-day Supplement<br>☐ 30-day Notice<br>☐ 135-day Supplement<br>☐ Real-time Review<br>☐ Amendment to PMA Supplement | ☐ Presubmission summary<br>☐ Original PDP<br>☐ Notice of intent to start clinical trials<br>☐ Intention to submit Notice of Completion<br>☐ Notice of Completion<br>☐ Amendment to PDP<br>☐ Report | ☒ Original submission:<br>☒ Traditional<br>☐ Special<br>☐ Abbreviated<br>☐ Additional information:<br>☐ Traditional<br>☐ Special<br>☐ Abbreviated | ☐ Pre-IDE meeting<br>☐ Pre-PMA meeting<br>☐ Pre-PDP meeting<br>☐ 180-day meeting<br>☐ Other (specify): |
| **IDE** | **Humanitarian Device Exemption** | **Class II Exemption** | **Evaluation of Automatic Class III Designation** | **Other Submission** |
| ☐ Original submission<br>☐ Amendment<br>☐ Supplement | ☐ Original submission<br>☐ Amendment<br>☐ Supplement<br>☐ Report | ☐ Original submission<br>☐ Additional information | ☐ Original submission<br>☐ Additional information | Describe submission: |

## Section B — Applicant or Sponsor

Company / Institution name: Ram Scientific, Inc.

Establishment registration number: 8010932

Division name (if applicable):

Phone number (include area code): ( 781 ) 433-0766

Street address: 124 Crescent Road

FAX number (include area code): ( 781 ) 433-0767

City: Needham

State / Province: MA

Country: USA

Contact name: Monique Muri

Contact title: President

Contact e-mail address:

## Section C — Submission correspondent (if different from above)

Company / Institution name: Venable, Baetjer, Howard & Civiletti

Establishment registration number:

Division name (if applicable):

Phone number (include area code): ( 202 ) 962-4923

Street address: 1201 New York Avenue, NW, Suite 1000

FAX number (include area code): ( 202 ) 962-8300

City: Washington

State / Province: DC

Country: USA

Contact name: Geoffrey Levitt

Contact title: Partner

Contact e-mail address: glevitt@venable.com

Version 2.0

FINAL DRAFT — May 8, 1998

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.



51

Records processed under FOIA Request #2016-6414; Released by CDRH on 08-29-2016.

## Section D1 — Reason for Submission — PMA, PDP, or HDE

- ☐ New device
- ☐ Withdrawal
- ☐ Additional or expanded indications
- ☐ Licensing agreement
- ☐ Process change
  - ☐ Manufacturing
  - ☐ Sterilization
  - ☐ Packaging
  - ☐ Other (specify below)
- ☐ Response to FDA correspondence:
  - ☐ Request for applicant hold
  - ☐ Request for removal of applicant hold
  - ☐ Request for extension
  - ☐ Request to remove or add manufacturing site
- ☐ Other reason (specify):
- ☐ Change in design, component, or specification:
  - ☐ Software
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other (specify below)
- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance Characteristics
  - ☐ Shelf life
  - ☐ Trade name
  - ☐ Other (specify below)
- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager
  - ☐ Distributor
- ☐ Report submission:
  - ☐ Annual or periodic
  - ☐ Post-approval study
  - ☐ Adverse reaction
  - ☐ Device defect
  - ☐ Amendment
- ☐ Change in ownership
- ☐ Change in correspondent

## Section D2 — Reason for Submission — IDE

- ☐ New device
- ☐ Addition of institution
- ☐ Expansion / extension of study
- ☐ IRB certification
- ☐ Request hearing
- ☐ Request waiver
- ☐ Termination of study
- ☐ Withdrawal of application
- ☐ Unanticipated adverse effect
- ☐ Notification of emergency use
- ☐ Compassionate use request
- ☐ Treatment IDE
- ☐ Continuing availability request
- ☐ Other reason (specify):
- ☐ Change in:
  - ☐ Correspondent
  - ☐ Design
  - ☐ Informed consent
  - ☐ Manufacturer
  - ☐ Manufacturing process
  - ☐ Protocol – feasibility
  - ☐ Protocol – other
  - ☐ Sponsor
- ☐ Report submission:
  - ☐ Current investigator
  - ☐ Annual progress
  - ☐ Site waiver limit reached
  - ☐ Final
- ☐ Response to FDA letter concerning:
  - ☐ Conditional approval
  - ☐ Deemed approved
  - ☐ Deficient final report
  - ☐ Deficient progress report
  - ☐ Deficient investigator report
  - ☐ Disapproval
  - ☐ Request extension of time to respond to FDA
  - ☐ Request meeting

## Section D3 — Reason for Submission — 510(k)

- ☒ New device
- ☐ Additional or expanded indications
- ☐ Other reason (specify):
- ☐ Change in technology
- ☐ Change in design
- ☐ Change in materials
- ☐ Change in manufacturing process



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

52

Records processed under FOIA Request #2016-6414; Released by CDRH on 08-29-2016.

## Section E — Additional Information on 510(k) Submissions

Product codes of devices to which substantial equivalence is claimed:

| 1 | 2 | 3 | 4 |
|---|---|---|---|
| 75JKA | | | |
| 5 | 6 | 7 | 8 |

Summary of, or statement concerning, safety and effectiveness data:
- ☐ 510(k) summary attached
- ☐ 510(k) statement

Information on devices to which substantial equivalence is claimed:

| 510(k) Number | Trade or proprietary or model name | Manufacturer |
|---|---|---|
| 1 K896206 | 1 Statspin Statsampler | 1 Statspin Technologies |
| 2 K833475 | 2 Capiject Capillary Blood Collection Sys. | 2 Terumo Medical Corp. |
| 3 K931368 | 3 Microtainer Brand Tube with EDTA | 3 Becton Dickinson & Co. |
| 4 | 4 | 4 |
| 5 | 5 | 5 |
| 6 | 6 | 6 |

## Section F — Product Information — Applicable to All Applications

Common or usual name or classification name:

Blood specimen collection device

| Trade or proprietary or model name | Model number |
|---|---|
| 1 SAFE-T-FILL Capillary Blood Collection System | 1 various |
| 2 | 2 |
| 3 | 3 |
| 4 | 4 |
| 5 | 5 |

FDA document numbers of all prior related submissions (regardless of outcome):

| | | | | | |
|---|---|---|---|---|---|
| 1 | 2 | 3 | 4 | 5 | 6 |
| 7 | 8 | 9 | 10 | 11 | 12 |

Data included in submission: ☐ Laboratory testing ☐ Animal trials ☐ Human trials

## Section G — Product Classification — Applicable to All Applications

Product code: 75JKA

C.F.R. Section: 21 CFR 862.1675

Device class:
- ☐ Class I
- ☒ Class II
- ☐ Class III
- ☐ Unclassified

Classification panel: Clinical Chemistry and Clinical Toxicology Devices

Indications (from labeling):

Sampling of blood via capillary action from a fingerstick or heelstick to be placed in a microtube for the purposes of obtaining a blood sample for testing.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

53

Records processed under FOIA Request #2016-6414; Released by CDRH on 08-29-2016.

| | |
|---|---|
| ***Note:*** Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form. | FDA Document Number: |

**Section II — Manufacturing / Packaging / Sterilization Sites Relating to a Submission**

(b)(4) Confidential and Proprietary Information

[redacted]

| | | | |
|---|---|---|---|
| ☐ Original<br>☐ Add ☐ Delete | FDA establishment registration number: | ☐ Manufacturer<br>☐ Contract manufacturer | ☐ Contract sterilizer<br>☐ Repackager / relabeler |
| *Company / Institution name:* | | *Establishment registration number:* | |
| Division name (if applicable): | | Phone number (include area code):<br>( ) | |
| Street address: | | FAX number (include area code):<br>( ) | |
| City: | State / Province: | | Country: |
| Contact name: | | | |
| Contact title: | | Contact e-mail address: | |

| | | | |
|---|---|---|---|
| ☐ Original<br>☐ Add ☐ Delete | FDA establishment registration number: | ☐ Manufacturer<br>☐ Contract manufacturer | ☐ Contract sterilizer<br>☐ Repackager / relabeler |
| Company / Institution name: | | Establishment registration number: | |
| Division name (if applicable): | | Phone number (include area code):<br>( ) | |
| Street address: | | FAX number (include area code):<br>( ) | |
| City: | State / Province: | | Country: |
| Contact name: | | | |
| Contact title: | | Contact e-mail address: | |



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

54

Records processed under FOIA Request #2016-6414; Released by CDRH on 08-29-2016.

