Records processed under FOIA Request 2013-6158; Released 10/14/14

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 12 2003

Mr. Peter Rumswinkel
VP/General Manager
Sarstedt, Inc.
P.O. Box 468
Newton, NC 28658-0468

Re: k031359
Trade/Device Name: S-Monovette® EDTA K_2-Gel
Regulation Number: 21 CFR 862.1675
Regulation Name: Blood specimen collection device
Regulatory Class: Class II
Product Code: JKA
Dated: August 12, 2003
Received: August 13, 2003

Dear Mr. Rumswinkel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

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

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

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

Enclosure

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

Records processed under FOIA Request 2013-6158; Released 10/14/14

SARSTEDT

Sarstedt, Inc. • P.O. Box 468 • Newton, NC 28658-0468

Instruments and Disposables for Medicine and Science

Indications for Use Statement

510(k) Number: K031359

Device Name: S-Monovette® EDTA K_2-Gel

Indications For Use:

The S-Monovette® EDTA K_2-Gel provides a means for collection, processing and transportation of a plasma specimen in a closed system. Following collection of the blood, the S-Monovette® EDTA K_2-Gel is to be centrifuged such that the gel creates a barrier between the plasma and cellular components. The plasma specimen can then be removed for testing or the specimen can be transported for testing at another location without the plasma mixing with the cellular components.

The plasma specimen produced by the S-Monovette® EDTA K_2-Gel can be used for Nucleic Acid Testing (NAT) by methods such as PCR – Polymerase Chain Reaction or for other procedures where the laboratory has determined that a plasma specimen is appropriate.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

Division Sign-Off for Jean Cooper

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K031359

Sarstedt, Inc.
P.O. Box 468
Newton, NC 28658-0468

Phone (828) 465-4000 Corporate
Telefax (828) 465-0718 Corporate
Phone (800) 257-5101 Sales
Telefax (828) 465-4003 Sales

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

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 12 2003

Mr. Peter Rumswinkel
VP/General Manager
Sarstedt, Inc.
P.O. Box 468
Newton, NC 28658-0468

Re: k031359
Trade/Device Name: S-Monovette® EDTA K_2-Gel
Regulation Number: 21 CFR 862.1675
Regulation Name: Blood specimen collection device
Regulatory Class: Class II
Product Code: JKA
Dated: August 12, 2003
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Dear Mr. Rumswinkel:

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If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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

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Sincerely yours,

Steven Gutman

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

Enclosure

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

Records processed under FOIA Request 2013-6158; Released 10/14/14

SARSTEDT

Sarstedt, Inc. • P.O. Box 468 • Newton, NC 28658-0468

Instruments and Disposables for Medicine and Science

Indications for Use Statement

510(k) Number: K031359

Device Name: S-Monovette® EDTA K_2-Gel

Indications For Use:

The S-Monovette® EDTA K_2-Gel provides a means for collection, processing and transportation of a plasma specimen in a closed system. Following collection of the blood, the S-Monovette® EDTA K_2-Gel is to be centrifuged such that the gel creates a barrier between the plasma and cellular components. The plasma specimen can then be removed for testing or the specimen can be transported for testing at another location without the plasma mixing with the cellular components.

The plasma specimen produced by the S-Monovette® EDTA K_2-Gel can be used for Nucleic Acid Testing (NAT) by methods such as PCR – Polymerase Chain Reaction or for other procedures where the laboratory has determined that a plasma specimen is appropriate.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

Albert Gutierrez
Division Sign-Off for Jean Cooper

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K031359

Sarstedt, Inc.
P.O. Box 468
Newton, NC 28658-0468

Phone (828) 465-4000 Corporate
Telefax (828) 465-0718 Corporate
Phone (800) 257-5101 Sales
Telefax (828) 465-4003 Sales

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

Records processed under FOIA Request 2013-6158; Released 10/14/14

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

July 15, 2003

SARSTEDT, INC.
1025 ST. JAMES CHURCH RD.
NEWTON, NC 28658
ATTN: PETER RUMSWINKEL

510(k) Number: K031359
Product: S-MONOVETTE EDTA K2-GEL

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

The deficiencies identified represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/cdrh/modact/leastburdensome.html

If after 30 days the requested information, or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

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

Records processed under FOIA Request 2013-6158; Released 10/14/14

If you have procedural or policy questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Supervisor Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

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

Records processed under FOIA Request 2013-6158; Released 10/14/14

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

May 02, 2003

SARSTEDT, INC.
1025 ST. JAMES CHURCH RD.
NEWTON, NC 28658
ATTN: PETER RUMSWINKEL

510(k) Number: K031359
Received: 01-MAY-2003
Product: S-MONOVETTE EDTA K2-GEL

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), 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.

The Act, as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA)(Public Law 107-250), authorizes FDA to collect user fees for premarket notification submissions. (For more information on MDUFMA, you may refer to our website at http://www.fda.gov/oc/mdufma).

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC)(HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review". Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

You should be familiar with the manual entitled, "Premarket Notification 510(k) Regulatory Requirements for Medical Devices" available from DSMICA. If you have other procedural or policy questions, or want information on how to check on the status of your submission, please contact DSMICA 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
Supervisory Consumer Safety Officer
Office of Device Evaluation
Center for Devices and Radiological Health

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

Records processed under FOIA Request 2013-6158; Released 10/14/14

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

April 30, 2003

SARSTEDT, INC.
1025 ST. JAMES CHURCH RD.
NEWTON, NC 28658
ATTN: PETER RUMSWINKEL

510(k) Number: K031359
Received: 30-APR-2003
Product: S-MONOVETTE EDTA K2-GEL

The Food and Drug Administration (FDA) Center for Devices and Radiological Heath (CDRH), Office of In Vitro Diagnostic Device Evaluation and Safety, 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. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

The Act, as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Public Law 107-250), specifies that a submission shall be considered incomplete and shall not be accepted for filing until fees have been paid (Section 738(f)). Our records indicate that you have not submitted the user fee payment and therefore your 510(k) cannot be filed and has been placed on hold. The payment information we need in order to begin the review of your 510(k) includes, the user fees cover sheet with the payment ID faxed to the Office of Financial Management at (301) 827-9213, a check mailed to US Bank with the payment ID number marked on it, and a copy of the user fee cover sheet faxed to CDRH at (301) 594-2977 referencing the 510(k) number. After the FDA has been notified of the receipt of your user fee payment, your 510(k) will be filed and the review will begin. If payment has not been received within 30 days, your 510k will be deleted from the system. Additional information on user fees and how to submit your user fee payment may be found at http://www.fda.gov/oc/mdufma.

Please note that since your 510(k) has not been reviewed, additional information may be required during the review process and the file may be placed on hold once again. If you are unsure as to whether or not you need to file an application with FDA or what type of application to file, you should first telephone the Division of Small Manufacturers, International and Consumer Assistance (DSMICA), for guidance at (301)443-6597 or its toll-fee number (800)638-2041, or contact them at their Internet address http://www.fda.gov/cdrh/dsmamain.html, or you may submit a 513(g) request to the Document Mail Center at the address above. If you have any questions concerning the contents of this letter, you may contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Office of Device Evaluation
Center for Devices and
Radiological Health

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

Records processed under FOIA Request 2013-6158; Released 10/14/14

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

MEDICAL DEVICE USER FEE COVER SHEET

PAYMENT IDENTIFICATION NUMBER: (b)(4)

Write the Payment Identification Number on your check.

See Instructions Before Completing This Cover Sheet

A completed cover sheet must accompany each original premarket application or supplement listed in Box 3 of this cover sheet. Other premarket application types do not require the use of this cover sheet; see list in the instructions. Payment instructions and fee rates can be found at the following website: http://www.fda.gov/oc/mdufma.The following three actions must be taken to properly submit your premarket application and fee payment:

1. FAX a copy of this completed cover sheet to the Food and Drug Administration at (301) 827-9213 before payment is sent.
2. Include a copy of this completed cover sheet with the check made payable to the Food and Drug Administration and mail them to the Food and Drug Administration, P.O. Box 956733, St. Louis, MO 63195-6733. *(Note: In no case should payment be submitted with the premarket application.)* Also remember that the Payment Identification Number must be written on the check.
   If you prefer to send a check by a courier, the courier may deliver the check and cover sheet to: US Bank, Attn: Government Lockbox, SL-MOC1GL, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. Contact the US Bank at 314-418-4821 if you have any questions concerning courier delivery.)
3. Include a copy of this completed cover sheet in volume one of the premarket application when submitting to the Food and Drug Administration at either the CBER or CDRH Document Mail Center.

1. COMPANY NAME AND ADDRESS (Include name, street address, city, state, country, and post office code)

SARSTEDT, INC.
1025 SAINT JAMES CHURCH ROAD
NEWTON, NC 28658
US

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
222004363

2. CONTACT NAME
PETER RUMSWINKEL

2.1 E-MAIL ADDRESS
sarstedt@bellsouth.net

2.2 TELEPHONE NUMBER (Include area code)
828-465-4000

2.3 FACSIMILE (FAX) NUMBER (Include area code)
828-464-3999

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/oc/mdufma)

Select an application type:

- [x] Premarket notification (510(k)); except for third party reviews
- [ ] Biologic License Application (BLA)
- [ ] Premarket Approval Application (PMA)
- [ ] Modular PMA
- [ ] Product Development Protocol (PDP)
- [ ] Premarket Report (PMR)

3.1 Select one of the types below:

- [x] Original Application

Supplement Types:

- [ ] Efficacy (BLA, PMR)
- [ ] Panel Track (PMA, PMR, PDP)
- [ ] Real-Time (PMA, PMR, PDP)
- [ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status.)

- [ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
- [x] NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number:

5. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE **EXCEPTIONS**? IF SO, CHECK THE APPLICABLE EXCEPTION.

- [ ] This application is the first PMA submitted by a qualified small business, including any affiliates, parents, and partner firms
- [ ] The sole purpose of the application is to support conditions of use for a pediatric population
- [ ] This biologic application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only
- [ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

6. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).)

- [ ] YES
- [x] NO

7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

(b)(4)

45

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

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SARSTEDT

K031359

Sarstedt, Inc. • P.O. Box 468 • Newton, NC 28658-0468

Instruments
and Disposables
for Medicine
and Science

April 29, 2003

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

2003 APR 30 A 9:27

510(k) Notification, S-Monovette® EDTA K_2-Gel

Att. Document Mail Clerk

This is to notify you of the intention by Sarstedt AG & Co. to introduce into interstate commerce a blood collection tube that results in a plasma specimen for Nucleic Acid Testing (NAT): S-Monovette® EDTA K_2-Gel.

According to FDA Publication „Classification Names for Medical Devices and In Vitro Diagnostics Devices", the FDA Clinical Chemistry Panel considers this device as Class II, Blood Specimen Collection Device 21 CFR 862.1675.

Enclosed you will find the Premarket Submission Cover Sheet as well as the necessary product information. The Medical Device User Fee Cover Sheet for Payment Identification Number: (b)(4) [redacted] is also enclosed.

Should you require any further information, please contact us by phone (828) 465-4000 or by fax (828) 464-3999.

Sincerely,

SARSTEDT, INC.

Peter Rumswinkel
VP/General Manager

Enclosures

cH
II

Sarstedt, Inc.
P.O. Box 468
Newton, NC 28658-0468

Phone (828) 465-4000 Corporate
Telefax (828) 465-0718 Corporate
Phone (800) 257-5101 Sales
Telefax (828) 465-4003 Sales

46

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

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SARSTEDT

Sarstedt, Inc. • P.O. Box 468 • Newton, NC 28658-0468

Instruments and Disposables for Medicine and Science

Indications for Use Statement

510(k) Number: K031359

Device Name: S-Monovette® EDTA K_2-Gel

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

Albert Sasso for Jean Cooper
Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K031359

Sarstedt, Inc.
P.O. Box 468
Newton, NC 28658-0468

Phone (828) 465-4000 Corporate
Telefax (828) 465-0718 Corporate
Phone (800) 257-5101 Sales
Telefax (828) 465-4003 Sales

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

Records processed under FOIA Request 2013-6158; Released 10/14/14

510 (k) submission

S-Monovette® EDTA K_2-Gel

New 510 (k)

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

Records processed under FOIA Request 2013-6158; Released 10/14/14

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

Records processed under FOIA Request 2013-6158; Released 10/14/14

Section B

Premarket Submission Cover Sheet

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

Records processed under FOIA Request 2013-6158; Released 10/14/14

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
Premarket Submission Cover Sheet

Date of Submission: April 28, 2003

FDA Document Number:

Section A — Type of Submission

- ☒ 510(k)
- ☐ 510(k) Add'l information
- ☐ IDE
- ☐ IDE Amendment
- ☐ IDE Supplement
- ☐ IDE Report
- ☐ PMA
- ☐ PMA Amendment
- ☐ PMA Report
- ☐ PMA Supplement - Regular
- ☐ PMA Supplement - Special
- ☐ PMA Supplement - 30 day
- ☐ PMA Supplement - Panel Track

Section B1 — Reason for Submission — 510(k)s Only

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

Section B2 — Reason for Submission — PMAs Only

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

Section B3 — Reason for Submission — IDEs Only

- ☐ New device
- ☒ Addition of institution
- ☐ Expansion / extension of study
- ☐ IRB certification
- ☐ Request hearing
- ☐ Request waiver
- ☐ Termination of study
- ☐ Withdrawal of application
- ☐ Unanticipated adverse effect
- ☐ Emergency use:
  - ☐ Notification of emergency use
  - ☒ Additional information
- ☐ Other reason (specify):
- ☒ Change in:
  - ☐ Correspondent
  - ☐ Design
  - ☐ Informed consent
  - ☒ Manufacturer
  - ☐ Manufacturing
  - ☐ 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
- ☐ IOL submissions only:
  - ☐ Change in IOL style
  - ☐ Request for protocol waiver

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

Records processed under FOIA Request 2013-6158; Released 10/14/14

FDA Document Number:

Section C — Product Classification

Product code: 75 JKA	C.F.R. Section: 862.1675	Device class: ☐ Class I ☒ Class II ☐ Class III ☐ Unclassified
Classification panel: Clinical Chemistry		

Section D — Information on 510(k) Submissions

Product codes of devices to which substantial equivalence is claimed:

1 75 JKA	2 75 JKA	3	4
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 Preamendment	1 S-Monovette EDTA	1 Sarstedt
2 K012043	2 Vacuette EDTA K2 Gel Tube	2 Greiner
3	3	3
4	4	4
5	5	5
6	6	6

Section E — Product Information — Applicable to All Applications

Common or usual name or classification name:
Tubes, Vials, Systems. Serum Separators, Blood Collection

Trade or proprietary or model name	Model number
1 S-Monovette EDTA K2-Gel	1
2	2
3	3
4	4
5	5
6	6

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

Indications (from labeling):
Provide a means for collection, processing and transportation of a plasma specimen for molecular diagnostic testing (such as PCR) or for other procedures where the laboratory determines that a plasma specimen is appropriate.

