



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

Mr. Harry Bala
President
Dana Products, Incorporated
7 Corey Drive
South Barrington, Illinois 60010

MAR 18 2010

Re: K092944

Trade/Device Name: Reusable Biological Indicator and Integrator Test Pack for Steam
Regulation Number: 21CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: II
Product Code: FRC
Dated: March 7, 2010
Received: March 10, 2010

Dear Mr. Bala:

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

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

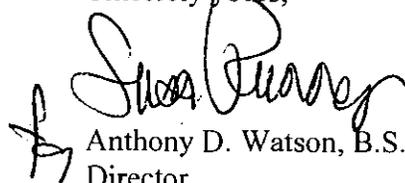
Page 2- Mr. Bala

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director

Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K092944

Device Name: Reusable Biological Indicator and Integrator Test Pack for Steam Sterilization.

Indications For Use:

Dana reusable test pack is designed to challenge steam sterilization process in healthcare facilities. It is intended to be used for routine monitoring of pre-vacuum steam sterilization cycles. It is validated to be used in 4 minute 270°F pre-vacuum steam sterilization cycles with 3M's 1292 Rapid Readout Biological Indicators along with or without SteriScan Integrators.

Prescription Use _____ AND/OR
(Part 21 CFR 801 Subpart D)

Over-The-Counter Use X
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elaine S. Marshall (Acting BC)
(Division Sign-Off) 3-18-10
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

Page 1 of 1

510(k) Number: K092944



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10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

Mr. Harry Bala
President
Dana Products, Incorporated
7 Corey Drive
South Barington, Illinois 60010

MAR 18 2010

Re: K092944

Trade/Device Name: Reusable Biological Indicator and Integrator Test Pack for Steam
Regulation Number: 21CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: II
Product Code: FRC
Dated: March 7, 2010
Received: March 10, 2010

Dear Mr. Bala:

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

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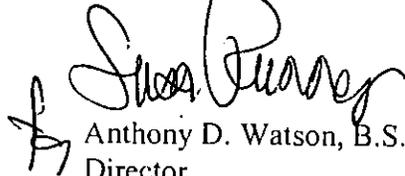
Page 2- Mr. Bala

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

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director

Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DJA 00003

Indications for Use

510(k) Number (if known): K092944

Device Name: Reusable Biological Indicator and Integrator Test Pack for Steam Sterilization.

Indications For Use:

Dana reusable test pack is designed to challenge steam sterilization process in healthcare facilities. It is intended to be used for routine monitoring of pre-vacuum steam sterilization cycles. It is validated to be used in 4 minute 270°F pre-vacuum steam sterilization cycles with 3M's 1292 Rapid Readout Biological Indicators along with or without SteriScan Integrators.

Prescription Use _____ AND/OR
(Part 21 CFR 801 Subpart D)

Over-The-Counter Use X
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elaine S. Marshall (Acting BC)
(Division Sign-Off) 3-18-10
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

Page 1 of 1

510(k) Number: K092944



U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

December 30, 2009

DANA PRODUCTS, INC.
7 COREY DR.
SOUTH BARRINGTON, ILLINOIS 60010
UNITED STATES
ATTN: HARRY BALA

510k Number: K092944

Product: DANA REUSABLE TEST PACK FOR ST

Extended Until: 06/04/2010

Based on your recent request, an extension of time has been granted for you to submit the additional information we requested.

If the additional information (AI) is not received by the "Extended Until" date shown above, your premarket notification will be considered withdrawn (21 CFR 807.87(l)). If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely yours,

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

DANA PRODUCTS, INC.
7 COREY DRIVE
SOUTH BARRINGTON, IL 60010
TEL. 847-455-2881 FAX. 847-455-2886

December 22, 2009

Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Document Mail Center - W 066-0609
10903 New Hampshire Ave.
Silver Spring, Maryland 20993-0002

FDA CDRH DMC

DEC 23 2009

~~DEC 22 2009~~

Received

12/11

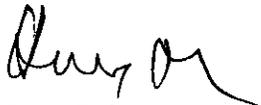
Dear Sir or Madam:

510(k) Number: K092944 Dana Reusable Test Pack - Your request for additional information dated December 08, 2009

I request you to grant us **180 days extension** to submit the additional information.

Thanking you.