# PREMARKET NOTIFICATION
# TRUTHFUL AND ACCURATE STATEMENT

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 55

Records processed under FOIA Request #2016-6414; Released by CDRH on 08-29-2016.

# Premarket Notification
# Truthful and Accurate Statement

**I certify that, in my capacity as President of RAM Scientific, Inc., I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.**

Monique Muri
October 7, 1998
K 983517

56

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-6414; Released by CDRH on 08-29-2016.

# PRODUCT DESCRIPTION



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-6414; Released by CDRH on 08-29-2016.

# PRODUCT DESCRIPTION

Device Name:
SAFE-T-FILL® Capillary Blood Collection System

RAM Scientific, Inc. Establishment Registration Number:
2246954

Classification:
This device is classified under the Clinical Chemistry and Clinical Toxicology Devices category, section 862.1675, Blood specimen collection device, Class II, product code 75JKA.

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 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.

The following products will be marketed:

| Stock Number | Description |
|---|---|
| 07 6041 | Serum Mini Capillary Collection 125 µl |
| 07 7150 | Serum Capillary Collection 200 µl |
| 07 6071 | Serum Gel Mini Capillary Collection 125 µl |
| 07 7122 | Serum Gel Capillary Collection 150 µl |
| 07 7120 | Serum Gel Capillary Collection 200 µl |
| 07 7450 | Serum Bili Capillary Collection 200 µl |
| 07 7423 | Serum Bili Gel Capillary Collection 150µl |
| 07 7421 | Serum Bili Gel Capillary Collection 200 µl |
| 07 6101 | Lith Hep Mini Capillary Collection 125 µl |
| 07 7250 | Lith Hep Capillary Collection 200 µl |
| 07 6111 | Lith Hep Gel Mini Capillary Collection 125 µl |
| 07 7220 | Lith Hep Gel Capillary Collection 200 µl |
| 07 7221 | Lith Hep Gel Capillary Collection 300 µl |
| 07 7340 | Na Fluoride Capillary Collection 200 µl |
| 07 7650 | $NH_4$ (AM) Hep Capillary Collection 200 µl |

*Liquid Dipotassium EDTA



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

58

Records processed under FOIA Request #2016-6414; Released by CDRH on 08-29-2016.

# COMPARATIVE TEST RESULTS



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

(b)(4) Confidential and Proprietary Information - Testing

(b)(4) Confidential and Proprietary Information - Testing

(b)(4) Confidential and Proprietary Information - Testing

(b)(4) Confidential and Proprietary Information - Testing

(b)(4) Confidential and Proprietary Information - Testing

(b)(4) Confidential and Proprietary Information - Testing

(b)(4) Confidential and Proprietary Information - Testing

(b)(4) Confidential and Proprietary Information - Testing

(b)(4) Confidential and Proprietary Information - Testing

(b)(4) Confidential and Proprietary Information - Testing

(b)(4) Confidential and Proprietary Information - Testing

(b)(4) Confidential and Proprietary Information - Testing

(b)(4) Confidential and Proprietary Information - Testing

(b)(4) Confidential and Proprietary Information - Testing

(b)(4) Confidential and Proprietary Information - Testing

(b)(4) Confidential and Proprietary Information - Testing

(b)(4) Confidential and Proprietary Information - Testing

(b)(4) Confidential and Proprietary Information - Testing

(b)(4) Confidential and Proprietary Information - Testing

(b)(4) Confidential and Proprietary Information - Testing

(b)(4) Confidential and Proprietary Information - Testing

(b)(4) Confidential and Proprietary Information - Testing

(b)(4) Confidential and Proprietary Information - Testing

(b)(4) Confidential and Proprietary Information - Testing

(b)(4) Confidential and Proprietary Information - Testing

(b)(4) Confidential and Proprietary Information - Testing

(b)(4) Confidential and Proprietary Information - Testing

(b)(4) Confidential and Proprietary Information - Testing

(b)(4) Confidential and Proprietary Information - Testing

(b)(4) Confidential and Proprietary Information - Testing

(b)(4) Confidential and Proprietary Information - Testing

(b)(4) Confidential and Proprietary Information - Testing

(b)(4) Confidential and Proprietary Information - Testing

(b)(4) Confidential and Proprietary Information - Testing

(b)(4) Confidential and Proprietary Information - Testing

(b)(4) Confidential and Proprietary Information - Testing

(b)(4) Confidential and Proprietary Information - Testing

(b)(4) Confidential and Proprietary Information - Testing

(b)(4) Confidential and Proprietary Information - Testing

Records processed under FOIA Request #2016-6414; Released by CDRH on 08-29-2016.

VENABLE, BAETJER, HOWARD & CIVILETTI, LLP
*Including professional corporations*

1201 New York Avenue, N.W., Suite 1000
Washington, D.C. 20005-3917
(202) 962-4800, Fax (202) 962-8300

OFFICES IN

WASHINGTON, D.C.
MARYLAND
VIRGINIA

VENABLE
ATTORNEYS AT LAW

Geoffrey M. Levitt
(202) 962-4923

September 2, 1998

Ms. Ann Hawthorne
Clinical Chemistry and Toxicology Branch
Division of Clinical Laboratory Devices
Office of Device Evaluation
Food and Drug Administration
Rockville, MD 20850

BY TELEFAX 301-594-5940

Re: RAM Scientific, Inc.

Dear Ms. Hawthorne:

I am writing on behalf of RAM Scientific, Inc., to confirm our recent conversations regarding clinical testing requirements to support RAM Scientific's forthcoming 510(k) for the blood collection products referred to in my letter to you of August 28, 1998. Specifically, it is RAM Scientific's understanding, based on our conversations, that the agency would like to see comparative tests run as follows:

(b)(4) Confidential and Proprietary Information - Testing

[redacted]

99

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-6414; Released by CDRH on 08-29-2016.

VENABLE
ATTORNEYS AT LAW



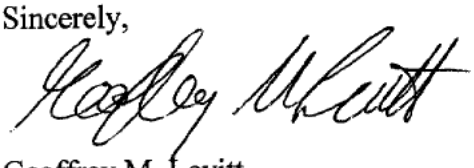
(b)(4) Confidential and Proprietary Information - Testing

[redacted]

Please let me know if you have any questions on the above.

RAM Scientific greatly appreciates your assistance on this matter.

Sincerely,



Geoffrey M. Levitt

cc: Dr. Alfred Montgomery
Ms. Monique Muri

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 160

Records processed under FOIA Request #2016-6414; Released by CDRH on 08-29-2016.

# STABILITY SUMMARY



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-6414; Released by CDRH on 08-29-2016.

(b)(4) Confidential and Proprietary Information - Testing

[redacted]



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

102

(b)(4) Confidential and Proprietary Information - Testing

(b)(4) Confidential and Proprietary Information - Testing

(b)(4) Confidential and Proprietary Information - Testing

(b)(4) Confidential and Proprietary Information - Testing

(b)(4) Confidential and Proprietary Information - Testing

(b)(4) Confidential and Proprietary Information - Testing

(b)(4) Confidential and Proprietary Information - Testing

Records processed under FOIA Request #2016-6414; Released by CDRH on 08-29-2016.

# PRODUCT LABELING



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-6414; Released by CDRH on 08-29-2016.