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

Records processed under FOIA Request 2013-6158; Released 10/14/14

	FDA Document Number:

Section F — Manufacturing / Packaging / Sterilization Sites

☒ Original ☐ Add ☐ Delete	FDA establishment registration number: 9617475	☒ Manufacturer ☐ Contract manufacturer	☐ Contract sterilizer ☐ Repackager / relabeler
Company / Institution name: SARSTEDT AG & Co.			
Division name (if applicable):		Phone number (include area code): (0049)2293/305-500	
Street address: Rommelsdorfer Strasse		FAX number (include area code): (0049)2993/305-501	
City: Nuembrecht	State / Province: NRW	Country: Germany	ZIP / Postal Code: 51588
Contact name: Jochen Hoffmann			
Contact title: Quality Management Manager			
☒ Original ☐ Add ☐ Delete	FDA establishment registration number:	☐ Manufacturer ☐ Contract manufacturer	☒ Contract sterilizer ☐ Repackager / relabeler

(b)(4)

[redacted]

☐ Original ☐ Add ☐ Delete	FDA establishment registration number:	☐ Manufacturer ☐ Contract manufacturer	☐ Contract sterilizer ☐ Repackager / relabeler
Company / Institution name:			
Division name (if applicable):		Phone number (include area code): ( )	
Street address:		FAX number (include area code): ( )	
City:	State / Province:	Country:	ZIP / Postal Code:
Contact name:			
Contact title:			

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

Records processed under FOIA Request 2013-6158; Released 10/14/14

	FDA Document Number:

Section G Applicant or Sponsor

Company / Institution name: SARSTEDT, INC.			FDA establishment registration number: 2242368
Division name (if applicable):			Phone number (include area code): (828) 465-4000
Street address: 1025 St. James Church Road			FAX number (include area code): (828) 464-3999
City: Newton	State / Province: NC	Country: USA	ZIP / Postal Code: 28658
Signature:			
Name: Peter Rumswinkel			
Title: Vice President / General Manager			

Section H Submission correspondent (if different from above)

Company / Institution name:			
Division name (if applicable):			Phone number (include area code): ( )
Street address:			FAX number (include area code): ( )
City:	State / Province:	Country:	ZIP / Postal Code:
Contact name:			
Contact title:			

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

Records processed under FOIA Request 2013-6158; Released 10/14/14

Section C

Reference Documents

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

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C. Reference Documents

The following list details the guidelines and standards on which the specifications of the EDTA K_2-Gel S-Monovette® as well as this 510 (k) submission are based.

1. Guidance dated January 1, 1997:
   In Vitro Diagnostic Devices: Guidance for the Preparation of 510 (k) Submissions.
   HHS Publication FDA 97-4224

2. ANSI/AAMI/ISO 11137 - 1994 Sterilization of Health Care Products – Requirements for Validation and Routine Control - Radiation Sterilization

3. ISO 6710 Single Use Containers for Blood Specimen Collection

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

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Section D

Device and Manufacturer Identification

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

Records processed under FOIA Request 2013-6158; Released 10/14/14

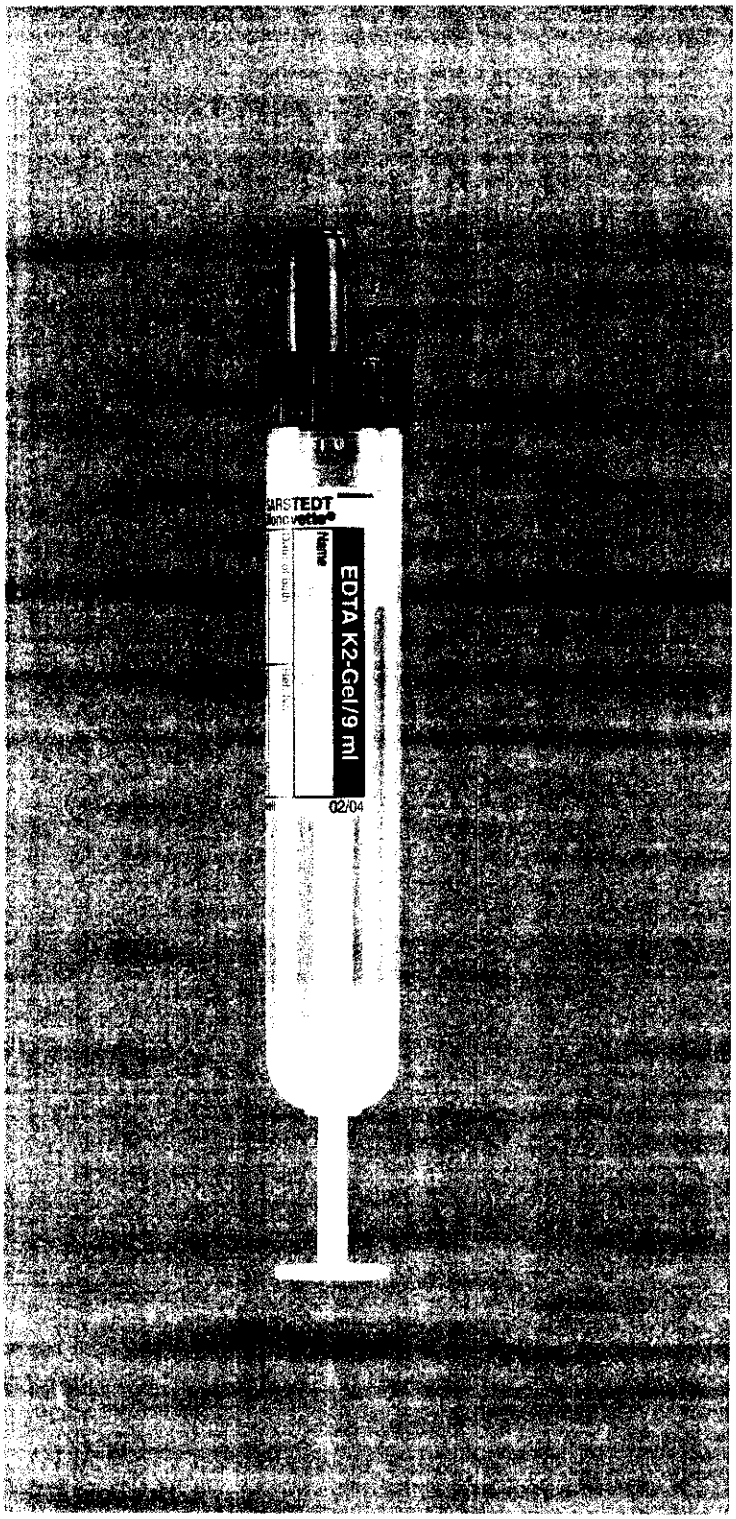
D.1 Device Identification

Proprietary Name:	S-Monovette® EDTA K_2-Gel
Common Name:	Blood Collection System
Classification Name:	Tubes, Vials, Systems, Serum Separators, Blood Collection
	21 CFR 862.1675 Class II
Product Code	75 JKA

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

Records processed under FOIA Request 2013-6158; Released 10/14/14

S-Monovette® EDTA K_2-Gel



The picture is of the 9ml S-Monovette® EDTA K_2-Gel and is representative of all sizes/volumes.

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

Records processed under FOIA Request 2013-6158; Released 10/14/14

D. 2 Manufacturer and Submitter Identification

Manufacturer Name:	SARSTEDT AG & Co.
Manufacturer Address:	Rommelsdorfer Strasse Nuembrecht, D-51588 Germany
Registration Number	9617475
Submitter Name:	Sarstedt Inc.
Submitter Address:	P.O. Box 468 Newton, NC 28658-0468
Registration Number:	2242368
Contact Person:	Peter Rumswinkel Tel. (828) 465-4000 Fax (828) 464-3999

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

Records processed under FOIA Request 2013-6158; Released 10/14/14

Section E

Labeling

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

Records processed under FOIA Request 2013-6158; Released 10/14/14

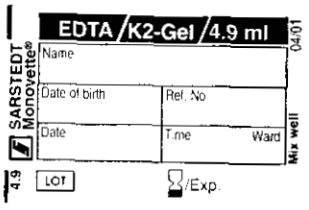
E. Labeling

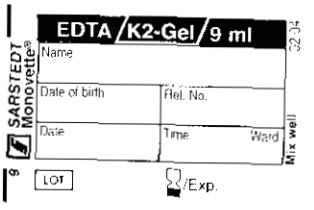
The S-Monovette® EDTA K_2-Gel is to be marketed as a blood collection tube for the collection, processing and transportation of venous blood. Upon centrifugation, the gel separates the plasma from the other components to provide a plasma specimen for use in Nucleic Acid Testing (NAT) methods such as PCR – Polymerase Chain Reaction or other procedures where an undiluted plasma specimen is required as determined by the laboratory.

The S-Monovette® EDTA K_2-Gel is sterile and labeled for single use only.
The S-Monovette® EDTA K_2-Gel has a shelf life of 9 months.
The S-Monovette® EDTA K_2-Gel is currently available in 4.9 ml and 9.0 ml, other sizes may be added.
The S-Monovette® EDTA K_2-Gel should be stored at room temperature.

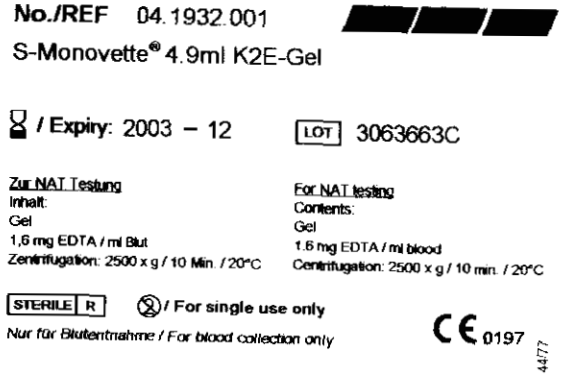
The S-Monovette® EDTA K_2-Gel is packaged 50 pieces per inner box. One outer box contains 10 inner boxes for a total of 500 pieces. The product is to be sold per inner box of 50.

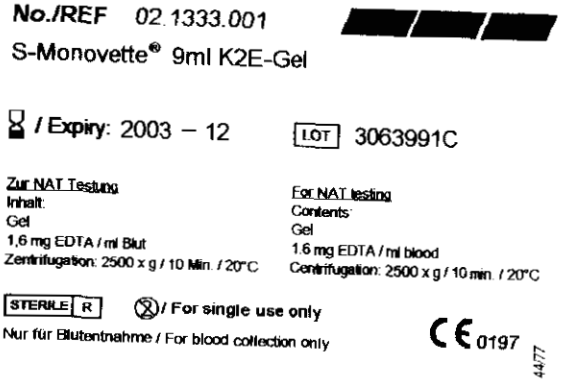
Each S-Monovette® EDTA K_2-Gel is affixed with a label which includes the volume, lot number, expiration date and space for written patient information or labeling. The label samples shown below are in the European color code. When produced for the US market the color code will be violet and brown (violet for EDTA and brown for gel).





Inner box label





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

Records processed under FOIA Request 2013-6158; Released 10/14/14

E. Labeling – Continued

Outer box label

St./pcs. **500** No./REF **04.1932.001**

S-Monovette® 4.9ml K2E-Gel

/ Expiry: 2003 – 12 LOT 3063663C

/ For single use only STERILE R

Lagern bei Raumtemperatur / Store at room temperature CE 0197

(01)04038917028868 (17)031200 (10)3063663C

SARSTEDT

SARSTEDT AG & Co. · D-51588 Nümbrecht

Made in Germany

43/90

St./pcs. **500** No./REF **02.1333.001**

S-Monovette® 9ml K2E-Gel

/ Expiry: 2003 – 12 LOT 3063991C

/ For single use only STERILE R

Lagern bei Raumtemperatur / Store at room temperature CE 0197

(01)04038917021357 (17)031200 (10)3063991C

SARSTEDT

SARSTEDT AG & Co. · D-51588 Nümbrecht

Made in Germany

43/90

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

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Records processed under FOIA Request 2013-6158; Released 10/14/14

E. Labeling – Continued

Text printed on IK boxes

GEBRAUCHSHINWEIS

A. Saugkolbenprinzip: S-Monovette® mit Kanüle komplettieren(1). Vene punktieren, Stauung lösen und Blut aufziehen(2). Bei Mehrfachentnahmen nachfolgende S-Monovette® in die liegende Kanüle einführen. Letzte S-Monovette® aus der Kanüle lösen(3), danach Kanüle aus der Vene ziehen. Kolben in den "Knack" ziehen und Kolbenstange abbrechen(4). S-Monovette® mit Antikoagulantien gut mischen!

B. Vakuumprinzip: Unmittelbar vor der Blutentnahme Kolben in die "Knackposition" ziehen; anschließend muss die Kolbenstange abgebrochen werden(5). Evakuierte S-Monovette® in die bereits in der Vene liegende Kanüle einführen(6). Nach Mehrfachentnahme letzte S-Monovette® aus der Kanüle lösen(7), danach Kanüle aus der Vene ziehen. S-Monovette® mit Antikoagulantien gut mischen!