Very truly Yours,



Harry Bala
President

DJA 00194

DJA 00195

DANA PRODUCTS, INC.
7 COREY DRIVE
SOUTH BARRINGTON, IL 60010
TEL. 847-455-2881 FAX. 847-455-2886

December 22, 2009

Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Document Mail Center - W 066-0609
10903 New Hampshire Ave.
Silver Spring, Maryland 20993-0002

FDA CDRH DMC

DEC 22 2009

Received

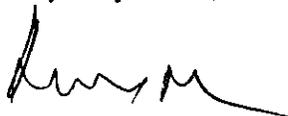
Dear Sir or Madam:

510(k) Number: K092944 Dana Reusable Test Pack - Your request for additional information dated December 08, 2009

I request you to grant us **180 days extension** to submit the additional information.

Thanking you.

Very truly Yours,



Harry Bala
President



U.S. Food and Drug Administration
 Center for Devices and Radiological Health
 Document Mail Center – WO66-G609
 10903 New Hampshire Avenue
 Silver Spring, MD 20993-0002

December 08, 2009

DANA PRODUCTS, INC.
 7 COREY DR.
 SOUTH BARRINGTON, ILLINOIS 60010
 UNITED STATES
 ATTN: HARRY BALA

510k Number: K092944

Product: DANA REUSABLE TEST PACK FOR ST

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 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 <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm>.

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/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceProvisionsofFDAModer nizationAct/ucm136685.htm>.

If after 30 days the additional information (AI), 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 (21 CFR 807.87(l)). Please note our guidance document entitled, "Guidance for Industry and FDA Staff, FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request. The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089735.htm>. 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.

DJA 00197

Records processed under FOIA Request # 2015-08131. Released by CDRH on 02/04/2016
Please remember that the safe Medical Device Act of 2013 states that you may not place a device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely yours,

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



U.S. Food and Drug Administration
 Center for Devices and Radiological Health
 Document Mail Center - WO66-G609
 10903 New Hampshire Avenue
 Silver Spring, MD 20993-0002

September 28, 2009

DANA PRODUCTS, INC.
 7 COREY DR.
 SOUTH BARRINGTON, ILLINOIS 60010
 UNITED STATES
 ATTN: HARRY BALA

510k Number: K092944

Received: 9/25/2009

Product: DANA REUSABLE TEST PACK FOR ST

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification, (510(k)), you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product and for the above referenced 510(k) submitter. Please note, if the 510(k) submitter is incorrect, please notify the 510(k) Staff immediately. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. We will notify you when the processing of your 510(k) 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.**

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 510(k) submission.

On September 27, 2007, the President signed an act reauthorizing medical device user fees for fiscal years 2008 - 2012. The legislation - the Medical Device User Fee Amendments of 2007 is part of a larger bill, the Food and Drug Amendments Act of 2007. Please visit our website at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/default.htm>

for more information regarding fees and FDA review goals. In addition, effective January 2, 2008, any firm that chooses to use a standard in the review of ANY new 510(k) needs to fill out the new standards form (Form 3654) and submit it with their 510(k). The form may be found at <http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm>.

We remind you that Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) amended the PHS Act by adding new section 402(j) (42 U.S.C. § 282(j)), which expanded the current database known as ClinicalTrials.gov to include mandatory registration and reporting of results for applicable clinical trials of human drugs (including biological products) and devices. Section 402(j) requires that a certification form <http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm> accompany 510(k)/HDE/PMA submissions. The agency has issued a draft guidance titled: "Certifications To Accompany Drug, Biological

Records processed under FOIA Request # 2015-8131; Released by CDRH on 02-01-2016
Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007”
<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134034.htm>. According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

Please note the following documents as they relate to 510(k) review: 1) Guidance for Industry and FDA Staff entitled, “Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements”. This guidance can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm>. Please refer to this guidance for information on a formalized interactive review process. 2) Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm>. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.html>. In addition, the 510(k) Program Video is now available for viewing on line at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm070201.htm>.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm>. If you have questions on the status of your submission, please contact DSMICA at (301)796-7100 or the toll-free number (800)638-2041 , or at their internet address <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm>. If you have procedural questions, please contact the 510(k) Staff at (301)796-5640.