# PRODUCT LABELING

Copies of all applicable labels and labeling are attached. This includes:

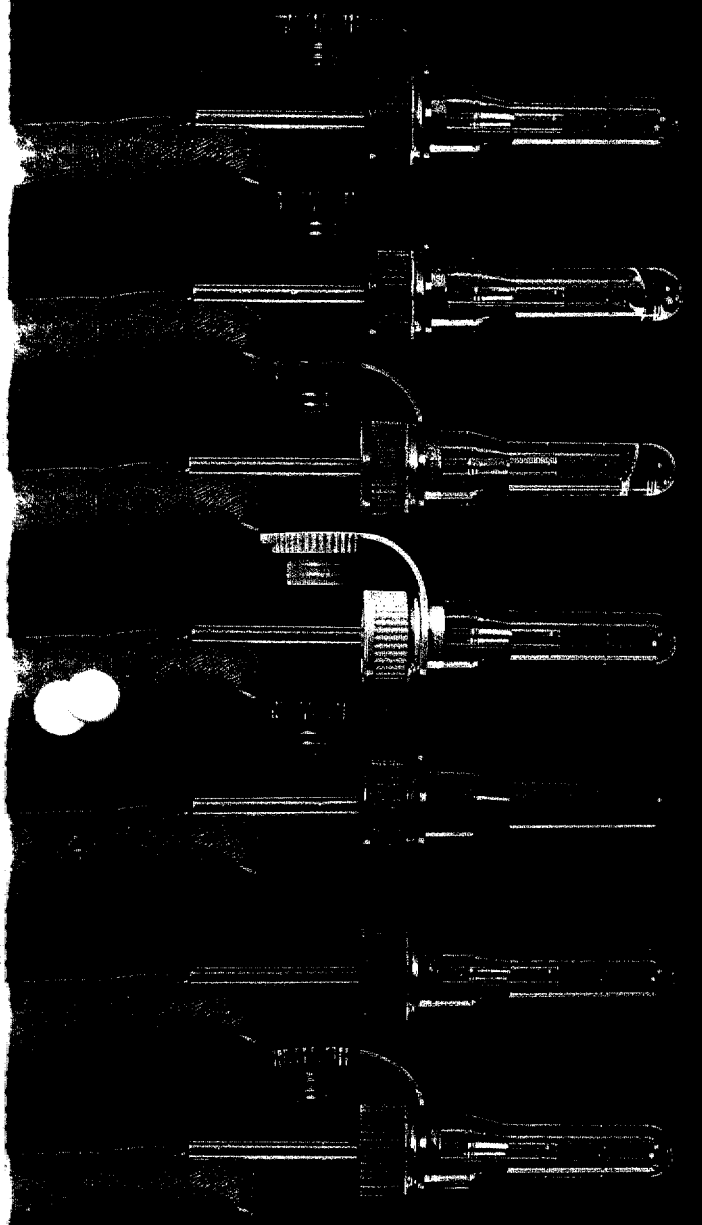
1. Promotional labeling
2. Product Labels
3. Instructions for Usage



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

# SAFE-T-FILL™

## FOR EASY, FAST, AND CLEAN BLOOD SAMPLE COLLECTION WITH CAPILLARY ACTION



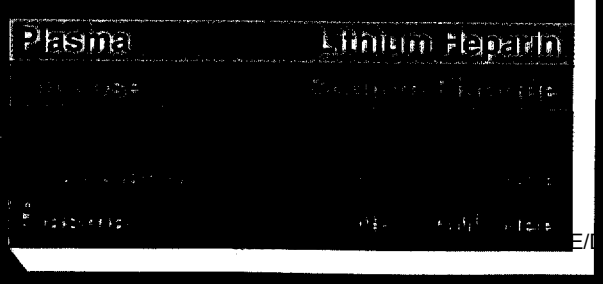
The SAFE-T-FILL Capillary Blood Collection System from RAM Scientific is completely preassembled and features 100% plastic construction for safer sample collection. The exclusive SAFE-T-FILL plastic capillary provides the ***capillary action*** of glass without the risks associated with the use of glass.

### SAFE-T-FILL Capillary Blood Collection System Offers the Following Advantages:

- No mess, easy-to-use, completely preassembled plastic components – ***no special training is required***
- Safer blood sample collection because blood flows directly to the bottom of the closed tube
- Anticoagulant coated capillary and tube to prevent clotting
- Tissue free samples because no "scooping" is needed
- Capillaries available in three sizes
- Increased patient comfort
- Compatibility with most microcentrifuges

SAFE-T-FILL also eliminates the possibility of cross-contaminated collection devices because it is a self-contained system.

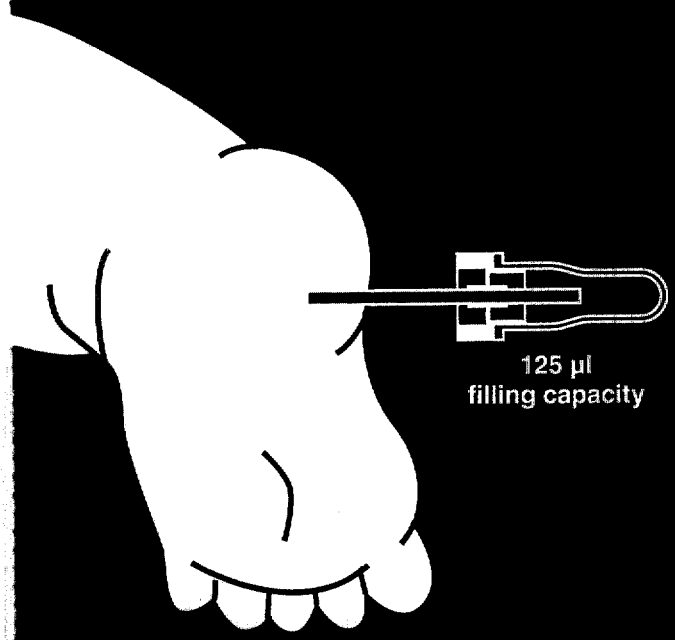
***A new 125 µl size SAFE-T-FILL for samples of 50 µl or less is now available.***



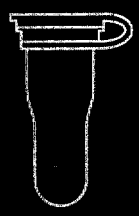

RAM SCIENTIFIC
P.O. BOX 586, NEEDHAM, MA 02194
1-800/535-6734 ■ FAX: 1-617/433-0767

E/I at CDRH-
VI-2

RAM SCIENTIFIC
P.O. BOX 586, NEEDHAM, MA 02194
1-800/535-6734 ■ FAX: 1-617/433-0767




Blood collection is complete when the capillary is filled end-to-end. If more blood is needed just keep it flowing continuously. To handle after blood collection, position tube vertically to allow blood to settle in base of microtube. Tap gently. Remove colored sleeve with capillary insert. Cap and mix thoroughly.




## SAFE-T-FILL™ Capillary Blood Collection System

| Stock No. | Description |
|---|---|
| 07 6011 | EDTA* Mini Capillary Collection 125 µl |
| 07 7052 | EDTA* Capillary Collection 150 µl |
| 07 7051 | EDTA* Capillary Collection 200 µl |
| 07 6041 | Serum Mini Capillary Collection 125 µl |
| 07 7150 | Serum Capillary Collection 200 µl |
| 07 6071 | Serum Gel Mini Capillary Collection 125 µl |
| 07 7122 | Serum Gel Capillary Collection 150 µl |
| 07 7120 | Serum Gel Capillary Collection 200 µl |
| 07 7450 | Serum Bili Capillary Collection 200 µl |
| 07 7423 | Serum Bili Gel Capillary Collection 150 µl |
| 07 7421 | Serum Bili Gel Capillary Collection 200 µl |
| 07 6101 | Lith Hep Mini Capillary Collection 125 µl |
| 07 7250 | Lith Hep Capillary Collection 200 µl |
| 07 6111 | Lith Hep Gel Mini Capillary Collection 125 µl |
| 07 7220 | Lith Hep Gel Capillary Collection 200 µl |
| 07 7340 | Na Fluoride Capillary Collection 200 µl |
| 07 7650 | $NH_4$ (AM) Hep Capillary Collection 200 µl |

*Liquid Dipotassium EDTA

## Unbreakable Plastic Hematocrit Capillaries

| Stock No. | Description |
|---|---|
| 06 0508 | Tubes, Plain 75 mm 0.5 ID |
| 06 0507 | Tubes, Heparinized 75 mm 0.5 ID |
| 06 0242 | Tubes, Heparinized 75 mm 1.1 ID |

Plastic blood gas capillaries and additional capillaries are also available. Please call for more information.

SAFE-T-FILL™ is a trademark of RAM SCIENTIFIC, INC.
© Copyright, RAM SCIENTIFIC, INC., 1994 Printed in USA

Records processed under FOIA Request #2016-6414; Released by CDRH on 08-29-2016.