Achtung! S-Monovette® nur zur Blutentnahme und nicht zur Injektion verwenden. Nur mit Kanülen / Adapter für die S-Monovette® verwenden.

INSTRUCTIONS FOR USE

A. Aspiration principle: Assemble S-Monovette® and needle(1), puncture vein, loosen tourniquet and draw up blood(2). When multiple sampling, secure the subsequent S-Monovette® onto the needle that is still in the vein and collect blood in the manner described above. Remove final S-Monovette® from the needle(3). Finally, remove the needle from the vein. Withdraw the piston past the stop mark and lock into the case of the S-Monovette®. Snap off piston rod(4), mix S-Monovette® thoroughly with anticoagulants!

B. Vacuum principle: Prior to blood collection, lock the piston into the base of the S-Monovette®. Once secured, the plunger must be snapped off(5). Insert the pre-evacuated S-Monovette® onto the needle already located in the vein(6). After multiple sampling remove the final S-Monovette® from the needle(7). Finally, remove the needle from the vein, mix S-Monovette® thoroughly with anticoagulants!

Attention! Use S-Monovette® only for blood collection. Do not use for injection. Use only with S-Monovette® needle / adapter.

MODE D'EMPLOI

A. Principe par aspiration: Compléter la S-Monovette® par l'aiguille(1), ponctionner la veine, détendre le garrot et prélever le sang(2). Lors d'un prélèvement multiple, brancher la S-Monovette® suivante sur l'aiguille en place. Dégager la dernière S-Monovette® de l'aiguille(3), puis retirer cette dernière de la veine, bloquer le piston au fond et casser la tige(4), mélanger soigneusement la S-Monovette® avec anticoagulants!

B. Principe sous vide: Avant le prélèvement, bloquer le piston à la base de la S-Monovette®. Une fois le piston verrouillé, la tige du piston doit être cassée(5). Brancher la S-Monovette® sous vide sur l'aiguille déjà en place dans la veine(6). Après un prélèvement multiple, dégager la S-Monovette® de l'aiguille(7), puis retirer cette dernière de la veine, mélanger soigneusement la S-Monovette® avec anticoagulants!

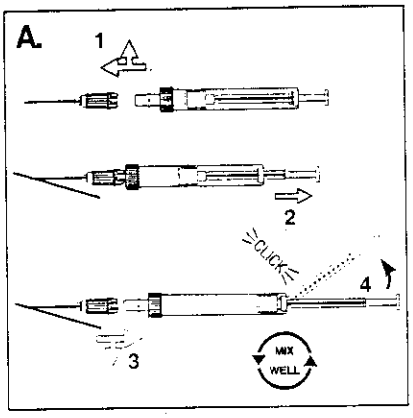
Attention! La S-Monovette® est à utiliser seulement pour le prélèvement sanguin et non pour l'injection. L'utiliser uniquement avec l'aiguille / l'adaptateur S-Monovette®.

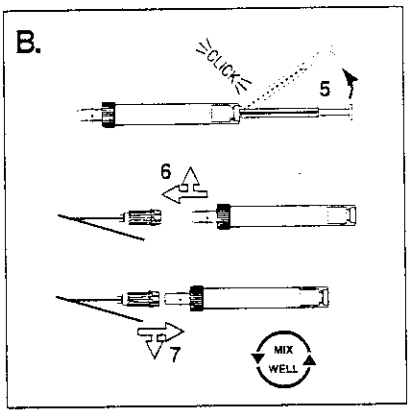
ISTRUZIONI PER L'USO

A. Principio di aspirazione: Inserire l'ago sulla S-Monovette®(1), inserire l'ago in vena, sciogliere il laccio emostatico ed aspirare il sangue(2). Per eseguire prelievi multipli inserire la S-Monovette® una dopo l'altra nell'ago ancora inserito in vena. Solo dopo aver tolto l'ultima S-Monovette® dall'ago(3), estrarre l'ago dalla vena, tirare il pistone a fine corsa, assicurandosi che sia innestato e spezzare l'asticella(4), agitare bene le S-Monovette® con anticoagulanti!

B. Principio a vuoto: Prima di prelevare il sangue, bloccare l'asticella alla base della S-Monovette®. Una volta fissato, il pistone deve essere spezzato(5). Creato così il vuoto nella S-Monovette® inserirla nell'ago già in vena(6). Dopo più prelievi togliere l'ultima S-Monovette® dall'ago(7) e quindi estrarre l'ago dalla vena, agitare bene le S-Monovette® con anticoagulanti!

Attenzione! Usare la S-Monovette® solo per il prelievo del sangue e non per iniezioni. Usare solo con l'ago / adattatore S-Monovette®.





INSTRUCCIONES PARA SU USO

A. Principio de aspiración por embolo: Completar la S-Monovette® con la aguja(1), punctionar la vena, aflojar el torniquete y aspirar la sangre(2). En caso de una extracción multiple colocar la S-Monovette® siguiente en la aguja. Soltar la ultima S-Monovette® de la aguja(3), extrayendo posteriormente la aguja de la vena, estirar el vastago hasta el final y al quedar fijado romperlo(4), mezclar con suavidad las S-Monovette® que contienen anticoagulantes!

B. Principio de vacio: Inmediatamente antes de la extracción se estira el vastago hasta que el embolo quede fijado en el fondo de la S-Monovette®; seguidamente hay que romper el vastago(5). Conectar la S-Monovette® con vacio a la aguja colocada en la vena(6). Despues de una extraccion multiple soltar la ultima S-Monovette® de la aguja(7), extrayendo posteriormente la aguja de la vena, mezclar con suavidad las S-Monovette® que contienen anticoagulantes!

Atencion! Utilice la S-Monovette® solo para extraccion de sangre. No la utilice para inyeccion. Usela solo con agujas / adaptadores S-Monovette®.

INSTRUÇÕES DE USO

A. Principio de aspiracão: Inserir a agulha na S-Monovette®(1), puncionar a veia, apertar o garrote e extrair o sangue(2). No caso de colheita multipla introduzir a S-Monovette® uma apos outra na agulha ainda inserida na veia. Somente apos ter retirado a ultima S-Monovette® da agulha(3), extrair esta da veia, caso necessario: bloquear o pistão e então partir o embolo(4), agite bem as S-Monovettes com os anticoagulantes!

B. Principio de vácuo: Antes de iniciar a colheita bloquear o pistão e então partir o embolo(5). Colocar a S-Monovette® com o vácuo já criado na agulha posicionada na veia(6). Depois da uma extracção multibla retirar a ultima S-Monovette® da agulha(7) e so então retirar esta da veia, agite bem as S-Monovettes com os anticoagulantes!

Atençaó! Utilize as S-Monovette® apenas para colheita de sangue. Não as use para injecção. Use apenas com a agulha da S-Monovette® ou com o adaptador proprio.

GEBRUIKSAANWIJZING

A. Aanzuigprincipe: S-Monovette® op de naald aansluiten(1), ader aanprikken, stuwing minderen en bloed optrekken(2). Bij meerdere afnamen sluit men telkens een volgende S-Monovette® aan op de naald die in de vene blijft. Nadat de laatste S-Monovette® van de naald is losgekoppeld(3), kan men de naald uit de vene trekken. Zuigerstang in de "knak" positie trekken en afbreken(4), S-Monovette® goed mengen met de anti-coagulantia!

B. Vacuümprincipe: Meteen voor de bloedafname de zuigerstang in de klikpositie trekken; daarna moet de zuigerstang afgebroken worden(5). De vacuüm-S-Monovette® aansluiten op de naald waarmee de vene reeds is aangeprikt(6). Na meerdere afnamen, maakt men de laatste S-Monovette® uit de naald los(7), en daarna trekt men de naald uit de vene. S-Monovette® goed mengen met de anti-coagulantia!

Opgelet! S-Monovette® enkel gebruiken voor bloedafname en niet voor injectie. Slechts te gebruiken met de naalden / adapters voor de S-Monovette®.

RESY 321

IK 72-c M
990615

Product Insert – see page 18

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

Records processed under FOIA Request 2013-6158; Released 10/14/14

S-Monovette® EDTA K_2-Gel

Intended Use of S-Monovette® EDTA K_2-Gel

The S-Monovette® EDTA K_2-Gel is intended for use as a blood collection, processing and transport device. After processing by centrifugation, the S-Monovette® EDTA K_2-Gel produces a plasma specimen for molecular diagnostic testing (such as PCR) or for other procedures where the laboratory has determined that a plasma specimen is appropriate.

Principle

The mean concentration of 1.6 mg EDTA/ml blood (when filled to the nominal volume specified on the device) serves as an anticoagulant. When centrifuged the blood sample results in a nearly undiluted (<1%) plasma specimen.

Reagents

The mean concentration of the anticoagulant is: EDTA-K_2 at a concentration of 1.6 mg EDTA/ml blood

The S-Monovette® Needle or Multifly® Needle is required for venous collection. The S-Monovette® Needle and Multifly® Needle are sold separately. The S-Monovette® Needle Protector for the S-Monovette® Needle is also sold separately. Equipment for processing and analysis of the specimen are not included.

Warning: For In Vitro Diagnostic Use Only. The S-Monovette® EDTA K_2-Gel is for blood collection only.

Specimens should be handled using aseptic techniques to avoid contamination. All specimens should be assumed as containing infectious organisms and should be handled with the appropriate precautions. Specimens should be disposed of in accordance with the user's local and state regulations.

Instructions for Use (see pictures on inside of box)

Aspiration principle: Assemble S-Monovette® and needle (1) puncture vein, loosen tourniquet and draw up blood (2) When multiple sampling, secure the subsequent S-Monovette® onto the needle that is still in the vein and collect blood in the manner described above. Remove final S-Monovette® from the needle (3) Finally remove the needle from the vein. Withdraw the piston past the stop mark and lock into the base of the S-Monovette®. Snap off piston rod (4), mix S-Monovette® thoroughly with anticoagulants.
Vacuum principle: Prior to blood collection, lock the piston into the base of the S-Monovette®. Once secured, the plunger must be snapped off (5). Insert the pre-evacuated S-Monovette® onto the needle already located in the vein (6). After multiple sampling remove the final S-Monovette® from the needle (7). Finally, remove the needle from the vein, mix S-Monovette® thoroughly with anticoagulants.

Recommended centrifugation: 2500 x g/10 minutes at 22 - 25°C. For optimal gel integrity, samples should be centrifuged in a swing-out or horizontal rotor.

Limitations

This device has been tested for molecular diagnostic testing (PCR) for HIV, HCV and HBV.

Expected Values

Recovery of HIV, HBV, and HCV from specimens collected with the S-Monovette® EDTA K_2-Gel is within the excepted performance of the PCR test.

Performance Characteristics

At the minimum detection levels of HIV, HCV and HBV (1000 ge/ml, 1000 ge/ml and 500 ge/ml, respectively), the S-Monovette® EDTA K_2-Gel does not interfere with PCR testing. This is true with storage at room temperature for 24 hours, and storage at 4°C for up to 96 hours.

SARSTEDT

Aktiengesellschaft & Co.
D-51588 Nümbrecht

For In Vitro Diagnostic Use Only
Technical Modifications Reserved
April 2003

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

Records processed under FOIA Request 2013-6158; Released 10/14/14

Section F

Device Description

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

Records processed under FOIA Request 2013-6158; Released 10/14/14

F. Device Description

F.1 Detailed Description

The S-Monovette® EDTA K_2-Gel is an expansion of the existing S-Monovette® product line. The S-Monovette® is a preamendment blood collection device. It is manufactured from plastic materials and incorporates a screw cap with membrane, a tube, a plunger and a piston. The screw cap is designed with three pins or projections. These pins function as a lock for the S-Monovette® Needle to attach.

The S-Monovette® can be filled by two methods: (b)(4) [redacted] (b)

(b)(4) [redacted]

(b)(4) [redacted]

The S-Monovette® EDTA K_2-Gel incorporates the widely used anticoagulant EDTA-K_2 and an acrylic/silicon gel for separation of the plasma and cellular components of blood by centrifugation. With the gel barrier, the plasma can be stored and mixed prior to sample removal without the trouble of possibly remixing the blood.

Because of the tiny volume of liquid EDTA in the S-Monovette® the plasma sample remains nearly undiluted (<1%). The plasma produced by the S-Monovette® EDTA K_2-Gel can be used for tests determined by the laboratory as appropriate for plasma. In addition to this general application, the S-Monovette® EDTA K_2-Gel can be used to produce a plasma specimen suitable for Nucleic Acid Testing (NAT). Specifically the S-Monovette® EDTA K_2-Gel is to be marketed for NAT testing, for HIV, HCV and/or HBV by methods such as PCR – Polymerase Chain Reaction..

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

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F. Device Description

F.1 Detailed Description - continued

The S-Monovette® EDTA K_2-Gel is currently being prepared for offering in 4.9 and 9.0 ml. These volumes are standard in the clinical laboratory. The specifications for the S-Monovette® EDTA K_2-Gel could be applied to other volumes available in the S-Monovette® product line.