Sincerely,

510(k) Staff



U.S. Food and Drug Administration
 Center for Devices and Radiological Health
 Document Mail Center – WO66-G609
 10903 New Hampshire Avenue
 Silver Spring, MD 20993-0002

September 25, 2009

DANA PRODUCTS, INC.
 7 COREY DR.
 SOUTH BARRINGTON, ILLINOIS 60010
 UNITED STATES
 ATTN: HARRY BALA

510k Number: K092944

Received: 9/24/2009

User Fee ID Number: (b)(4)

Product: DANA REUSABLE TEST PACK

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 all 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 Federal Food, Drug, and Cosmetic Act (the Act), as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) and the FDA Amendments Act of 2007 (FDAAA) (Public Law 110-85), authorizes FDA to collect user fees for certain types of 510(k) submissions. The submission cannot be accepted for review until the fee is paid in full ; therefore, the file has been placed on hold. When your user fee payment has been received , review of the 510(k) will resume as of that date. Alternatively, you may request withdrawal of your submission. You now have the option to pay online by credit card. We recommend this form of payment. Credit card payments are directly linked to your user fee cover sheet and are processed the next business day. You may also pay by check. If you choose to mail a check, please send a check to one of the addresses listed below:

By Regular Mail

Food and Drug Administration
 P.O. Box 956733
 St. Louis, MO 63195-6733.

By Private Courier(e.g.,Fed Ex, UPS, etc.)

U.S. Bank
 956733
 1005 Convention Plaza
 St. Louis, MO 63101
 (314) 418-4983

The check should be made out to the Food and Drug Administration referencing the payment identification number, and a copy of the User Fee Cover sheet should be included with the check. A copy of the Medical Device User Fee Cover Sheet should be faxed to CDRH at (301)847-8120 referencing the 510(k) number if you have not already sent it in with your 510(k) submission. 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 510(k) will be deleted from the system. Additional information on user fees and how to submit your user fee payment may be found at www.fda.gov/cdrh/mdufma/fy09userfee.html. In addition, the 510k Program Video is now available for viewing on line at

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm070201.htm>.

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, or HDE) with an electronic copy. For more information about the program, including the formatting requirements,

please visit our web site at

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.htm>.

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 a 510k Submission with FDA or what type of submission to submit, you should first telephone the Division of Small Manufacturers, International and Consumer Assistance (DSMICA), for guidance at (301)796-7100 or its toll-free number (800)638-2041, or contact them at their Internet address <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm>, or you may submit a 513(g) request for information regarding classification to the Document Mail Center at the address above. If you have any questions concerning receipt of your payment, please contact Diane Garcia at Diane.Garcia@fda.hhs.gov or directly at (301)796-6559. If you have questions regarding the status of your 510(k) Submission, please contact DSMICA at the numbers or address above.

Sincerely yours,

Diane Garcia
Public Affairs Specialist
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

DJA 00227



U.S. Food and Drug Administration
 Center for Devices and Radiological Health
 Document Mail Center – WO66-G609
 10903 New Hampshire Avenue
 Silver Spring, MD 20993-0002

March 10, 2010

DANA PRODUCTS, INC.
 7 COREY DR.
 SOUTH BARRINGTON, ILLINOIS 60010
 UNITED STATES
 ATTN: HARRY BALA

510k Number: K092944

Product: DANA REUSABLE TEST PACK FOR ST

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 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 <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm>. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm>. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

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 in 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.

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely,

510(k) Staff

DANA PRODUCTS, INC.
7 COREY DRIVE
SOUTH BARRINGTON, IL 60010
TEL. 847-455-2881 FAX. 847-455-2886

K092944/51

March 7, 2010

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center -W066-0609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

FDA CDRH DMC

MAR 10 2010

Received

K-34

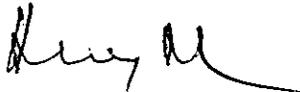
Dear Sir or Madam:

510(k) Number: K 092944 Dana Reusable Test Pack - Your request for additional information dated December 07, 2009

Following is the additional information you requested in your letter dated 12/07/2009. I have made every effort to produce all the information you have requested.

Thanking you,

Very truly Yours,



Harry Bala

DJA 00034

DJA 00035

DEVICE DESCRIPTION

ITEM - 1

The device consists of an (b)(4) tube (attachment A, fig.1) (Photo-1). One end of the tube (b)(4) (attachment A, fig.2).

Between item A, (b)(4), and item B, (b)(4) (b)(4) (shown in attachment A, fig.3). All three are bolted together.