#07 6041 SAFE-T-FILL®
MINI CAPILLARY BLOOD COLLECTION
PREPARED FOR SERUM

QUANTITY : 50
CAPACITY : 125 µl

LOT NO :
EXP DATE :

IMPORTED BY
RAM SCIENTIFIC INC
800-535-6734
MADE IN GERMANY BY
KABE LABORTECHNIK GMBH

#07 6041 SAFE-T-FILL®
MINI CAPILLARY BLOOD COLLECTION
PREPARED FOR SERUM

QUANTITY : 50
CAPACITY : 125 µl

LOT NO :
EXP DATE :

IMPORTED BY
RAM SCIENTIFIC INC
800-535-6734
MADE IN GERMANY BY
KABE LABORTECHNIK GMBH

114

Questions? Contact FDA/CDRH/OCE/DID at CDRH-EOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-6414; Released by CDRH on 08-29-2016.

#07 7150 SAFE-T-FILL®

CAPILLARY BLOOD COLLECTION

PREPARED FOR SERUM

QUANTITY : 50
CAPACITY : 200 µl

LOT NO :
EXP DATE :

IMPORTED BY
RAM SCIENTIFIC INC
800-535-6734

MADE IN GERMANY BY
KABE LABORTECHNIK GMBH

#07 7150 SAFE-T-FILL®

CAPILLARY BLOOD COLLECTION

PREPARED FOR SERUM

QUANTITY : 50
CAPACITY : 200 µl

LOT NO :
EXP DATE :

IMPORTED BY
RAM SCIENTIFIC INC
800-535-6734

MADE IN GERMANY BY
KABE LABORTECHNIK GMBH

115

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-6414; Released by CDRH on 08-29-2016.

#07 6071 SAFE-T-FILL®
MINI CAPILLARY BLOOD COLLECTION
PREPARED FOR SERUM WITH GEL

QUANTITY : 50
CAPACITY : 125 µl

LOT NO :
EXP DATE :

IMPORTED BY
RAM SCIENTIFIC INC
800-535-6734
MADE IN GERMANY BY
KABE LABORTECHNIK GMBH

#07 6071 SAFE-T-FILL®
MINI CAPILLARY BLOOD COLLECTION
PREPARED FOR SERUM WITH GEL

QUANTITY : 50
CAPACITY : 125 µl

LOT NO :
EXP DATE :

IMPORTED BY
RAM SCIENTIFIC INC
800-535-6734
MADE IN GERMANY BY
KABE LABORTECHNIK GMBH

116

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-6414; Released by CDRH on 08-29-2016.

#07 7122 SAFE-T-FILL®

CAPILLARY BLOOD COLLECTION

PREPARED FOR SERUM WITH GEL

QUANTITY : 50
CAPACITY : 150 µl

LOT NO :
EXP DATE :

IMPORTED BY
RAM SCIENTIFIC INC
800-535-6734

MADE IN GERMANY BY
KABE LABORTECHNIK GMBH

#07 7122 SAFE-T-FILL®

CAPILLARY BLOOD COLLECTION

PREPARED FOR SERUM WITH GEL

QUANTITY : 50
CAPACITY : 150 µl

LOT NO :
EXP DATE :

IMPORTED BY
RAM SCIENTIFIC INC
800-535-6734

MADE IN GERMANY BY
KABE LABORTECHNIK GMBH

117

Questions? Contact FDA/CDRH/OCE/DID at CDRH-EOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-6414; Released by CDRH on 08-29-2016.

#07 7120 SAFE-T-FILL®

CAPILLARY BLOOD COLLECTION

PREPARED FOR SERUM WITH GEL

QUANTITY : 50
CAPACITY : 200 µl

LOT NO :
EXP DATE :

IMPORTED BY
RAM SCIENTIFIC INC
800-535-6734

MADE IN GERMANY BY
KABE LABORTECHNIK GMBH

#07 7120 SAFE-T-FILL®

CAPILLARY BLOOD COLLECTION

PREPARED FOR SERUM WITH GEL

QUANTITY : 50
CAPACITY : 200 µl

LOT NO :
EXP DATE :

IMPORTED BY
RAM SCIENTIFIC INC
800-535-6734

MADE IN GERMANY BY
KABE LABORTECHNIK GMBH

118

Questions? Contact FDA/CDRH/OCE/DID at CDRH-EOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-6414; Released by CDRH on 08-29-2016.

#07 7450 SAFE-T-FILL®

CAPILLARY BLOOD COLLECTION

PREPARED FOR SERUM BILIRUBIN

QUANTITY : 50
CAPACITY : 200 µl

LOT NO :
EXP DATE :

IMPORTED BY
RAM SCIENTIFIC INC
800-535-6734

MADE IN GERMANY BY
KABE LABORTECHNIK GMBH

#07 7450 SAFE-T-FILL®

CAPILLARY BLOOD COLLECTION

PREPARED FOR SERUM BILIRUBIN

QUANTITY : 50
CAPACITY : 200 µl

LOT NO :
EXP DATE :

IMPORTED BY
RAM SCIENTIFIC INC
800-535-6734

MADE IN GERMANY BY
KABE LABORTECHNIK GMBH

119

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-6414; Released by CDRH on 08-29-2016.

#07 7423 SAFE-T-FILL®

CAPILLARY BLOOD COLLECTION

PREPARED FOR SERUM BILIRUBIN WITH GEL

QUANTITY : 50
CAPACITY : 150 µl

LOT NO :
EXP DATE :

IMPORTED BY
RAM SCIENTIFIC INC
800-535-6734

MADE IN GERMANY BY
KABE LABORTECHNIK GMBH

#07 7423 SAFE-T-FILL®

CAPILLARY BLOOD COLLECTION

PREPARED FOR SERUM BILIRUBIN WITH GEL

QUANTITY : 50
CAPACITY : 150 µl

LOT NO :
EXP DATE :

IMPORTED BY
RAM SCIENTIFIC INC
800-535-6734

MADE IN GERMANY BY
KABE LABORTECHNIK GMBH

120

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-6414; Released by CDRH on 08-29-2016.

#07 7421 SAFE-T-FILL®

CAPILLARY BLOOD COLLECTION

PREPARED FOR SERUM BILIRUBIN WITH GEL

QUANTITY : 50
CAPACITY : 200 µl

LOT NO :
EXP DATE :

IMPORTED BY
RAM SCIENTIFIC INC
800-535-6734

MADE IN GERMANY BY
KABE LABORTECHNIK GMBH

#07 7421 SAFE-T-FILL®

CAPILLARY BLOOD COLLECTION

PREPARED FOR SERUM BILIRUBIN WITH GEL

QUANTITY : 50
CAPACITY : 200 µl

LOT NO :
EXP DATE :

IMPORTED BY
RAM SCIENTIFIC INC
800-535-6734

MADE IN GERMANY BY
KABE LABORTECHNIK GMBH

121

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-6414; Released by CDRH on 08-29-2016.

#07 6101 SAFE-T-FILL®
MINI CAPILLARY BLOOD COLLECTION
PREPARED WITH LITHIUM HEPARIN

QUANTITY : 50
CAPACITY : 125 µl

LOT NO :
EXP DATE :

IMPORTED BY
RAM SCIENTIFIC INC
800-535-6734
MADE IN GERMANY BY
KABE LABORTECHNIK GMBH

#07 6101 SAFE-T-FILL®
MINI CAPILLARY BLOOD COLLECTION
PREPARED WITH LITHIUM HEPARIN

QUANTITY : 50
CAPACITY : 125 µl

LOT NO :
EXP DATE :

IMPORTED BY
RAM SCIENTIFIC INC
800-535-6734
MADE IN GERMANY BY
KABE LABORTECHNIK GMBH

122

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-6414; Released by CDRH on 08-29-2016.

#07 7250 SAFE-T-FILL ®

CAPILLARY BLOOD COLLECTION

PREPARED WITH LITHIUM HEPARIN

QUANTITY : 50
CAPACITY : 200 µl

LOT NO :
EXP DATE :

IMPORTED BY
RAM SCIENTIFIC INC
800-535-6734

MADE IN GERMANY BY
KABE LABORTECHNIK GMBH

#07 7250 SAFE-T-FILL ®

CAPILLARY BLOOD COLLECTION

PREPARED WITH LITHIUM HEPARIN

QUANTITY : 50
CAPACITY : 200 µl

LOT NO :
EXP DATE :

IMPORTED BY
RAM SCIENTIFIC INC
800-535-6734

MADE IN GERMANY BY
KABE LABORTECHNIK GMBH

123

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-6414; Released by CDRH on 08-29-2016.