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

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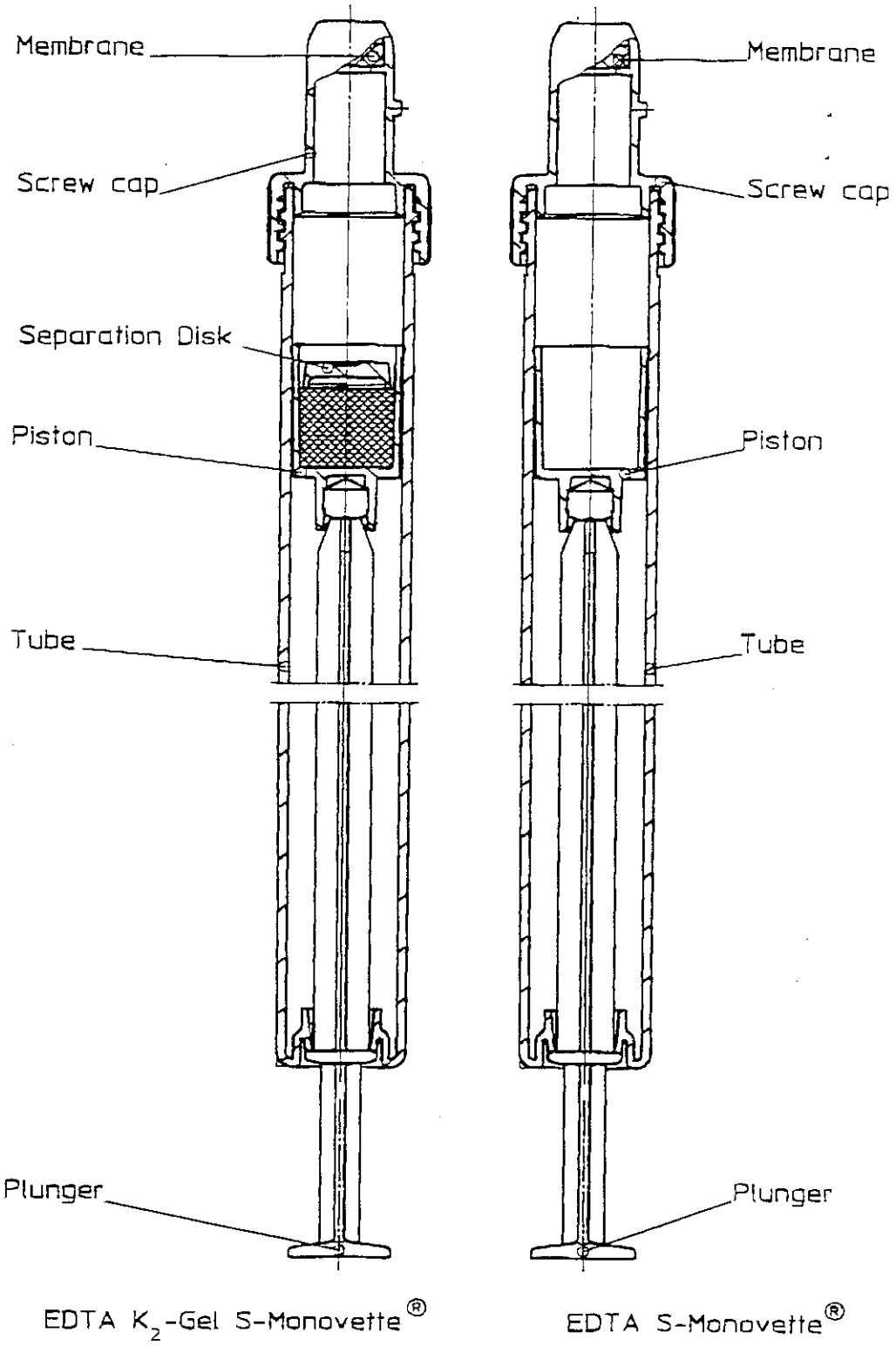
F. Device Description

F.2 Drawing of S-Monovette® EDTA K_2-Gel and S-Monovette® EDTA



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F. Device Description Continued

F.3 Intended Use

The S-Monovette® EDTA K_2-Gel provides a means for collection, processing and transportation of a plasma specimen in a closed system. Following collection of the blood, the S-Monovette® EDTA K_2-Gel is to be centrifuged such that the gel creates a barrier between the plasma and cellular components. The plasma specimen can then be removed for testing or the specimen can be transported for testing at another location without the plasma mixing with the cellular components.

The plasma specimen produced by the S-Monovette® EDTA K_2-Gel can be used for Nucleic Acid Testing (NAT) by methods such as PCR – Polymerase Chain Reaction or for other procedures where the laboratory has determined that a plasma specimen is appropriate.

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F. Device Description Continued

F.4 Specifications

F.4.a Technical Data

The dimensions of the S-Monovette® EDTA K_2-Gel

	Outer tube diameter	Outer diameter screw cap	Tube length with screw cap	Tube length without screw cap
9.0 ml	16 mm (0.63 in)	19 mm (0.75 in)	108 mm (4.25 in)	92 mm (3.62 in)
4.9 ml	13 mm (0.51 in)	16 mm (0.63 in)	106 mm (4.17 in)	90 mm (3.54 in)

The S-Monovette® EDTA K_2-Gel contains EDTA-K_2 as anticoagulant and a mean of 650 mg Gel (4.9 ml) or 1175 mg Gel (9.0 ml) per S-Monovette® as well as a separation disk.

The nominal concentration of EDTA is 1.6 mg EDTA/ml blood.

When the device is used according to the instructions for use, it will fill to the volume specified on the part label. Currently the S-Monovette® EDTA K_2-Gel is to be offered in 4.9 and 9.0 ml.

Recommended centrifugation for proper separation between plasma and cellular components: 2500 x g / 10 minutes @ 22 - 25°C

Materials:

Tube .....Polypropylene
Plunger .....Polystyrene
Piston.....Polyethylene
Separation disk .....Plexiglas
Screw cap.....Polyethylene
Preparation.....EDTA-K_2
Gel.....*Acrylic polymer and silicone dioxide mixture: Density 1.04 g/cm^3*

Sterilization Specifications:

(b)(4) [redacted]

Biocompatibility Specifications:

Not applicable according to Attachment from General Program Memorandum - #G 95-1

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Section G

Comparison to a Legally Marketed Blood Collection Device

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G Descriptive Comparison to a Legally Marketed Device

Sarstedt believes that the S-Monovette® EDTA K_2-Gel described in this Premarket Notification is equivalent to two devices, the Sarstedt S-Monovette® EDTA and the Greiner Vacuette EDTA K_2 Gel Tube. The Sarstedt S-Monovette® EDTA is a preamendment device. The Greiner Vacuette EDTA K_2 Gel Tube (K012043) was found substantially equivalent by FDA on September 24, 2001. Our determination is based on the comparison of intended use, features and performance detailed in the Performance Studies of the S-Monovette® EDTA K_2-Gel and S-Monovette® EDTA , and the 510(k) for the Greiner Vacuette EDTA K_2 Gel Tube (K012043). A copy of the 510(k) Substantial Equivalence Letter and 510(k) Summary for the Greiner Vacuette EDTA K_2 Gel Tube are on pages 27 - 30 of this premarket notification.

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

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K012043

SEP 2 4 2001

June 27, 2001

510(k) Summary

CONTACT:

Douglas L. Harris
Greiner Vacuette North America, Inc.
P.O Box 1026
Monroe, NC 28111

NAME OF DEVICES:

Trade Name:	Vacuette® EDTA K2 Gel Tubes
Common Names/Descriptions:	Evacuated Blood Collection System
Classification Name:	Tubes, Vials, Systems, Serum Separators, Blood Collection

PREDICATE DEVICE:

Becton Dickinson Vacutainer® Brand PPT™ Plasma Preparation Tube (K972075)

DEVICE DESCRIPTION:

INTENDED USE: The **VACUETTE®** EDTA K2 Gel tube provides a means for collection, processing and transportation of an undiluted plasma specimen in a closed evacuated system. The tube contains spray-dried EDTA, yielding a ratio of 1.8mg/mL of blood when the evacuated tube is filled correctly to its fill volume, and a gel barrier material.

PRODUCT DESCRIPTION: The **VACUETTE®** EDTA K2 Gel Tube is used for plasma preparation and is made of plastic for the collection of venous blood which upon centrifugation separates undiluted plasma for use in molecular diagnostic test methods (such as but not limited to PCR – Polymerase Chain Reaction), or other procedures where an undiluted plasma specimen is required as determined by the laboratory.

SUBSTANTIAL EQUIVALENCE:

The VACUETTE® EDTA K2 Gel Tube and the Becton Dickinson Vacutainer® Brand PPT™ Plasma Preparation Tube are substantially equivalent in intended use, design and composition.

Studies were conducted to evaluate the use of the Greiner VACUETTE® EDTA K2 Gel Tubes. The objective of the studies was to demonstrate substantial equivalence to the Becton Dickinson (BD) Vacutainer® Brand PPT™ Plasma Preparation Tube when samples from these tubes are used in PCR assays.

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The substantial equivalence studies included:

- Limited validation testing on the HIV and HCV PCR assays using WHO standards at the lower detection limits; comparison of HIV and HCV lower detection limits using both types of tubes;
- Comparison of HIV and HCV recovery using both types of tubes;
- Equivalency studies of Greiner and BD tubes with regard to results of HIV and HCV PCR testing;
- Evaluation of effects of delay in separation of plasma and blood cells on HIV and HCV results using both types of tubes;
- Determination of equivalency of HIV and HCV results from fresh and once frozen samples collected in the two tube types;
- Determination of equivalency of HIV and HCV results from fresh and multiple freeze/thaw samples using both types of tubes.

The conclusions from the study were:

- Both tubes demonstrated similar sensitivity and recovery at the lower detection limits for both HIV and HCV quantitation;
- Both tubes demonstrated substantially equivalent results in HIV and HCV quantitation;
- No effect was seen when plasma collected from the Greiner tube was separated from blood cells within 24 hours for HIV or HCV;
- There was no difference in HIV or HCV results within or between the two tube types for fresh versus once frozen samples or when plasma samples were exposed to 5 freeze/thaw cycles for HIV or 1 freeze/thaw cycle for HCV.

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

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Greiner Vacuette North America, Inc.
c/o Ms. Judi Smith
Sienna Partners, L.L.C.
P.O. Box 103
Baldwin, MD 21013

SEP 2 4 2001

Re: k012043
Trade/Device Name: Vacuette® EDTA K2 Gel Tubes
Regulation Number: 21 CFR 862.1675
Regulation Name: Blood specimen collection device
Regulatory Class: Class II
Product Code: JKA
Dated: August 28, 2001
Received: August 30, 2001

Dear Ms. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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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" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

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 301-796-8118

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Table I: Substantial Equivalent Comparison of Sarstedt S-Monovette® EDTA K_2-Gel, Sarstedt S-Monovette® EDTA and Greiner Vacuette EDTA K_2 Gel Tube

feature	S-Monovette® EDTA K_2-Gel	S-Monovette® EDTA	Vacuette EDTA K_2 Gel Tube	Comparison
Manufacturer	Sarstedt	Sarstedt	Greiner	
510(k)	submitted	preamendment	K012043	
Classification	JKA	JKA	JKA	same
Intended Use	blood collection, processing, and transport device producing a plasma specimen for molecular diagnostic testing (such as PCR)	blood collection, processing, and transport device producing a plasma specimen	blood collection, processing, and transport device producing a plasma specimen for molecular diagnostic testing (such as PCR)	comparable to S-Monovette® EDTA and same as Vacuette
User	hospitals, clinics and reference laboratories	hospitals, clinics and reference laboratories	hospitals, clinics and reference laboratories	same
Anticoagulant	EDTA – K_2	EDTA – K_3	EDTA – K_2	comparable to S-Monovette® EDTA and same as Vacuette
Gel – separation media	Acrylic polymer & silicone dioxide mixture	not applicable	olefinoligomer (main component)	comparable
Materials	plastic	plastic	plastic	exactly the same as S-Monovette® EDTA and comparable to Vacuette
Collection Method	(b)(4) [redacted]	Aspiration principle or vacuum (evacuated tube) principle	Evacuated tube	same as S-Monovette® EDTA and comparable to Vacuette
Processing Method	Centrifugation	Centrifugation	Centrifugation	same
Performance	Provides plasma specimen for molecular diagnostic testing (PCR)	No claim; however, performance studies show favorable results	Provides plasma specimen for molecular diagnostic testing (PCR)	same for S-Monovette® EDTA K2-Gel and S-Monovette® EDTA based on performance testing, same for Vacuette based on claim.

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

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G. Comparison to a Legally Marketed Blood Collection Device.

Discussion:

The S-Monovette® EDTA K_2-Gel is intended for use as a blood collection, processing and transport device. The S-Monovette® EDTA K_2-Gel produces a plasma specimen for molecular diagnostic testing (NAT) such as PCR. The S-Monovette® EDTA K_2-Gel is being compared to the preamendment S-Monovette® EDTA and the substantially equivalent Greiner Vacuette EDTA K_2 Gel Tube (see page 31 comparison table). This comparison shows that the S-Monovette® EDTA K_2-Gel is the same and/or comparable to the S-Monovette® EDTA and the Vacuette EDTA K_2 Gel Tube. From this comparison Sarstedt claims that the S-Monovette® EDTA K_2-Gel is substantially equivalent to the preamendment S-Monovette® EDTA and the Greiner Vacuette EDTA K_2 Gel Tube.

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

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SECTION H

Performance Evaluation

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H. Performance Evaluation

(b)(4)

[redacted]

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(b)(4)

[redacted]

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Evaluation of the Sarstedt EDTA-Gel S-Monovette® System for Application in Molecular Viral Diagnostics

K. Gubbe and A. Karl
DRK Blutspendedienst Sachsen gGmbH

Summary
Objective: Evaluation of Sarstedt EDTA-Gel S-Monovettes as an enclosed blood collection system for application in the preanalytic stage of molecular biological diagnostics by means of a direct comparison with the Sarstedt EDTA S-Monovette® system. Material and method applied: Full blood was spiked with 1000ge/ml HCV and HIV, resp., and 500ge/ml HBV. After spiking, viral titres were determined after 24h full blood storage under room temperature conditions as well as 48h and 96h plasma storage at 4°C. Results: The average viral load values determined for HCV, HIV and HBV in both S-Monovette® systems revealed comparable results. Viral stability was not influenced by the type of S-Monovette® system tested. Conclusion: The Sarstedt EDTA-Gel S-Monovette® system offers distinct operational advantages as compared with conventional blood sample collection systems. On account of the fact that the plasma and cellular components are efficiently separated by a gel barrier, the sample material can be mixed, with an enhanced possibility of reproducing the test results.