Photos 2 and 3 illustrate the assembly. The (b)(4) (b)(4) (b)(4). The (b)(4) next to the thread in the tube seats the (b)(4). This ensures that this end of the device can be totally sealed. The bore at the other end of the tube is (b)(4)

(attachment A, fig.4) can be (b)(4) (b)(4)

(b)(4) The (b)(4)

(b)(4) (b)(4)

(b)(4) . This is clearly shown in photo 4. A

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

REMOVABLE PLUG
(b)(4)



TUBE
(b)(4)



CAP
(b)(4)



PHOTO -1

(b)(4)



↑
KNURLED
(b)(4)
DISC



(b)(4) DISC

PHOTO - 2



(b)(4) RING

(b)(4) THREADED PLUG

(b)(4)

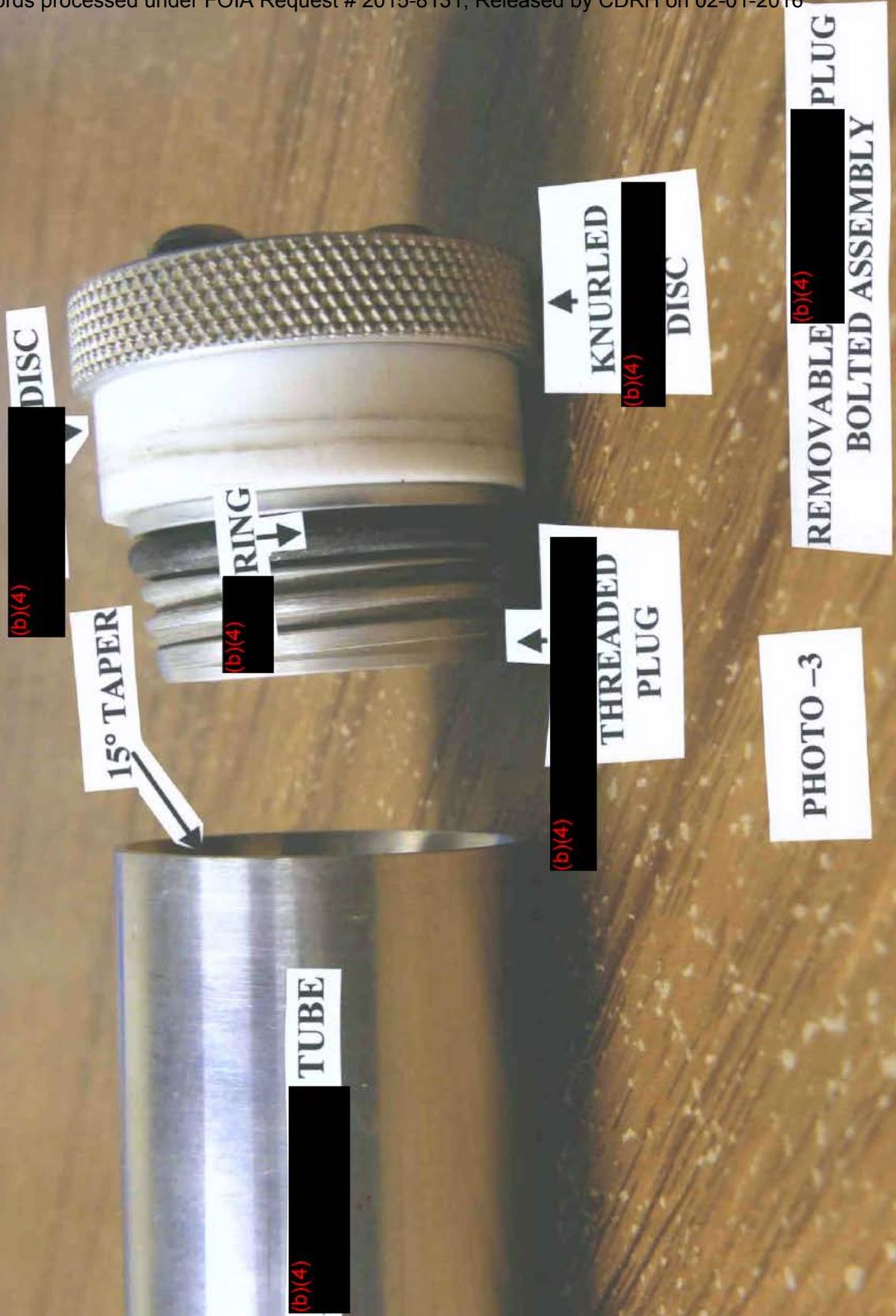


PHOTO -3

(b)(4)