#07 6111 SAFE-T-FILL®

MINI CAPILLARY BLOOD COLLECTION

PREPARED WITH LITHIUM HEPARIN AND GEL

QUANTITY : 50
CAPACITY : 125 µl

LOT NO :
EXP DATE :

IMPORTED BY
RAM SCIENTIFIC INC
800-535-6734

MADE IN GERMANY BY
KABE LABORTECHNIK GMBH

#07 6111 SAFE-T-FILL®

MINI CAPILLARY BLOOD COLLECTION

PREPARED WITH LITHIUM HEPARIN AND GEL

QUANTITY : 50
CAPACITY : 125 µl

LOT NO :
EXP DATE :

IMPORTED BY
RAM SCIENTIFIC INC
800-535-6734

MADE IN GERMANY BY
KABE LABORTECHNIK GMBH

D4

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-6414; Released by CDRH on 08-29-2016.

#07 7220 SAFE-T-FILL®
CAPILLARY BLOOD COLLECTION
PREPARED WITH LITHIUM HEPARIN AND GEL

QUANTITY : 50
CAPACITY : 200 µl

LOT NO :
EXP DATE :

IMPORTED BY
RAM SCIENTIFIC INC
800-535-6734
MADE IN GERMANY BY
KABE LABORTECHNIK GMBH

#07 7220 SAFE-T-FILL®
CAPILLARY BLOOD COLLECTION
PREPARED WITH LITHIUM HEPARIN AND GEL

QUANTITY : 50
CAPACITY : 200 µl

LOT NO :
EXP DATE :

IMPORTED BY
RAM SCIENTIFIC INC
800-535-6734
MADE IN GERMANY BY
KABE LABORTECHNIK GMBH

125

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-6414; Released by CDRH on 08-29-2016.

#07 7221 SAFE-T-FILL®
CAPILLARY BLOOD COLLECTION
PREPARED WITH LITHIUM HEPARIN AND GEL

QUANTITY : 50
CAPACITY : 300 µl

LOT NO :
EXP DATE :

IMPORTED BY
RAM SCIENTIFIC INC
800-535-6734
MADE IN GERMANY BY
KABE LABORTECHNIK GMBH

#07 7221 SAFE-T-FILL®
CAPILLARY BLOOD COLLECTION
PREPARED WITH LITHIUM HEPARIN AND GEL

QUANTITY : 50
CAPACITY : 300 µl

LOT NO :
EXP DATE :

IMPORTED BY
RAM SCIENTIFIC INC
800-535-6734
MADE IN GERMANY BY
KABE LABORTECHNIK GMBH

126

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-6414; Released by CDRH on 08-29-2016.

#07 7340 SAFE-T-FILL®
CAPILLARY BLOOD COLLECTION
PREPARED WITH SODIUM FLUORIDE

QUANTITY : 50
CAPACITY : 200 µl

LOT NO :
EXP DATE :

IMPORTED BY
RAM SCIENTIFIC INC
800-535-6734
MADE IN GERMANY BY
KABE LABORTECHNIK GMBH

#07 7340 SAFE-T-FILL®
CAPILLARY BLOOD COLLECTION
PREPARED WITH SODIUM FLUORIDE

QUANTITY : 50
CAPACITY : 200 µl

LOT NO :
EXP DATE :

IMPORTED BY
RAM SCIENTIFIC INC
800-535-6734
MADE IN GERMANY BY
KABE LABORTECHNIK GMBH

127

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-6414; Released by CDRH on 08-29-2016.

#07 7650 SAFE-T-FILL®
CAPILLARY BLOOD COLLECTION
PREPARED WITH AMMONIUM HEPARIN

QUANTITY : 50
CAPACITY : 200 µl

LOT NO :
EXP DATE :

IMPORTED BY
RAM SCIENTIFIC INC
800-535-6734
MADE IN GERMANY BY
KABE LABORTECHNIK GMBH

#07 7650 SAFE-T-FILL®
CAPILLARY BLOOD COLLECTION
PREPARED WITH AMMONIUM HEPARIN

QUANTITY : 50
CAPACITY : 200 µl

LOT NO :
EXP DATE :

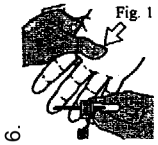
IMPORTED BY
RAM SCIENTIFIC INC
800-535-6734
MADE IN GERMANY BY
KABE LABORTECHNIK GMBH

128

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

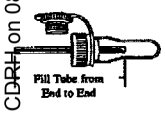
## INSTRUCTIONS FOR USE:

Fig. 1



1. Hold SAFE-T-FILL in a horizontal position.

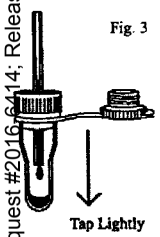
Fig. 2




2. Fill capillary tube "end to end". Do not

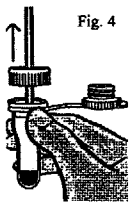
(Available in volumes of 125,150, and 200µl)

Fig. 3




3. Hold tube vertically to allow blood to flow to the bottom of the microtube.

Fig. 4



4. Remove capillary together with colored

Fig. 5

5. Close tube with attached cap and mix as required.

## References:

1. Procedures for the Collections of Diagnostic Blood Specimens by Skin Puncture-Second Edition; Approved Standard. NCCLS publication H4-A3. Villanova, PA: July 1986

**RAM Scientific, Inc**

P.O. Box 586
Needham, MA 02494-0004
Phone (781) 433-0766
Fax (781) 433-0767
www.ramsci.com

SAFE-T-FILL®

©1998 SAFE-T-FILL® is a Registered Trademark of RAM Scientific, Inc.

# SAFE-T-FILL®

## CAPILLARY BLOOD COLLECTION SYSTEMS

PRODUCT INFORMATION

Records processed under FOIA Request #2016-6414; Released by CDRH on 08-29-2016.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

## INTENDED USE:

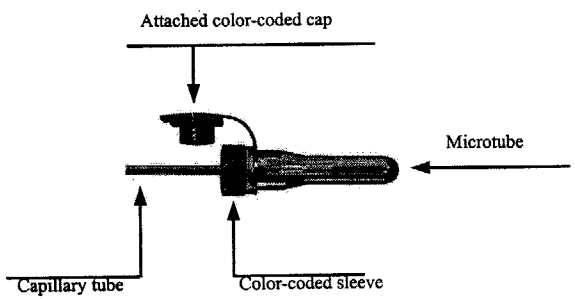
The SAFE-T-FILL Capillary Blood Collections System is used to collect blood samples from skin puncture for laboratory analysis.

## DESCRIPTION:

The plastic SAFE-T-FILL Capillary Blood Collection System is completely preassembled and ready for use. It is composed of a capillary tube that is inserted into a color-coded sleeve defining the type of additive or anticoagulant (if any) that is contained within the system. Both capillary tube and sleeve are attached to a microtube with a color-coded plastic cap. SAFE-T-FILL is a non-sterile, single-use, disposable system. It is available with the following additives, with or without gel*:

| | | |
|---|---|---|
| Hematology | Liquid EDTA ($K_2$) | non-gel |
| Serum | Clotting activator | non-gel/gel |
| Plasma | Lithium heparin | non-gel/gel |
| Glucose | Sodium fluoride | non-gel |
| Serum Bilirubin | Clotting activator | non-gel/gel |

* The gel barrier contains inert material with a specific gravity between that of serum and blood cells. Centrifuge the SAFE-T-FILL at 4000 g† for 5 minutes to allow the inert material to rise and separate the serum/plasma from the cell clot.




## PREPARATION:

The SAFE-T-FILL Capillary Blood Collection Systems do not require preassembly. Prior to collecting the patient sample, gather the following materials:

1. Marking pen/labels
2. Disposable gloves
3. Alcohol wipe or swab (70% aqueous solution isopropanol)
4. Lancing device
5. SAFE-T-FILL Systems
6. Puncture-resistant bio-hazard container
7. Dry cotton or gauze
8. Adhesive bandage.

## PROCEDURE:

1. Identify the patient.

2. Perform a skin puncture as outlined in the NCCLS publication: Procedures for the collection of Diagnostic Blood Specimens by Skin Puncture Second Edition; Approved Standard. NCCLS publication H4-A2. Villanova, PA: July 1986.

3. Blood tests ordered requiring different tubes must be collected in the following order:

   a. EDTA (purple)

   b. Lithium heparin (green)

   c. Serum (red).