NAT – Nucleic acid amplification technique; ge – genome equivalents

Introduction

Preanalytical factors are of decisive influence on the sensitivity and reliability of test systems in molecular viral diagnostics. Further to the storage period and temperature, the type and nature of the sample material are an important criterium for viral stability. Accordingly, standardized conditions of preanalytics carry a crucial weight to ensure correct test results. Enclosed blood collection systems provide a better means to meet these requirements than conventional systems.
The subject of this study was to analyze the characteristic features of two enclosed systems for the preparation of EDTA plasma by comparing the Sarstedt EDTA-Gel S-Monovette® system with the EDTA S-Monovette® system, with a particular view to the influence on viral stability of HCV, HIV and HBV in EDTA plasma and specific handling features concerned.

Material and Methods

Specimens of a donor confirmed to be HBsAg, anti-HCV and anti-HIV negative and spiked with a nominal quantity of 1000 ge HCV and HIV, resp., as well as 500 ge HBV per ml of full blood were subjected to analysis (WHO-HCV-RNA-standard 96/790, CLB-Pelipsy-HIV-RNA-Monitor, and Pelipsy-HBV-DNA-Monitor). 20 EDTA S-Monovettes and EDTA-Gel-S-Monovettes each of full blood were collected.
Samples were tested immediately after spiking, after 24h storage under room temperature conditions as well as after 48h and 96h storage at 4 °C.

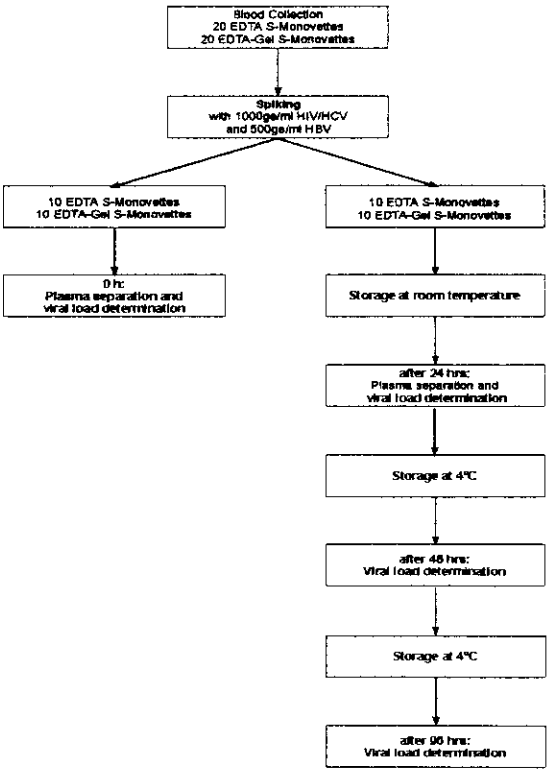

Fig. 1: Test sequence

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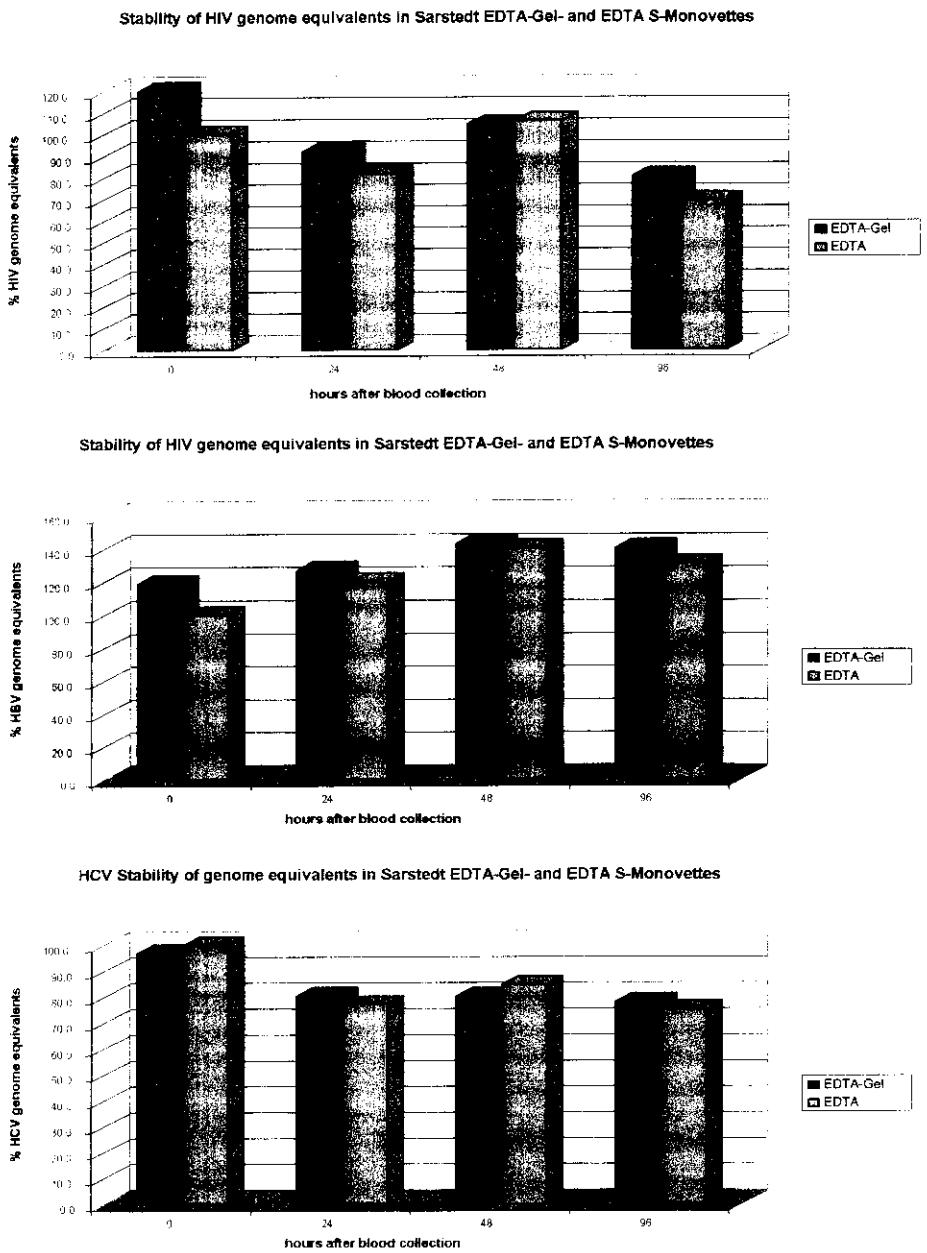

Fig. 2: Average HBV, HCV, HIV viral load (in %)

	EDTA-Gel S-Monovette				EDTA S-Monovette			
Time	0h	24h	48h	96h	0h	24h	48h	96h
HIV								
AV	120.9	91.9	104.6	80.5	100	81.5	106.0	69.3
S	36.3	35.7	29.5	33.5	34.6	17.2	35.2	19.0
VC	30.0	38.8	28.2	41.6	34.6	21.1	33.2	27.4
HBV								
AV	118.8	126.8	142.9	140.2	100	119.9	140.1	130.5
S	16.4	31.3	40.7	55.2	21.0	39.6	54.3	42.2
VC	13.8	24.7	28.5	39.4	21.0	33.1	38.8	32.3
HCV								
AV	97.0	80.6	80.4	78.0	100	77.2	84.7	75.3
S	17.1	16.6	29.2	9.8	7.1	22.7	8.2	16.4
VC	17.6	20.5	36.2	12.6	7.1	29.4	9.7	21.8

Table 1: Survey on proportion of viral genome equivalents in Sarstedt EDTA-Gel and EDTA S-Monovettes (EDTA S-Monovettes at 0h = 100%, AV = average value [%], S = standard deviation VC = variation coefficient [%])

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Ten (10) S-Monovettes each of both systems were subjected to centrifugation for 10 min. either immediately after spiking to determine the initial viral load or after a storage time of 24hrs. under room temperature conditions at 2,500 x g in order to separate the plasma from the cells. Plasma aliquots of 500µl each were analysed. The plasma in the EDTA S-Monovettes was not mixed prior to collecting sample aliquots so as to prevent destruction of the barrier between plasma and cells. Samples from the EDTA-Gel-S-Monovettes were collected correspondingly.

The summarized test sequence is based on the general logistic conditions prevailing in blood transfusion centres, taking into account figures of most unfavourable transport and storage times and temperatures. As a matter of fact, for instance, a period of 24hrs. may lapse between collecting blood and separating the plasma from the cells, and a continuous temperature of 4°C might not be complied with in every singular case. Blood donation campaigns carried out at weekends may even leave full blood tubes already subjected to centrifugation to be stored for 48hrs.

Baxter/Imuno`s IQ-PCR assay was employed to determine the viral load. Virus concentration by means of ultra centrifugation, extraction of nucleic acids using phenol/chloroform as well as the detection of amplificates via laser-induced fluorescence (1, 2) are the most fundamental features of these PCR assays

Test Results

As a general tendency, HIV viral titres were ascertained to decrease as storage periods of the sample material were increasing, such decrease being very similar in both S-Monovette® systems. No reduction of HBV titres was observed. The 24hrs., 48hrs. and 96hrs. test values obtained for either S-Monovette® type were ranging at around 30% above the average value determined at 0hr. For HCV, a decrease in the viral load of roughly 20% was detected with both S-Monovette® systems within an initial 24hrs. storage period of full blood samples under room temperature conditions while HCV titres detected were ascertained to remain almost constant after plasma separation and storage at 4°C (Fig. 2).

A significant correlation of average viral loads in EDTA and Gel S-Monovettes was detected for both HIV and HCV (r=0.86 and 0.94) as well as for HBV (r=0.97), while in a majority of cases, average viral loads of EDTA-Gel-S-Monovettes were found to be higher than those detected in EDTA-S-Monovettes.

The titre variations ascertained for all viral parameters were established to be within the method variation range (Table 1) and are almost identical for both Sarstedt S-Monovette® systems. No PCR inhibitor was detected with the gel system.

Conclusion

This study aims at evaluating the Sarstedt EDTA-Gel-S-Monovette® system for application in molecular biological diagnostics. For this purpose, this new system was to be compared with the EDTA-S-Monovette® system. A donor's full blood sample was spiked with defined viral quantities, with concentrations of abt. 1,000 ge/ml ranging in the neighbourhood of the 95% cut off of the PCR method applied. Accordingly, proceeding from correspondingly low virus titres will serve to precisely determine the influence likely to be caused on viral stability by the blood collection system applied.

HCV and HIV titres determined to be abt. 20% after storing the full blood sample for a period of 24hrs. under room temperature conditions shows good compliance with the data ascertained by Davis et al. (3). HBV concentrations, on the other hand, did not show any decrease, implying a distinctly increased HBV stability. HBV, HCV and HIV figures are ranging within the limits of fluctuation acceptable for the PCR assays applied (Table1).

An increasing variation of viral loads was ascertained as storage periods increased, a fact likely to be induced by uneven distribution of the viral material, as the plasma of both S-Monovette® systems was not mixed prior to collecting aliquots. EDTA-Gel S-Monovettes, however, can be mixed prior to sample collection without destroying the gel barrier safely separating plasma and cells.

Virus titres determined in the EDTA-Gel S-Monovettes were found to be slightly higher than those detected in the EDTA S-Monovettes. Accordingly, this implies a higher virus stability and would, as such, have a positive effect on the sensitivity of NAT tests. However, these findings are to be confirmed by analysing still a larger quantity of sample material. Accordingly, it is to be assumed that the type of S-Monovette® system used did not show any influence on viral stability.

No negative PCR result whatsoever, i.e. a decrease in viral titres below the point of detection in PCR assays, was obtained. Proceeding from these facts and taking into account the optimum correlation between the figures received for both the EDTA and EDTA-Gel S-Monovettes, it is to be expected that both collection systems can be used in the pre-analytical stage of molecular biological analyses.

Using enclosed collection systems in favour of open systems distinctly reduces the risk of coming into contact with infective blood. The EDTA concentration and, thus, the sample

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compound is hardly ever impaired by subjective errors, as collection volumes are kept at constant level.
The fact that the plasma can be mixed after having been separated from the blood cells so as to increase the reproducibility of test results is a decisive benefit of the EDTA-Gel system as compared to the EDTA S-Monovettes. Moreover, the EDTA-Gel S-Monovettes may be used for sample storage after plasma separation. To sum up the results obtained, it is to be assumed that EDTA S-Monovettes, above all, represent an optimum alternative to both open and enclosed blood collection systems without gel barrier.

Glossary:

1) T. Hämmerle, et. al.
A sensitive PCR assay system for the quantitation of viral genome equivalents:
Hepatitis C virus (HCV)
Arch Virol (1996) 141: 2103-2114

2) T. Hämmerle, et. al.
A sensitive PCR assay system for the quantitation of viral genome equivalents:
Human immunodeficiency virus type 1 (HIV-1) and hepatitis B virus (HBV)
Arch Virol (1997) 142: 1297-1306

3) G. Davis, et al.
Quantitative detection of hepatitis C virus RNA with a solid phase signal amplification method: Definition of optimal conditions for specimen collection and clinical application in interferon-treated patients.
Hepatology (1994) 19: 1337-1341

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SECTION I

510 (k) Statement

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I. 510 (k) statement according to 21 CFR §807.93

Device identification

Trade Name:	S-Monovette® EDTA K_2-Gel
Common Name:	Blood Collection System
Classification Name	Tubes, Vials, Systems, Serum Separators, Blood Collection 75 JKA 21 CFR 862.1675

I certify in my capacity as General Manager of Sarstedt Inc., I will make available all information included in this premarket notification on safety and effectiveness within 30 days of request by any person if the device described in the premarket notification is determined to be substantially equivalent. The information I agree to make available will be a duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding all patient identifiers, and trade secret and confidential commercial information as defined in 21 CFR 20.61.