PHOTO -4

SPIRAL

(b)(4)
HOLE

(b)(4)
CAP

(b)(4)
TUBE

(b)(4)

(b)(4)
DISC
↓

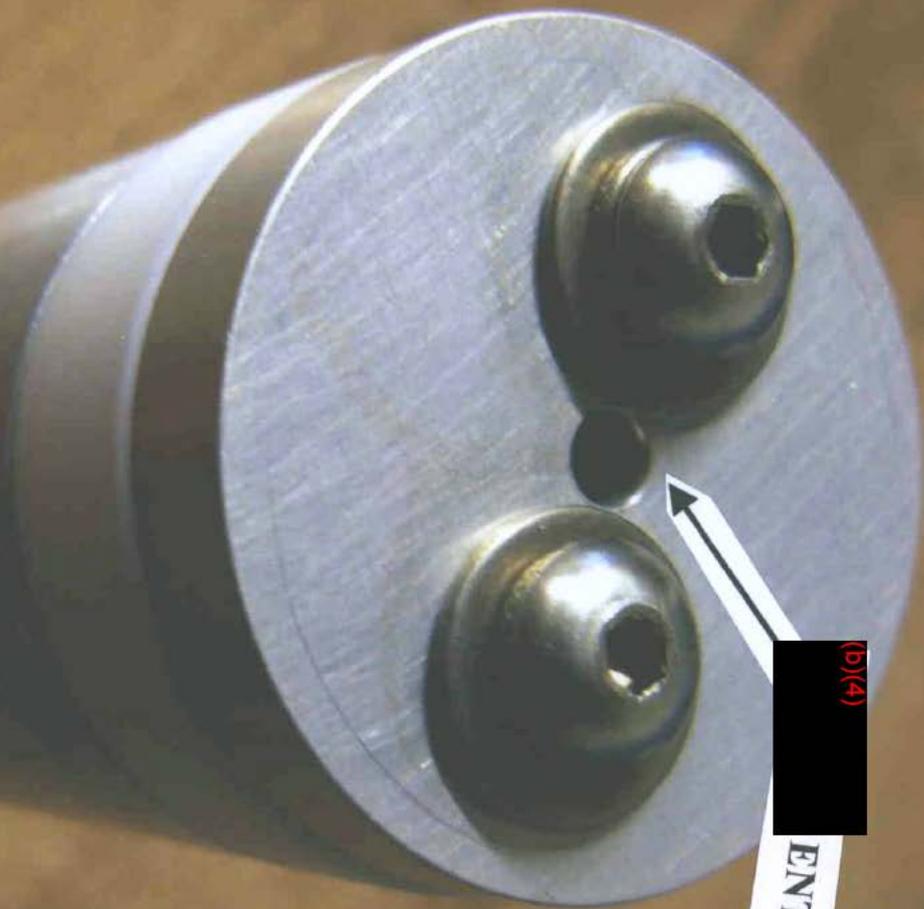
(b)(4)
DISC
↓

(b)(4)
CAP
↓

(b)(4)
TUBE

PHOTO-5

(b)(4)



(b)(4)

ENTRY

(b)(4)

CAP
BOLTED ASSEMBLY

PHOTO -6

(b)(4)



SLEEVE

(b)(4)