4. After wiping away the first drop of blood, draw sample into the capillary tube as it appears at the puncture site. Hold the SAFE-T-FILL horizontally to avoid the introduction of air bubbles into the capillary tube.

5. Fill the capillary tube "end to end". Do not milk, scoop, or overfill the capillary tube.

6. Turn the SAFE-T-FILL to a vertical position to allow the sample to flow into the microtube. Gently tap the bottom of the microtube on a hard surface to deliver the last drop of sample into the microtube.

7. Remove the capillary tube via the color-coded sleeve and discard the capillary tube and sleeve into a biohazard container.

8. Close the microtube with the attached color-coded cap and invert eight-ten times. Process sample according to your organization's guidelines.

## PROCEDURE (cont.):

### Procedure for Serum Separation:

1. Allow blood to clot for a minimum of 20 minutes.

2. Centrifuge for a minimum of 90 seconds at 4000 g†

   (Centrifuge serum gel tubes for 5 minutes at 4000 g).†

3. Remove tube from centrifuge and process sample according to your organization's guidelines.

† Speed in revolutions per minute (rpm) may be related to relative centrifugal force (g) by the following formula:

$$g = 1.12 \times 10^5 \times r \times (rpm)^2$$

Where "r", expressed in cm, is the radial distance from the center of the centrifuge head to the bottom of the tube.

## PRODUCT USES:

Clinical tests have shown suitability of RAM Scientific's SAFE-T-FILL Capillary Blood Collection System for the following determinations:

| | |
|---|---|
| **WBC** | **Glucose** |
| **RBC** | **BUN** |
| **HGB** | **NA+** |
| **MCH** | **K+** |
| **MCV** | **CL-** |
| **MCHC** | **Alkaline Phosphatase** |
| **HCT** | **Total Protein** |
| **Platelets** | **Calcium** |

## LIMITATIONS:

SAFE-T-FILL has been designed for capillary blood collection. Milking the skin may cause hemolysis and thus affect the accuracy of some determinations.[1]

## Caution:

Handle all biological samples and blood collection products in accordance with your organization's policies and procedures.

Records processed under FOIA Request #2016-6414 Released by CDRH on 08-29-2016
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-6118.

Records processed under FOIA Request #2016-6414; Released by CDRH on 08-29-2016.

# STATEMENT OF INDICATIONS FOR USAGE

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-6414; Released by CDRH on 08-29-2016.



**510(k) Number (if known):** K983517

**Device Name:** _____

# Indications For Use:

## STATEMENT OF INDICATIONS FOR USAGE

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 testing.

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

**Concurrence of CDRH, Office of Device Evaluation (ODE)**

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K983517

**Prescription Use** ✓
(Per 21 CFR 801.109)

OR

**Over-The-Counter Use** ____

(Optional Format 1-2-96)

B2

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-6414; Released by CDRH on 08-29-2016.

# STATEMENT OF SUBSTANTIAL EQUIVALENCE



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-6414; Released by CDRH on 08-29-2016.

# SUBSTANTIAL EQUIVALENCE

Attached are competitive labels, labeling and promotional materials as available to RAM Scientific, Inc.

A comparison of RAM Scientific and competitor labels, labeling and packaging clearly demonstrates that the RAM Scientific SAFE-T-FILL® Capillary Blood Collection System is substantially equivalent to the products presently on the market. Below is a simple chart outlining the similarities and differences.

| 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 |



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-6414; Released by CDRH on 08-29-2016.

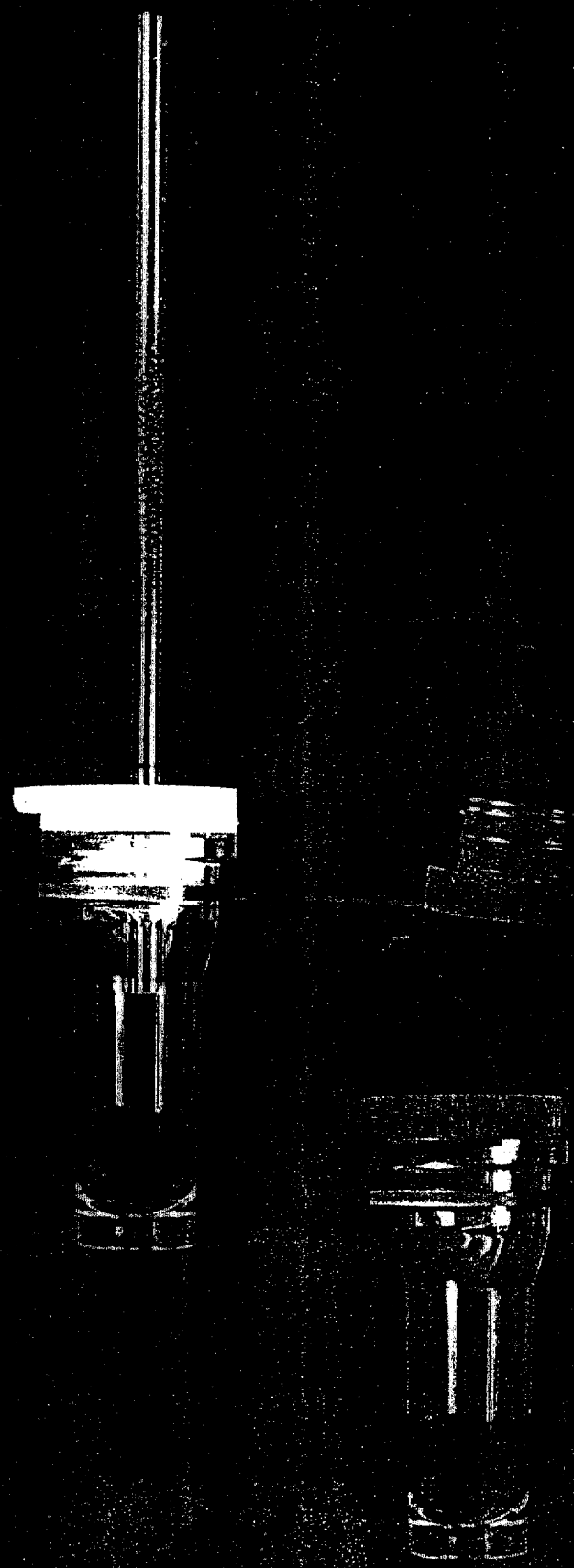
# STATSAMPLER® LABELING





Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

# StatSampler®



PRODUCTIVITY TOOLS FOR DIAGNOSTICS

VIII-3
DRH-0137

136

Records processed under FOIA Request #2016-6414; Released by CDRH on 08-29-2016.

# StatSampler®

## For "finger-stick" collection

## StatSampler Collection Tubes

### ■ Immediate anticoagulation with capillary tube

StatSpin's "finger-stick" collection tube provides immediate and thorough mixing of blood with anticoagulant. Microclots are eliminated, making it ideal for hematology. Small sample size – the 100µL StatSampler with EDTA is perfect for hematology instruments requiring small volumes. Small samples mean minimum trauma finger-stick.

### ■ Easy sample collection

The unique combination of a capillary tube with a microtube permits rapid, easy collection and processing of blood. Collection is by capillary action and not by gravity.

### ■ Rapid separation of plasma

Samples for chemistry testing are collected into either untreated or heparinized capillary tubes. Microtubes can be spun at high speed. Plasma/serum is ready in seconds. Barrier gel isolates cells and maximizes plasma/serum yield. Accidental remixing of cells and plasma/serum is eliminated.

### ■ Product Number

| Sample Size | Anticoagulant | Separator Gel | Product Number 50 / pack | 300 / case |
|---|---|---|---|---|
| 100 µL | EDTA | None | SS1E | SS1E-06 |
| 200 µL | EDTA | None | SS2E | SS2E-06 |
| 200 µL | Heparin | Yes | SS2H | SS2H-06 |
| 200 µL | None | Yes | SS2U | SS2U-06 |
| 200 µL | EDTA | Yes | SS2X | SS2X-06 |

## StatSpin Centrifuge

### ■ Separates blood sample in 30 seconds

After collection into StatSampler, blood can be separated for chemistry testing in 30 seconds in a StatSpin centrifuge. The StatSpin rotates at 16,000 rpm (12,600 x g). Other centrifuges can require over 10 minutes.

### ■ Easy to load

Rotor attaches with simple push-on / pull-off action. No tools required.