(Signature)

Peter Rumswinkel

April 28, 2003

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Section J

Truthful and Accurate Statement

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

Records processed under FOIA Request 2013-6158; Released 10/14/14

J . Truthful and Accurate Statement

As required by 21 CFR 807. 87 (k) I certify that, in my capacity a General Manager of Sarstedt Inc., I believe to the best of my knowledge, that all data and information submitted in this premarket notification are truthful and accurate and that no material fact has been omitted.

(Signature)

Peter Rumswinkel

April 28, 2003

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

Records processed under FOIA Request 2013-6158; Released 10/14/14

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Memorandum

From: Reviewer(s) - Name(s) Ruth Chesler

Subject: 510(k) Number K031359/S1

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

- ☐ Refused to accept.
- ☐ Requires additional information (other than refuse to accept).
- ☒ Is substantially equivalent to marketed devices.
- ☐ NOT substantially equivalent to marketed devices.
- ☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.)

21CFR 862.1675 Tubes, vials, systems, serum separators, blood collection

Is this device subject to Section 522 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)? Please fill out form on H Drive 510k/boilers	☐ YES	☒ NO

Truthful and Accurate Statement ☐ Requested ☒ Enclosed

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

☐ The required certification and summary for class III devices NA

☒ The indication for use form

Combination Product Category (Please see algorithm on H drive 510k/Boilers) No

Animal Tissue Source ☐ YES ☒ NO Material of Biological Origin ☐ YES ☒ N

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

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

Predicate Product Code with class: 75 JKA, Class II

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

Review [signature] OCTD 9/12/03
(Branch Chief) for Jean Cooper (Branch Code) (Date)

Final Review: [signature] 9/12/03
(Division Director) (Date)

Revised 4/2/03

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

Records processed under FOIA Request 2013-6158; Released 10/14/14

Memorandum

Date: July 14, 2003

From: Ruth A. Chesler, Scientific Reviewer, FDA, CDRH, OIVD

To: The Record of PMN, K031359, S-Monovette EDTA K2 Gel

Subject: Telephone Hold

Contact: Mr. Peter Rumswickel

Phone: 1-828-464-4000 FAX 1-828-464-3999

On July 11, 2003, I called Mr. Peter Rumswickel to request additional information. Dr. Guang Gao of CBER, DETTD, OBRR reviewed the submission and requested the following additional information. Mr. Rumswickel was out of the office and I was informed that he would return on July 14, 2003. I called on July 14 and was informed that he would be out of the office until July 21. I spoke with Mr. Hendel and told him that I would send the request for additional information by Fax and that I would place the submission on telephone hold.

(b)(4)

[redacted]

4. Please send revised labeling to reflect the revisions.

5. Please provide a statement to certify conformance with the standard regarding the sterility of the tubes.

Ruth A. Chesler

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

Records processed under FOIA Request 2013-6158; Released 10/14/14

****
*** TX REPORT ***
****

TRANSMISSION OK

TX/RX NO	2944
CONNECTION TEL	918284643999
SUBADDRESS	
CONNECTION ID	SARSTEDT MGMT
ST. TIME	07/14 10:12
USAGE T	00'50
PGS.	3
RESULT	OK

FDA

Center for Devices and Radiological Health
CDRH

Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health
Food & Drug Administration
2098 Gaither Road, HFZ-440
Rockville, Maryland 20850

Office Director's # 301-594-3084 *Chemistry & Toxicology Division # 301-594-1243*
Microbiology Division # 301-594-2096 *Immunology & Hematology Division # 301-594-1293*

FAX # 301-594-5940, 301-594-5941 or 301-827-2704

"THIS DOCUMENT IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER APPLICABLE LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by telephone and return it to us at the above address by mail. Thank you."

To: Mr. Peter Rumswickel 828-464-3999

35

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

Records processed under FOIA Request 2013-6158; Released 10/14/14

FDA

Center for Devices and Radiological Health
CDRH

Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health
Food & Drug Administration
2098 Gaither Road, HFZ-440
Rockville, Maryland 20850

Office Director's # 301-594-3084 *Chemistry & Toxicology Division # 301-594-1243*
Microbiology Division # 301-594-2096 *Immunology & Hematology Division # 301-594-1293*

FAX # 301-594-5940, 301-594-5941 or 301-827-2704

"THIS DOCUMENT IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER APPLICABLE LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by telephone and return it to us at the above address by mail. Thank you."

To: Mr. Peter Rumwickel 828-464-3999
Sarstedt, Inc

From: Ruth Chesler
CDRH/OIVD

Total Pages: 3

Comments:

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

Records processed under FOIA Request 2013-6158; Released 10/14/14

Memorandum

Date: July 14, 2003

From: Ruth A. Chesler, Scientific Reviewer, FDA, CDRH, OIVD

To: Mr. Peter Rumswickel, Sarsted Inc.

Subject: K031359, S-Monovette EDTA K2 Gel

Phone: 1-828-464-4000 FAX 1-828-464-3999

Dear Mr. Rumswickel,

After review of your submission K031359, we request the following additional information. Dr. Guang Gao of CBER, DETTD reviewed the submission and requested the following additional information:

(b)(4)

[redacted]

4. Please send revised labeling to reflect the modifications.

5. Please provide a statement to certify conformance with the standard regarding the sterility of the tubes.

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

Records processed under FOIA Request 2013-6158; Released 10/14/14

We will place your submission on telephone hold until you provide the requested information. Please send your response to the CDRH Document Mail Center, Attention: Ruth Chesler

Thanks,

Ruth

Ruth Chesler

Scientific Reviewer,

FDA/CDRH/OIVD

301-594-1243 X 150

rac@cdrh.fda.gov

Ruth A. Chesler

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

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Chesler, Ruth A

From: Gao, Guang *
Sent: Wednesday, June 25, 2003 10:09 AM
To: Chesler, Ruth A
Cc: Biswas, Robin
Subject: FW:

Good morning, Ruth,
Here is my review memo, Although I have three comments in my memo, the performances of this new device and its predicate are the same.
By the way, do you allow sponsors to have all investigational assay done in other countries?

-----Original Message-----
From: Biswas, Robin
Sent: Tuesday, June 24, 2003 3:41 PM
To: Gao, Guang *
Subject: FW:

Guang: While I concur with your concerns--and these must be transmitted to the primary reviewer at CDRH--please note that for a 510 (k) approval, the investigational assay need only be substantially equivalent (SBE) to the predicate assay.

You can forward this. Robin

-----Original Message-----
From: Gao, Guang *
Sent: Tuesday, June 24, 2003 3:07 PM
To: Biswas, Robin
Subject:

K031359_S_monovette_EDTA K2 Ge...

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

Records processed under FOIA Request 2013-6158; Released 10/14/14

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1401 Rockville Pike
Rockville, MD 20852-1448

Review Memo

STN: 510 (k) K031359

Date: June 24, 2003

Reviewer: Guang Gao, Ph.D, HFM 310, (301) 827-3680

To: Ruth A Chesler, MT, CDRH, OIVD, HFZ440

Through: Robin Biswas, MD, Associate Director, DETTD, OBRR

Sponsor / Product: Sarstedt AG & Co., S-Monovette® EDTA K_2-Gel

Purpose of the Submission: 510 (k) Notification

Summary:
Sarstedt AG & Co has submitted **a** 510 (k) to notify the agency of its intention to induce into interstate commerce a blood tube that results in a plasma specimen for Nucleic Acid Testing (NAT): S-Monovette® EDTA K_2-Gel.

The S-Monovette® EDTA K_2-Gel can be used for collection, processing and transportation of a plasma specimen. Following collection of the blood, the tube can be centrifugated so that the gel creates a barrier between plasma and cellular components. The plasma specimen can then be removed for testing or the specimens can be transported for testing at another location without the plasma mixing with cellular components.

The plasma specimen produced by the S-Monovette® EDTA K_2-Gel can be used for Nucleic Acid Testing by methods such as PCR or for other procedures where the laboratory has determined that a plasma specimen is appropriate.

The sponsor has carried out the following performance evaluation:

(b)(4)

[redacted]

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

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(b)(4)

[redacted]

Questions and Comments:

After reviewing the submission, I have the following comments:

(b)(4)

[redacted]

Records processed under FOIA Request 2013-6158; Released 10/14/14

Interoffice Memorandum

Date: June 6, 2003

To: Guang Gao, Ph.D.
CBER, DETTD
HFM 310
Phone: 301-827-3680
Fax: 301-480-7928

From: Ruth A. Chesler, MT (ASCP), CDRH, OIVD/HFZ-440

Subject: Request for Consultation for K031359

Device: Sarstedt S-Monovette® EDTA K_2-Gel

Dear Dr. Gao,

As we discussed in our phone conversation today, I am requesting a consult review for this device. Please review the submission as a consult and provide review comments and questions/ revisions for the sponsor to me.

This 510(k) is from Sarstedt AG & Co. for a blood collection tube that results in a plasma specimen for Nucleic Acid Testing. The sponsor claims substantial equivalence to the Greiner Vacuette EDTA K2 Tube, which you reviewed in August 2001 (K012043), and the Sarstedt S-Monovette EDTA (pre-amendment). The equivalence study evaluates the equivalence of HIV, HBV and HCV assay results using plasma collected in the Sarstedt S-Monovette EDTA tube vs. the Sarstedt S-Monovette EDTA K2 tube. I would appreciate if you could send me your comments by June 30, 2003.

Thank you very (again) much for your cooperation,

Ruth A Chesler, MT (ASCP)

Ruth A. Chesler
RAC@CDRH.FDA.GOV
HFZ-440
301-594-1243, ext 150
fax 301-594-5940

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

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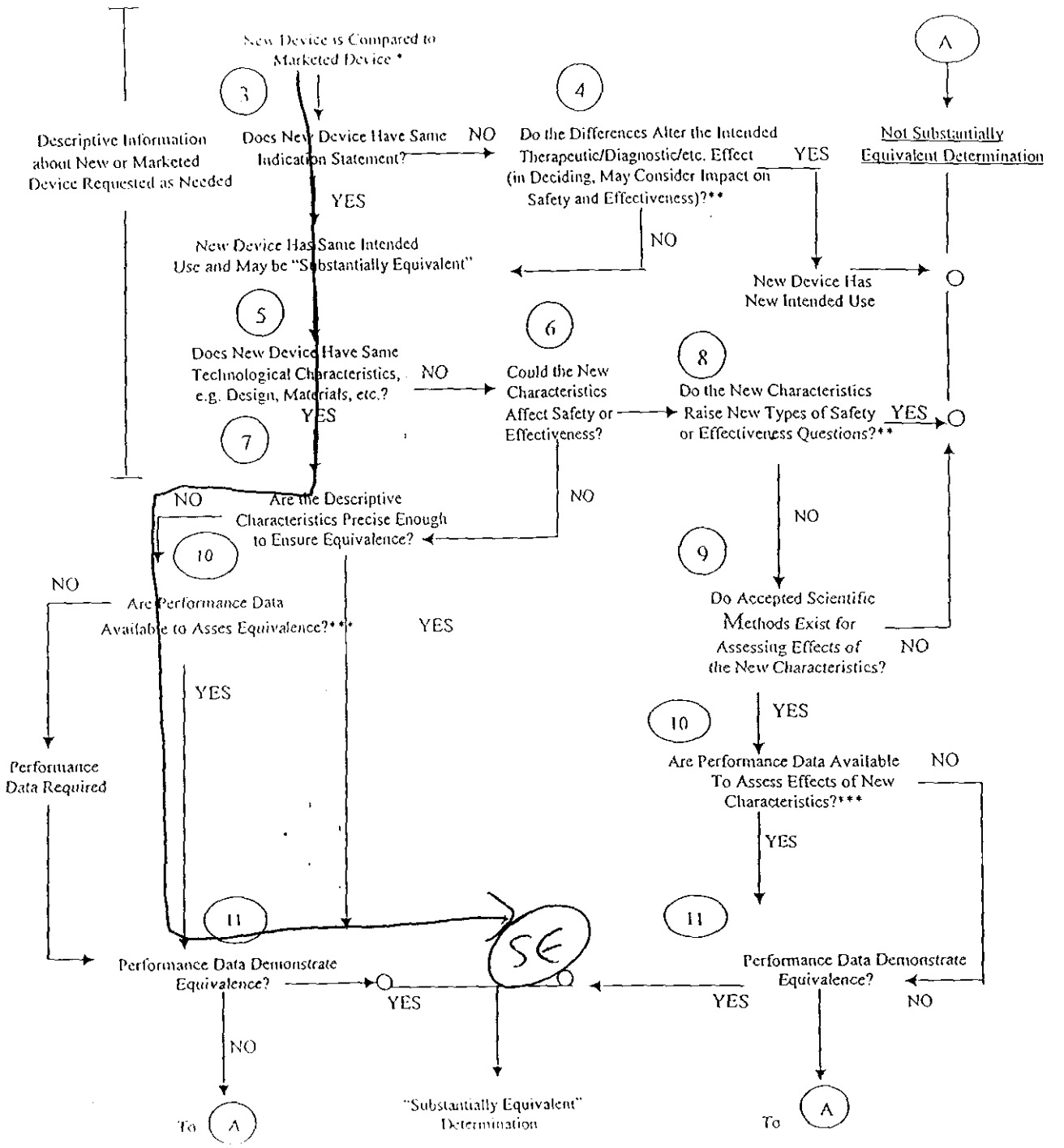
510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



* 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.

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

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REVISED:3/14/95

THE 510(K) DOCUMENTATION FORMS ARE AVAILABLE ON THE LAN UNDER 510(K) BOILERPLATES TITLED "DOCUMENTATION" AND MUST BE FILLED OUT WITH EVERY FINAL DECISION (SE, NSE, NOT A DEVICE, ETC.).