PHOTO -7

FULLY ASSEMBLED DEVICE



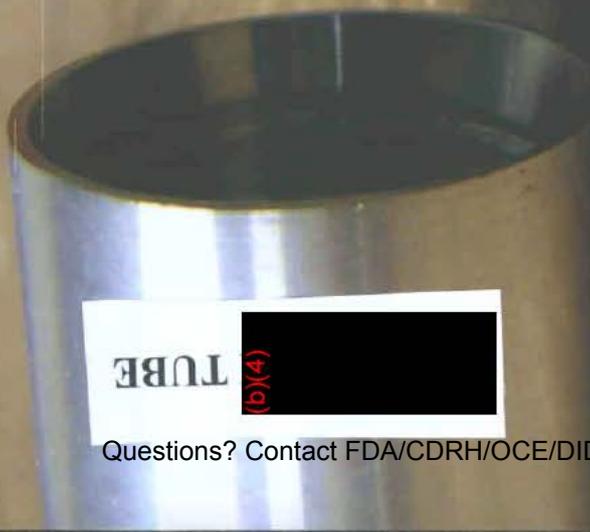
PHOTO-8

ITEM – 2

To use the device, one has to unscrew and remove the plug and place the 3M 1292 rapid readout BI with open end first (into the sleeve as shown in attachment, A fig. 8) in the (b)(4) tube of the test pack. Photo 9 clearly shows that the open end of the BI is inserted first in the (b)(4) tube. Photo 10 shows the removable (b)(4) plug along with the BI in relation to the open end of (b)(4) tube. After the BI is in the test pack the (b)(4) plug is screwed back on tight. This will ensure that the chamber will be sealed from this end. Figure 8-1 shows the BI in the test pack. The test pack is sterilized along with the load. (b)(4)

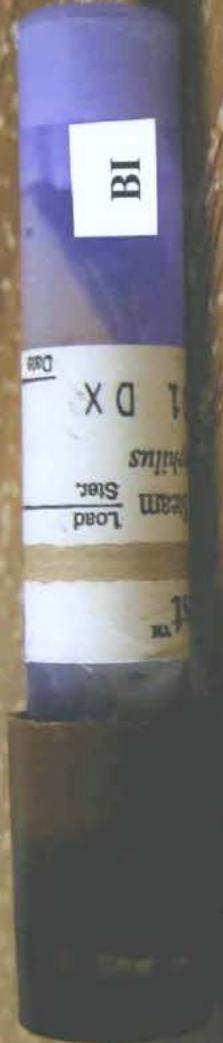
(b)(4) (shown in the (b)(4) diagram in this section). During sterilization the (b)(4) (b)(4) Studies 1,2 and 3 clearly show that test pack performance is not (b)(4) (b)(4)

(b)(4)



TUBE
(b)(4)

OPEN END OF BI
↓



BI

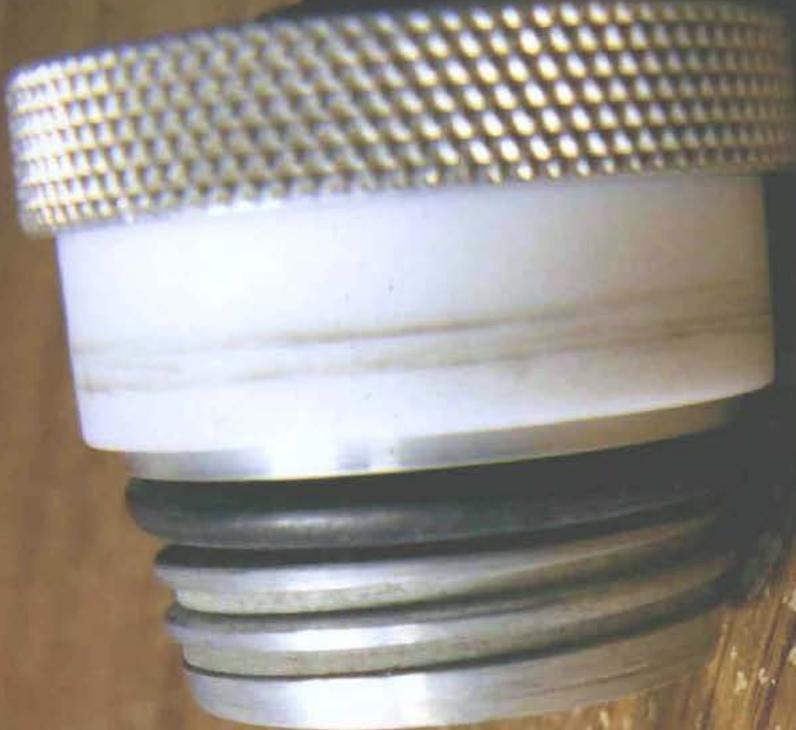
Beam Load Sec.
Dose

←
INSERT

PHOTO -9

PLACEMENT OF BI
IN TEST PACK

(b)(4)



↑
REMOVABLE
PLUG
(b)(4)



BI

↓
INSERT

PLACEMENT OF BI
IN TEST PACK

PHOTO - 10

TUBE

(b)(4)

DJA 00059

ITEM - 3

(b)(4) Tube Fig.1 Attachment A

	Dimension- inches	Tolerance -inches
Outer Diameter	1.25	(b)(4)
Length	6	(b)(4)
Inner Diameter	1.000	(b)(4)
Inner Diameter Cap end	1.022	(b)(4)
Inner Diameter Thread end	1.020	(b)(4)
Thread	(b)(4)	(b)(4)