### ■ Whisper quiet.

Barely audible at 55dB.

### ■ Small and lightweight

Portable, minimal bench space required.

| | | |
|---|---|---|
| Diameter | 6-5/8" | 16.25 cm |
| Height | 5-1/4" | 13.12 cm |
| Weight | 5.5 lbs | 2.5 kg |

### ■ Product Number

**StatSpin MP Centrifuge**

| | |
|---|---|
| SSMP | 120 volt |
| SSMP-10 | 100 volt |
| SSMP-22 | 220 volt |

**StatSpin RP Centrifuge**

| | |
|---|---|
| SSRP | 120 volt |
| SSRP-10 | 100 volt |
| SSRP-22 | 220 volt |

137

**StatSpin®**

PRODUCTIVITY TOOLS FOR DIAGNOSTICS

85 Morse Street
Norwood, Massachusetts
02062 USA

Telephone 617.551.0100
Toll Free 800.782.8774
Telefax 617.551.0036

Questions? Contact FDA/CDRH/OCBQ/DMD at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118



6 SM

Records processed under FOIA Request #2016-6414; Released by CDRH on 08-29-2016.

# CAPIJECT® CAPILLARY BLOOD COLLECTION SYSTEM LABELING



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-6414; Released by CDRH on 08-29-2016

# Because Every Drop Counts

Capillary Blood Collection System

CAPIJECT®

*Capillary Blood Collection Tubes*

139

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118

Records processed under FOIA Request #2016-6414; Released by CDRH on 08-29-2016.

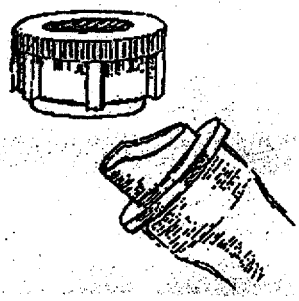
# Getting a Better Grip on Blood Collection

## *Every Drop is Precious*

CapiJect®, the first one-piece collection tube, allows you to work quickly and efficiently. Consider the advantages:

- A wide, built-in collection lip that allows blood to flow more easily into the tube.
- Silicone coating which helps reduce red blood cell hang up and facilitate blood flow to the bottom of the tube.
- A superior olefin-based gel that provides cleaner separations and allows for a wider range of clinical testing.
- A cap with added ridges that provide a more secure grip, making it easier to remove.

## *The Most Gentle Collection System*



***Extra wide lip improves specimen flow and reduces risk of contamination***

Unlike competitive systems that may have a separate collection lip, CapiJect is a one-piece system. Since the lip doesn't have to be removed, there is less chance of a spill or contamination. The extra width of the lip also reduces the risk of contamination. When biohazard risks are mini-

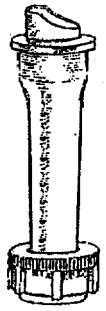
140

Records processed under FOIA Request #2016-6414; Released by CDRH on 08-29-2016.

mized, you can concentrate more fully on the comfort and care of your patients.

The unique CapiJect® cap can also be nested on the bottom of the collection tube so that the tube stands on its own.

*Nesting the cap at the bottom frees both hands*



## *Redesigned for Even Greater Safety*

CapiJect makes blood collection easier for you and for your patients. Consider the benefits:

- With a convenient integral design, the CapiJect tube will allow for a simple and efficient way of collecting capillary samples.
- The wide choice of additives provides you with a full line of capillary blood collection tubes *including potassium oxalate/sodium fluoride.* Also, Terumo is the only manufacturer to offer both $NA_2$ and $K_2$ EDTA tubes.
- When you can assure consistent draws and less clotting, you minimize the need for repeat draws.

Terumo Medical Corporation is committed to taking healthcare to a higher level of excellence. Which is why,

**Quality is in Our Blood.**

Records processed under FOIA Request #2016-6414; Released by CDRH on 08-29-2016.

Capillary Blood Collection System

# CAPIJECT

| Catalog Number | Color Code | Description | Packaging |
|---|---|---|---|
| **T-MG** | **Cherry Red** | | |
| **Each tube contains silica particles to accelerate clotting and an inert gel.** | | Gel Barrier Capillary Blood Collection Tube: Which forms a barrier between serum and cells when the tube is centrifuged. Tube is used for many laboratory procedures requiring serum. Tube is ready for centrifugation within 20 minutes after collection. | 250 Tubes Per Box (5 Bags x 50 Tubes) 1,000 Tubes Per Case (4 Boxes x 250 Tubes) |
| **T-MQ** | **Lavender** | | |
| **Each tube contains 0.78 mg of disodium EDTA.** | | Disodium EDTA Capillary Blood Collection Tube: The addition of 500 µL of blood provides a ratio of anticoagulant to blood that is optimal for most hematology procedures and tests requiring whole blood or plasma. | 250 Tubes Per Box (5 Bags x 50 Tubes) 1,000 Tubes Per Case (4 Boxes x 250 Tubes) |
| **T-MQK** | **Lavender** | | |
| **Each tube contains 0.78 mg of dipotassium EDTA.** | | Potassium EDTA Capillary Blood Collection Tube: The addition of 500 µL of blood provides a ratio of anticoagulant to blood that is optimal for most hematology procedures and tests requiring whole blood or plasma. | 250 Tubes Per Box (5 Bags x 50 Tubes) 1,000 Tubes Per Case (4 Boxes x 250 Tubes) |
| **T-M** | **Brick Red** | | |
| **Tube contains no active additives.** | | Plain Capillary Blood Collection Tube: Used when a clotted sample is required. It is especially useful for blood banking procedures or other laboratory procedures requiring serum. Tube is ready for centrifugation within 30 minutes after collection. | 250 Tubes Per Box (5 Bags x 50 Tubes) 1,000 Tubes Per Case (4 Boxes x 250 Tubes) |
| **T-MLH** | **Green** | | |
| **Each tube contains 12.5 IU of lithium heparin.** | | Lithium Heparin Capillary Blood Collection Tube: The addition of 500 µL of blood provides a 25 IU/mL ratio of anticoagulant to blood. Tube is used for many chemistry procedures that require heparinized whole blood or plasma. | 250 Tubes Per Box (5 Bags x 50 Tubes) 1,000 Tubes Per Case (4 Boxes x 250 Tubes) |
| **TMLHG** | **Green** | | |
| **Each tube contains 12.5 IU of lithium heparin and an inert gel.** | | Lithium Heparin Gel Barrier Capillary Blood Collection Tube: Which forms a barrier between plasma and cells. The addition of 500 µL of blood provides a 25 IU/mL ratio of anticoagulant to blood. Tube is used for many chemistry procedures that require heparinized whole blood or plasma. | 250 Tubes Per Box (5 Bags x 50 Tubes) 1,000 Tubes Per Case (4 Boxes x 250 Tubes) |
| **T-MPS** | **Gray** | | |
| **Each tube contains 0.72 mg of sodium fluoride and 0.58 mg of potassium oxalate.** | | Sodium Fluoride/Potassium Oxalate Capillary Blood Collection Tube: The addition of 250 µL of whole blood provides a concentration of sodium fluoride that is optimal for procedures where inhibition of glycolysis is important (e.g. blood glucose determinations). | 250 Tubes Per Box (5 Bags x 50 Tubes) 1,000 Tubes Per Case (4 Boxes x 250 Tubes) |
| **Each tube contains silica particles to accelerate clotting and an inert gel.** | | Amber-Colored Gel Barrier Capillary Blood Collection Tube: The amber color is especially useful for preserving the integrity of serum for bilirubin testing. Tube may also be used for the many laboratory procedures requiring serum. Tube is ready for centrifugation within 20 minutes after collection. | 250 Tubes Per Box (5 Bags x 50 Tubes) 1,000 Tubes Per Case (4 Boxes x 250 Tubes) |

TERUMO

*Terumo Medical Corporation*
*2100 Cottontail Lane*
*Somerset, NJ 08873*
*Phone: 1-800-2 TERUMO*
*908-230-2900*
*Fax: 908-230-2383*

142



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

2/96 ®,TERUMO and CAPIJECT are registered in the U.S. Patent and Trademark Office by TERUMO CORPORATION.