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K031359

Reviewer: Ruth A. Chesler

Division/Branch: OIVD/DCTD/HFZ-440

Device Name: Sarstedt S-Monovette® EDTA K_2-Gel tube

Product To Which Compared: Sarstedt S-Monovette® EDTA tube, pre-amendment

	YES	NO	
1. Is Product A Device	X		If **NO** = Stop
2. Is Device Subject To 510(k)?	X		If **NO** = Stop
3. Same Indication Statement?	X		If **YES** = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If **YES** = Stop **NE**
5. Same Technological Characteristics?	X		If **YES** = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?			If **YES** = Go To 8
7. Descriptive Characteristics Precise Enough?		X	If **NO** = Go To 10 If **YES** = Stop **SE**
8. New Types Of Safety Or Effectiveness Questions?			If **YES** = Stop **NE**
9. Accepted Scientific Methods Exist?			If **NO** = Stop **NE**
10. Performance Data Available?	X		If **NO** = Request Data
11. Data Demonstrate Equivalence?	X		Final Decision:SE

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

Records processed under FOIA Request 2013-6158; Released 10/14/14

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" *response requires an* explanation.

1. Intended Use:

2. Device Description: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device for home use or prescription use? Does the device contain drug or biological product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

1. Explain why not a device:

2. Explain why not subject to 510(k):

3. How does the new indication differ from the predicate device's indication:

4. Explain why there is or is not a new effect or safety or effectiveness issue:

5. Describe the new technological characteristics:

6. Explain how new characteristics could or could not affect safety or effectiveness:

7. Explain how descriptive characteristics are not precise enough:
   Because the clinical use of this *in vitro* diagnostic device is based upon its performance characteristics, descriptive characteristics alone are not sufficient to support a claim of substantial equivalence to marketed *in vitro* diagnostic devices.

8. Explain new types of safety or effectiveness questions raised or why the questions are not new:

9. Explain why existing scientific methods can not be used:

10. Explain what performance data is needed:
    The performance data in support of a claim of substantial equivalence include the following: comparison studies, stability studies

11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:
    Because the performance data are customary for an *in vitro* diagnostic device measuring this analyte, these data demonstrate that the device is substantially equivalent.

ATTACH ADDITIONAL SUPPORTING INFORMATION

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

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Internal Administrative Form

K03 1359

	Yes	No
1. Did the firm request expedited review?		X
2. Did we grant expedited review?		X
3. Have you verified that the document is labeled Class III for GMP purposes?		X
4. If not, has POS been notified?		X
5. Is the product a device?	X	
6. Is the device exempt from 510(k) by regulation or policy?		X
7. Is the device subject to review by CDRH?	X	
8. Are you aware that this device has been the subject of a previous NSE decision?		X
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?		X
11. If yes, consult the ODE Integrity Officer.		
12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #191-2 and Federal Register 90N0332, September 10, 1991.)		

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

Records processed under FOIA Request 2013-6158; Released 10/14/14

510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE

A. 510(k) Number:
K031359

B. Analyte:
Blood collection tube

C. Type of Test:
Collection, processing and transportation of a plasma sample for Nucleic Acid Testing (NAT)

D. Applicant:
Sarstedt Inc.

E. Proprietary and Established Names:
S-Monovette® EDTA K_2-Gel

F. Regulatory Information:

1. Regulation section:
   862.1675; Tubes, vials, systems, serum separators, blood collection
2. Classification:
   Class II
3. Product Code:
   JKA
4. Panel:
   75

G. Intended Use:

1. Indication(s) for use:
   The S-Monovette® EDTA K_2-Gel tube provides a means for collection, processing, and transportation of a plasma specimen in a closed system. Following collection of the blood, the S-Monovette® EDTA K_2 Gel is to be centrifuged such that the gel creates a barrier between the plasma and cellular components. The plasma specimen can then be removed for testing or the specimen can then be removed for testing, or the specimen can be transported for testing at another location without the plasma mixing with the cellular components. The plasma specimen produced by the S-Monovette® EDTA K_2 Gel can be used for Nucleic Acid Testing (NAT) by methods such as PCR - Polymerase chain reaction or other procedures where the laboratory has determined that a plasma specimen is appropriate.
2. Special condition for use statement(s):
   NA
3. Special instrument Requirements:
   NA

H. Device Description:
The S-Monovette® EDTA K_2 Gel tube is manufactured from plastic materials and incorporates a screw cap with membrane, a tube, a plunger, and a piston. The screw

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

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cap is designed with three pins which function as a lock for the needle to attach. The S-Monovette® can be filled by two methods: the vacuum principle and the aspiration principle. In the vacuum principle, the S-Monovette® is evacuated prior to blood collection by pulling the plunger until the piston locks in the base of the tube. Once this occurs, the plunger is broken off. The needle is inserted into the vein, the pre-evacuated S-Monovette® is then attached to the needle by inserting the cap onto the back of the needle and turning the S-Monovette® clockwise to lock the pins. Multiple samples can be taken without removing the needle from the vein by removing the previous S-Monovette® by turning it counter-clockwise to unlock the pins and then inserting the next S-Monovette®. In the aspiration principle, the S-Monovette® is attached to the needle and the needle is inserted into the vein. The blood is drawn into the S-Monovette® by the user pulling back on the plunger until the piston reaches the base of the tube. The S-Monovette® is removed from the needle and the piston is locked in the base of the tube. Multiple samples can be taken in the same manner. This principle allows the user to adjust the flow rate into the S-Monovette®. EDTA K_2 is used as the anticoagulant and an acrylic/silicon gel for separation. The S-Monovette® EDTA K_2 Gel is available in 4.9 and 9.0 mL volumes.

I. Substantial Equivalence Information:

1. Predicate device name(s):
   Sarstedt S-Monovette® EDTA tube
2. Predicate K number(s):
   Pre-amendment
3. Comparison with predicate:

Similarities		
Item	**S-Monovette® EDTA K_2**	**S-Monovette® EDTA**
Material	Plastic	Plastic
Collection method	Aspiration principle or vacuum	Aspiration principle or vacuum
Differences		
Item	**S-Monovette® EDTA K_2**	**S-Monovette® EDTA**
Anticoagulant	EDTA K_2	EDTA K_3
Gel	Acrylic polymer and silicone dioxide mixture	None
Performance	Provides plasma specimen for molecular diagnostic testing (PCR)	No claim

J. Standard/Guidance Document Referenced (if applicable):

ANSI/AAMI/ISO 11137 - 1994, Sterilization of Health Care Products - Requirements for Validation and Routine Control - Radiation Sterilization; ISO 6710 - Single Use Containers for Blood Specimen Collection

K. Test Principle:

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

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The mean concentration of 1.6 mg EDTA/mL blood (when filled to the nominal volume specified) serves as an anticoagulant. When centrifuged, the blood sample results in a nearly undiluted plasma sample.

L. Performance Characteristics (if/when applicable):

1. Analytical performance:
   - *a. Precision/Reproducibility:*
     NA
   - *b. Linearity/assay reportable range:*
     NA
   - *c. Traceability (controls, calibrators, or method):*
     NA
   - *d. Detection limit:*
     NA
   - *e. Analytical specificity:*
     NA
   - *f. Assay cut-off:*
     NA
2. Comparison studies:
   - *a. Method comparison with predicate device:*
     (b)(4) [redacted]
   - *b. Matrix comparison:*
     NA
3. Clinical studies:
   - *a. Clinical sensitivity:*
     NA
   - *b. Clinical specificity:*
     NA
   - *c. Other clinical supportive data (when a and b are not applicable):*
     NA
4. Clinical cut-off:
   NA
5. Expected values/Reference range:

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

Records processed under FOIA Request 2013-6158; Released 10/14/14

NA

M. Conclusion:

Based upon review of the information provided in this 510(k), I recommend that this device is substantially equivalent to devices regulated by 21 CFR 809.10; and regulations 21 CFR 862.1675, tubes, vials, systems, serum separators, blood collection; 75 JKA; Class II.

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

Records processed under FOIA Request 2013-6158; Released 10/14/14

N. Other Supportive Information:
The form *Certification: Financial Interests and Arrangements of Clinical Investigators* is included.

O. Administrative Information:

1. Applicant contact information:

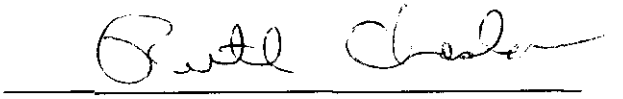
   a. *Name of applicant*:
   Sarstedt, Inc.
   b. *Mailing address*:
   P.O. Box 468
   Newton, NC 28658
   c. *Phone #*:
   828-465-4000
   d. *Fax #*:
   828-464-3999
   e. *E-mail address (optional)*:

   f. *Contact*:
   Mr. Peter Rumswinkel
   Ms. Susan Smith

2. Review documentation:

June 6, 2003	Consult review requested from Dr. Guang Gao of CBER, DETTD
June 25, 2003	Dr. Gao's review received
July 14, 2003	Additional information requested, telephone hold
August 11, 2003	Teleconference with sponsor
August 13, 2003	Additional information received by DMC
August 29, 2003	Additional information, financial disclosure form requested from sponsor
September 8, 2003	Additional information received
September 9, 2003	Reviewer recommends SE

P. Reviewer Name and Signature:



Ruth Chesler
CDRH/OIVD/DCTD

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

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FAX TRANSMISSION

SARSTEDT P.O. Box 468 Newton, NC 28658 Tel.: (828) 465-4000 Fax: (828) 465-0718

Fax No: 301-594-5940	Total Pages: 2	Date: September 8, 2003
To: Food and Drug Administration		
Attn: Ruth Chesler		
From: Sarstedt, Inc.	Sender: Susan Smith	

RE: **K031359 510(k) Notification, S-Monovette® EDTA K_2-Gel**

Attached you will find the completed Financial Interest Statement as requested.

Sincerely,

SARSTEDT, INC.

Susan S. Smith
Quality Assurance Manager

Peter Rumswinkel
VP/General Manager

NOTICE OF CONFIDENTIALITY

The information contained in and transmitted with this facsimile may be confidential, subject to the attorney-client privilege, attorney work Product, and/or exempt from disclosure under applicable law and is intended only for the individual or entity named above. If you are not the intended recipient, you are hereby notified that inadvertent disclosure of this information to you does not constitute a waiver of confidentiality or privilege and that any review, disclosure, copying, or use of the contents of the facsimile by you is prohibited. If you have received this facsimile in error, please immediately call the sender collect at the above phone number, so that we can arrange for the return of the original facsimile at our cost.

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

Records processed under FOIA Request 2013-6158; Released 10/14/14

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration

Form Approved: OMB No. 0910-0396
Expiration Date: 3/31/02

CERTIFICATION: FINANCIAL INTERESTS AND ARRANGEMENTS OF CLINICAL INVESTIGATORS

TO BE COMPLETED BY APPLICANT

With respect to all covered clinical studies (or specific clinical studies listed below (if appropriate)) submitted in support of this application, I certify to one of the statements below as appropriate. I understand that this certification is made in compliance with 21 CFR part 54 and that for the purposes of this statement, a clinical investigator includes the spouse and each dependent child of the investigator as defined in 21 CFR 54.2(d).

Please mark the applicable checkbox.

☒ (1) As the sponsor of the submitted studies, I certify that I have not entered into any financial arrangement with the listed clinical investigators (enter names of clinical investigators below or attach list of names to this form) whereby the value of compensation to the investigator could be affected by the outcome of the study as defined in 21 CFR 54.2(a). I also certify that each listed clinical investigator required to disclose to the sponsor whether the investigator had a proprietary interest in this product or a significant equity in the sponsor as defined in 21 CFR 54.2(b) did not disclose any such interests. I further certify that no listed investigator was the recipient of significant payments of other sorts as defined in 21 CFR 54.2(f).

(b) (6)

[redacted]

☐ (2) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that based on information obtained from the sponsor or from participating clinical investigators, the listed clinical investigators (attach list of names to this form) did not participate in any financial arrangement with the sponsor of a covered study whereby the value of compensation to the investigator for conducting the study could be affected by the outcome of the study (as defined in 21 CFR 54.2(a)); had no proprietary interest in this product or significant equity interest in the sponsor of the covered study (as defined in 21 CFR 54.2(b)); and was not the recipient of significant payments of other sorts (as defined in 21 CFR 54.2(f)).

☐ (3) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that I have acted with due diligence to obtain from the listed clinical investigators (attach list of names) or from the sponsor the information required under 54.4 and it was not possible to do so. The reason why this information could not be obtained is attached.

NAME	TITLE
Jochen Hoffmann	Official Correspondent
FIRM/ORGANIZATION: Sarstedt AG & Co. KG	
SIGNATURE	DATE: September 8, 2003

Paperwork Reduction Act Statement

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Public reporting burden for this collection of information is estimated to average 1 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the necessary data, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information to the address to the right:

Department of Health and Human Services
Food and Drug Administration
5600 Fishers Lane, Room 14C-03
Rockville, MD 20857

FORM FDA 3454 (3/99)

Created by Electronic Document Services/USDHHS (301) 443-2454 EF

GESAMT SEITEN 02

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

Records processed under FOIA Request 2013-6158; Released 10/14/14

Telephone Memorandum

Date: September 8, 2003

From: Ruth A. Chesler, Scientific Reviewer, FDA, CDRH, OIVD

To: Ms. Susan Smith, Sarsted Inc.

Subject: K031359, S-Monovette EDTA K2 Gel

Phone: 1-828-464-4000 FAX 1-828-464-3999

I spoke with Ms. Smith on August 29, 2003 and asked her to provide the form Certification: Financial Interests and Arrangements of Clinical Investigators. She sent the signed form by Fax on September 8, 2003.

Ruth Chesler
Scientific Reviewer,
FDA/CDRH/OIVD
301-594-1243 X 150
rac@cdrh.fda.gov

Ruth A. Chesler

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

Records processed under FOIA Request 2013-6158; Released 10/14/14

RE Sarstedt Inc. 510 (k) K031359 S-Monovette EDTA K2 Gel.txt

From: Gao, Guang *
Sent: Thursday, August 14, 2003 11:20 AM
To: Chesler, Ruth A
Subject: RE: Sarstedt, Inc. / 510 (k) K031359 S-Monovette EDTA K2 Gel

Yes, it is acceptable.
Thank you, Ruth.

-----Original Message-----
From: Chesler, Ruth A
Sent: Thursday, August 14, 2003 10:29 AM
To: Gao, Guang *
Subject: FW: Sarstedt, Inc. / 510 (k) K031359 S-Monovette EDTA K2 Gel

Hi Guang,

Thanks so much for discussing this with Sarstedt. Can you look at the labeling and let me know if it is acceptable to you?

Thanks again,
Ruth

-----Original Message-----
From: Sarstedt, Inc. [mailto:sarstedt@bellsouth.net]
Sent: Wednesday, August 13, 2003 11:07 AM
To: RAC@CDRH.FDA.GOV
Subject: Sarstedt, Inc. / 510 (k) K031359 S-Monovette EDTA K2 Gel

As discussed you will find our response (three files) to your memorandum dated July 14, 2003. The original documents have been sent to the Document Mail Center.

Best Regards,

Susan Smith
Sarstedt, Inc.

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

Records processed under FOIA Request 2013-6158; Released 10/14/14

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

August 13, 2003

SARSTEDT, INC.
1025 ST. JAMES CHURCH RD.
NEWTON, NC 28658
ATTN: PETER RUMSWINKEL

510(k) Number: K031359
Product: S-MONOVETTE EDTA K2-GEL

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. 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 one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

If you have procedural or policy questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

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

Records processed under FOIA Request 2013-6158; Released 10/14/14

K031359/S1

SARSTEDT

Instruments
and Disposables
for Medicine
and Science

Sarstedt, Inc. • P.O. Box 468 • Newton, NC 28658-0468

August 12, 2003

Attention: Ruth Chesler
Document Mail Center (HFZ 401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850 USA

FDA/CDRH
2003 AUG 13 A 11: 2

K031359
510(k) Notification, S-Monovette® EDTA K_2-Gel

Dear Ms. Chesler,

This letter is in response to your fax memorandum dated July 14, 2003 regarding the above mentioned 510(k) submission. Our responses are as follows:

(b)(4)

[redacted]

Sarstedt, Inc.
P.O. Box 468
Newton, NC 28658-0468

Phone (828) 465-4000 Corporate
Telefax (828) 465-0718 Corporate
Phone (800) 257-5101 Sales
Telefax (828) 465-4003 Sales

SKI 19

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

Records processed under FOIA Request 2013-6158; Released 10/14/14

If you have any additional questions regarding our submission or this response, please contact Peter Rumswinkel by phone at (828) 465-4000, by fax at (828) 464-3999 or by e-mail at sarstedt@bellsouth.net

Sincerely,

SARSTEDT, INC.

Peter Rumswinkel
VP/General Manager

Enclosures (in duplicate)

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

Records processed under FOIA Request 2013-6158; Released 10/14/14

ATTACHMENT I

S-Monovette® EDTA K_2-Gel

Intended Use of S-Monovette® EDTA K_2-Gel

The S-Monovette® EDTA K_2-Gel is intended for use as a blood collection, processing and transport device. After processing by centrifugation, the S-Monovette® EDTA K_2-Gel produces a plasma specimen for molecular diagnostic testing (such as PCR) or for other procedures where the laboratory has determined that a plasma specimen is appropriate.

Principle

The mean concentration of 1.6 mg EDTA/ml blood (when filled to the nominal volume specified on the device) serves as an anticoagulant. When centrifuged the blood sample results in a nearly undiluted (<1%) plasma specimen.

Reagents

The mean concentration of the anticoagulant is: EDTA-K_2 at a concentration of 1.6 mg EDTA/ml blood

The S-Monovette® Needle or Multifly® Needle is required for venous collection. The S-Monovette® Needle and Multifly® Needle are sold separately. The S-Monovette® Needle Protector for the S-Monovette® Needle is also sold separately. Equipment for processing and analysis of the specimen are not included.

Warning: For In Vitro Diagnostic Use Only. The S-Monovette® EDTA K_2-Gel is for blood collection only. Do not use for injection. Use with S-Monovette® Needle/Adapter or Multifly® Needle Only.

Specimens should be handled using aseptic techniques to avoid contamination. All specimens should be assumed as containing infectious organisms and should be handled with the appropriate precautions. Specimens should be disposed of in accordance with the user's local and state regulations.

Instructions for Use (see pictures on inside of box)

Aspiration principle: Assemble S-Monovette® and needle (1) puncture vein, loosen tourniquet and draw up blood (2) When multiple sampling, secure the subsequent S-Monovette® onto the needle that is still in the vein and collect blood in the manner described above. Remove final S-Monovette® from the needle (3) Finally remove the needle from the vein. Withdraw the piston past the stop mark and lock into the base of the S-Monovette®. Snap off piston rod (4), mix S-Monovette® thoroughly with anticoagulants.

Vacuum principle: Prior to blood collection, lock the piston into the base of the S-Monovette®. Once secured, the plunger must be snapped off (5). Insert the pre-evacuated S-Monovette® onto the needle already located in the vein (6). After multiple sampling remove the final S-Monovette® from the needle (7). Finally, remove the needle from the vein, mix S-Monovette® thoroughly with anticoagulants.

Recommended centrifugation: 2500 x g/10 minutes at 22 - 25°C. For optimal gel integrity, samples should be centrifuged in a swing-out or horizontal rotor.

Storage of the specimen before centrifugation should be minimized and should not exceed 24 hours or the limit specified by local or regional regulations.

Limitations

This device has been tested for molecular diagnostic testing (PCR) for HIV, HCV and HBV.

Expected Values

Recovery of HIV, HBV, and HCV from specimens collected with the S-Monovette® EDTA K_2-Gel is within the expected performance of the PCR test.

Performance Characteristics

After spiking the samples with low levels of HIV, HCV and HBV (1000 ge/ml, 1000 ge/ml and 500 ge/ml, respectively), the S-Monovette® EDTA K_2-Gel was found not to interfere with PCR testing. This is true with storage at room temperature for 24 hours, and storage at 4°C for up to 96 hours.

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

Records processed under FOIA Request 2013-6158; Released 10/14/14
ATTACHMENT I

S-Monovette® EDTA K_2-Gel

Intended Use of S-Monovette® EDTA K_2-Gel

The S-Monovette® EDTA K_2-Gel is intended for use as a blood collection, processing and transport device. After processing by centrifugation, the S-Monovette® EDTA K_2-Gel produces a plasma specimen for molecular diagnostic testing (such as PCR) or for other procedures where the laboratory has determined that a plasma specimen is appropriate.

Principle

The mean concentration of 1.6 mg EDTA/ml blood (when filled to the nominal volume specified on the device) serves as an anticoagulant. When centrifuged the blood sample results in a nearly undiluted (<1%) plasma specimen.

Reagents

The mean concentration of the anticoagulant is: EDTA-K_2 at a concentration of 1.6 mg EDTA/ml blood

The S-Monovette® Needle or Multifly® Needle is required for venous collection. The S-Monovette® Needle and Multifly® Needle are sold separately. The S-Monovette® Needle Protector for the S-Monovette® Needle is also sold separately. Equipment for processing and analysis of the specimen are not included.

Warning: For In Vitro Diagnostic Use Only. The S-Monovette® EDTA K_2-Gel is for blood collection only. Do not use for injection. Use with S-Monovette® Needle/Adapter or Multifly® Needle Only.

Specimens should be handled using aseptic techniques to avoid contamination. All specimens should be assumed as containing infectious organisms and should be handled with the appropriate precautions. Specimens should be disposed of in accordance with the user's local and state regulations.

Instructions for Use (see pictures on inside of box)

Aspiration principle: Assemble S-Monovette® and needle (1) puncture vein, loosen tourniquet and draw up blood (2) When multiple sampling, secure the subsequent S-Monovette® onto the needle that is still in the vein and collect blood in the manner described above. Remove final S-Monovette® from the needle (3) Finally remove the needle from the vein. Withdraw the piston past the stop mark and lock into the base of the S-Monovette®. Snap off piston rod (4), mix S-Monovette® thoroughly with anticoagulants.

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Limitations

This device has been tested for molecular diagnostic testing (PCR) for HIV, HCV and HBV.

Expected Values

Recovery of HIV, HBV, and HCV from specimens collected with the S-Monovette® EDTA K_2-Gel is within the expected performance of the PCR test.

Performance Characteristics

After spiking the samples with low levels of HIV, HCV and HBV (1000 ge/ml, 1000 ge/ml and 500 ge/ml, respectively), the S-Monovette® EDTA K_2-Gel was found not to interfere with PCR testing. This is true with storage at room temperature for 24 hours, and storage at 4°C for up to 96 hours.

SARSTEDT

Aktiengesellschaft & Co.
D-51588 Nümbrecht

For In Vitro Diagnostic Use Only
Technical Modifications Reserved
August 2003

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

Records processed under FOIA Request 2013-6158; Released 10/14/14

ATTACHMENT II

Declaration of Conformance to a Standard

SARSTEDT AG & Co. certifies that the sterilization of the S-Monovette® EDTA K_2-Gel is in conformance with the following standard.

ANSI/AAMI/ISO 11137 - 1994 Sterilization of Health Care Products – Requirements for Validation and Routine Control - Radiation Sterilization

In my capacity as Vice President/General Manager of Sarstedt, Inc. certify that the above claims made by SARSTEDT AG & CO. are correct.

Peter Rumswinkel
Vice President/General Manager

August 12, 2003

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

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Peter Rumswinkel
Vice President/General Manager

August 12, 2003

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

Records processed under FOIA Request 2013-6158; Released 10/14/14

Chesler, Ruth A

From: Sarstedt, Inc. [sarstedt@bellsouth.net]
Sent: Wednesday, August 13, 2003 11:07 AM
To: RAC@CDRH.FDA.GOV
Subject: Sarstedt, Inc. / 510 (k) K031359 S-Monovette EDTA K2 Gel

Product Insert.doc (67 KB) | Declaration of Conformance to ... | Cover letter.doc (35 KB)

As discussed you will find our response (three files) to your memorandum dated July 14, 2003. The original documents have been sent to the Document Mail Center.

Best Regards,

Susan Smith
Sarstedt, Inc.

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

Records processed under FOIA Request 2013-6158; Released 10/14/14

August 12, 2003

Attention: Ruth Chesler
Document Mail Center (HFZ 401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850 USA

K031359
510(k) Notification, S-Monovette® EDTA K_2-Gel

Dear Ms. Chesler,

This letter is in response to your fax memorandum dated July 14, 2003 regarding the above mentioned 510(k) submission. Our responses are as follows:

(b)(4)

[redacted]

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

Records processed under FOIA Request 2013-6158; Released 10/14/14

If you have any additional questions regarding our submission or this response, please contact Peter Rumswinkel by phone at (828) 465-4000, by fax at (828) 464-3999 or by e-mail at sarstedt@bellsouth.net

Sincerely,

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Peter Rumswinkel
VP/General Manager

Enclosures (in duplicate)

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Records processed under FOIA Request 2013-6158; Released 10/14/14

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Reagents

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

Records processed under FOIA Request 2013-6158; Released 10/14/14

Declaration of Conformance to a Standard

SARSTEDT AG & Co. certifies that the sterilization of the S-Monovette® EDTA K_2-Gel is in conformance with the following standard.

ANSI/AAMI/ISO 11137 - 1994 Sterilization of Health Care Products – Requirements for Validation and Routine Control - Radiation Sterilization

In my capacity as Vice President/General Manager of Sarstedt, Inc. certify that the above claims made by SARSTEDT AG & CO. are correct.

_____
Peter Rumswinkel
Vice President/General Manager

August 12, 2003

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

Records processed under FOIA Request 2013-6158; Released 10/14/14

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1401 Rockville Pike
Rockville, MD 20852-1448

Teleconference Minutes

STN: K031359

Date: August 11, 2003

Reviewer: Guang Gao, Ph.D, HFM 310, (301) 827-3680

To: Ruth A. Chesler, Scientific Reviewer, OIVD, CDRH, FDA

Sponsor / Product: Sarstedt, Inc., S-Monovette EDTA K2 Gel Tube

Attendees:

Sarstedt: Mr. Hoffman, Dr. Harnisch, Dr. Gubbe
FDA: Dr. Gao

Background:

FDA sent a review memo to Sarstedt, Inc on July 14, 2003 regarding its K031359, S-Monovette EDTA K2 Gel. In the memo, we listed 5 items which need the sponsor to provide additional information. The telecon was requested and set up by Susan Smith, Quality Assurance Manager of Sarstedt.

(b)(4)

[redacted]

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

Records processed under FOIA Request 2013-6158; Released 10/14/14

From: Chesler, Ruth A
Sent: Monday, August 04, 2003 4:37 PM
To: Gao, Guang *
Subject: RE: Saratedt, K031359

If you want to talk with them by telecon, I think that would be adequate. I don't know if I have anything more to add. If you want me to be there by phone, I will be here Wednesday but not Thursday. Next Monday I have a meeting from 9-10. Attached is a copy of the questions I asked them, which are mostly yours. I don't think we have access to video conferencing either.

Phone hold memo.doc
(32 KB)

Thanks, Ruth

-----Original Message-----

From: Gao, Guang *
Sent: Monday, August 04, 2003 4:00 PM
To: Chesler, Ruth A
Cc: Biswas, Robin
Subject: Saratedt, K031359

Ruth,
Susan Smith, Vice President of Sarstedt, just called regarding our questions in the review memo for 510 (k) K031359, Sarstedt AG & Co., S-Monovetteâ EDTA K_2-Gel. She wanted to a vidio-telecon with their testing site in Germany. I think my questions were small and telecon should solve them. I was just wondering if you should present at the telecon and I don't know if we have the access to video telecon. They proposed following time: Wed, Thur. AM before 10, Next Monday and Tuesday.
Let me know what you think. Thanks.

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