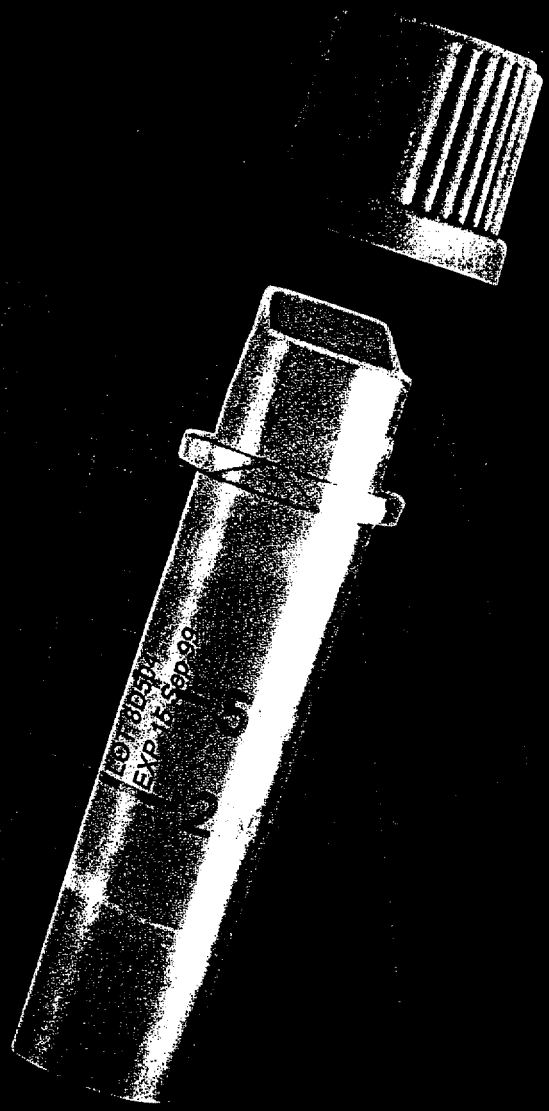
Records processed under FOIA Request #2016-6414; Released by CDRH on 08-29-2016.

# MICROTAINER® TUBE WITH EDTA AND MICROGARD™ CLOSURE LABELING



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118

# The next generation in microcollection

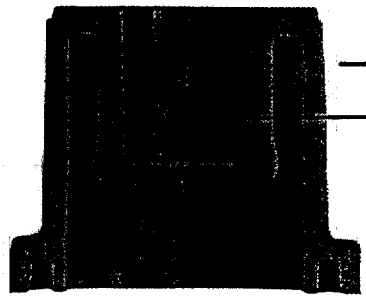


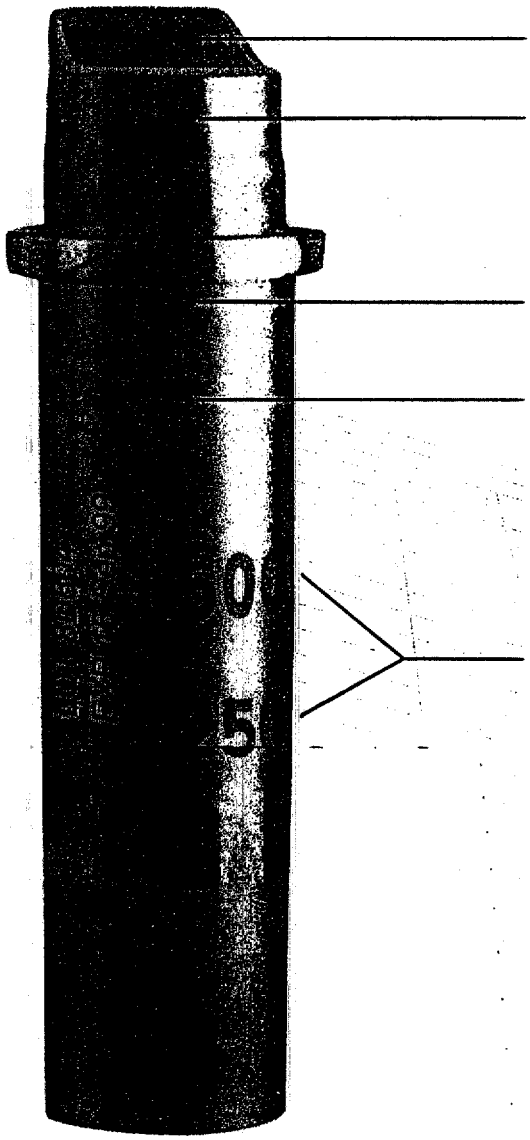

DESIGN • USE • DISPOSAL
FOCUS ON SAFETY

BECTON DICKINSON

Records processed under FOIA Request #2016-6414; Released by CDRH on 08-29-2016.

# MICROTAINER® TUBE with EDTA and MICROGARD™ CLOSURE





## A generation ahead in safety, handling and performance

## Engineered for safety: Exclusive MICROGARD Closure

- *"Twist-assist"—an engineering-control design—significantly reduces blood splatter upon removal, compared with other products*[1]
- *Recessed sealing plug helps prevent contamination of gloves and surrounding surfaces*[1]

*Snap-lock mechanism audibly assures tube is completely sealed*

- *Closure design reduces rolling on flat surfaces*

145
~~144~~

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-6414; Released by CDRH on 08-29-2016.

**MICROGARD™ Closure**

**R**
**:ealing plug**

**ntegral collector**

**Vider tube**
**iameter**

**'extured**
**nner surface**

**'recisely measured**
**DTA ($K_2$)**

**'rinted lot #, fill lines**
**nd expiration date**

*he MICROGARD Closure has*
*een cut away to demonstrate*
*s unique features.*

## *Designed for convenience...*

- *Integral collector eliminates the need for assembly*
- *MICROGARD Closure nests securely on bottom of tube or extender*
- *8-mm inner tube diameter allows for easy probe access*
- *Printed fill lines avoid overfills*
- *Lot number and expiration dates printed, for increased quality control*

## *...and performance*

- *Wider tube reservoir with exclusive textured inner surface improves flow and mixability without compromising 4-hour platelet stability[1]*
- *Precisely measured and dispensed EDTA ($K_2$) helps ensure fast anticoagulant action and accurate results[1]*

**Reference:**
*1. Data on file. Becton Dickinson VACUTAINER Systems, Franklin Lakes, New Jersey.*

# *Supersedes ordinary microcollection devices*

146

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-6414; Released by CDRH on 08-29-2016.

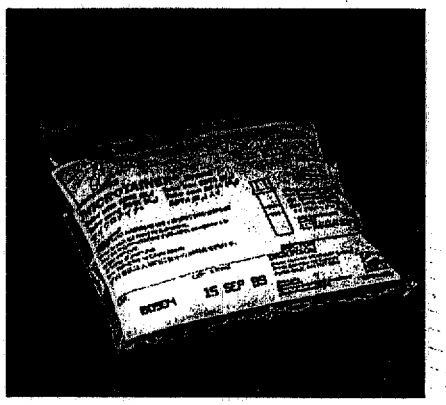
# The next generation in microcollection...

# MICROTAINER® TUBE with EDTA and MICROGARD™ CLOSURE

## Supersedes ordinary microcollection devices

### New, space-saving packaging

*Redesigned to store more tubes in less space*



### Ordering information

| | Reorder number | Quantity per case |
|---|---|---|
| **MICROTAINER® Tube with EDTA and MICROGARD™ Closure** | 365974 | 200 |
| **MICROTAINER® Tube Extender** | 365976 | 200 |

*For more information, please call* ***1-800-631-0174***

**Caution:**

*Handle all biologic samples and blood collection products in accordance with the policies and procedures of your facility.*

*Obtain appropriate medical attention in the event of any exposure to biologic samples (for example, through a puncture injury) since the samples may transmit HBV (HEPATITIS), HIV (AIDS), or other infectious diseases.*

*Discard all products contaminated with blood in biohazard containers approved for their disposal.*

**BECTON DICKINSON**

Becton Dickinson VACUTAINER Systems, Franklin Lakes, New Jersey 07417-1885
MICROTAINER, MICROGARD and VACUTAINER are trademarks of Becton Dickinson and Company.
U.S. Patent Nos: 5,268,466; 357,985; 356,453; 5,458,854; 5,384,096; 5,458,113
©1996
Printed in USA 9/96 VS5137-1

147

Questions? Contact FDA/CDRH/OCE/DID at CDRHFOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2016-6414; Released by CDRH on 08-29-2016.

# 510(k) SUMMARY



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.