Knurled (b)(4) (b)(4) Disc Fig.2 AttachmentA

Outer Diameter	1.37	(b)(4)
Length	0.282	(b)(4)
Hole 2 ea. diameter	0.188	(b)(4)
Center distance between holes	0.600	(b)(4)
Length of flat	0.50	(b)(4)

(b)(4) Threaded Plug Fig.2 AttachmentA

Outer Diameter	1.125	(b)(4)
Outer Diameter Thread	1.070	(b)(4)
Length	0.49	(b)(4)
Thread	(b)(4)	(b)(4)
Holes 2 ea.	(b)(4)	(b)(4)
Center distance between holes	0.600	(b)(4)

DJA 00060

(b)(4) Disc Fig.3 AttachmentA

Outer Diameter	1.123	(b)(4)
Length	0.375	
Holes 2 ea. diameter	0.188	
Center distance between holes	0.600	

(b)(4) Cap Fig.4 AttachmentA

Outer Diameter	1.0205	(b)(4)
Length	1.393	
Groove	10 Turns Per Inch 0.011 deep 0.06 wide	
Holes 2 ea.	(b)(4)	
Center distance between holes	0.600	
Center hole	1/8	

(b)(4) Discs Fig.5 AttachmentA

Outer Diameter	1.123	(b)(4)
Length	0.375	
Holes 2 ea. diameter	0.188	
Center distance between holes	0.600	
Center hole	1/8	

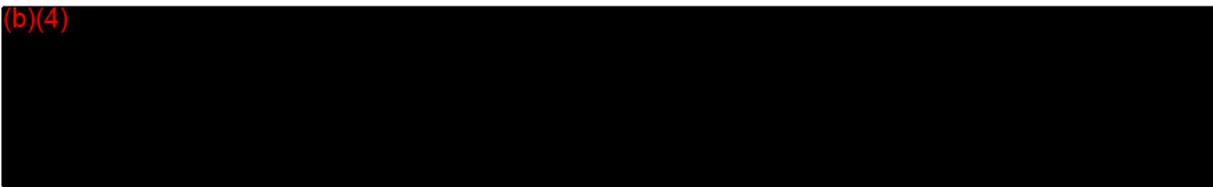
(b)(4) Inner Sleeve Fig.5 AttachmentA

Outer Diameter	0.938	(b)(4)
Length	3.750	
Inner Diameter	0.875	
Cut Out	¼ radius	
Bottom Thickness	1/8	

DJA 00061

ITEM - 4

(b)(4)



ITEM - 5 to 9

All your recommendations are incorporated in the attached Indications for Use. This IFU statement is to replace the one submitted.

Indications for Use

510(k) Number (if known): K092944

Device Name: Reusable Biological Indicator and Integrator Test Pack for Steam Sterilization.

Indications For Use:

Dana reusable test pack is designed to challenge steam sterilization process in healthcare facilities. It is intended to be used for routine monitoring of pre-vacuum steam sterilization cycles. It is validated to be used in 4 minute 270°F pre-vacuum steam sterilization cycles with 3M's 1292 Rapid Readout Biological Indicators along with or without SteriScan Integrators. It can also be used with SteriScan Integrators.

Prescription Use _____ AND/OR
(Part 21 CFR 801 Subpart D)

Over-The-Counter Use X
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1

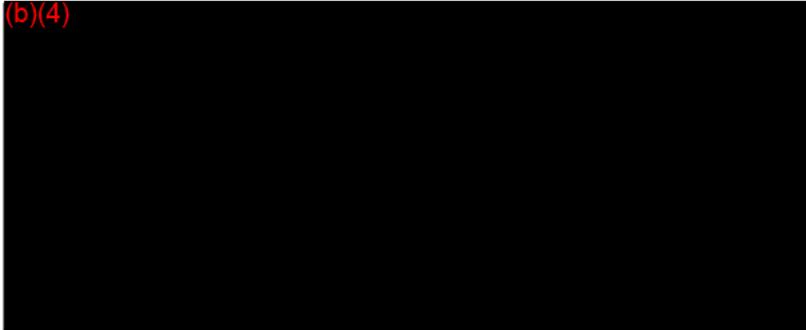
DJA 00063

BIOCOMPATABILITY:

ITEM – 10

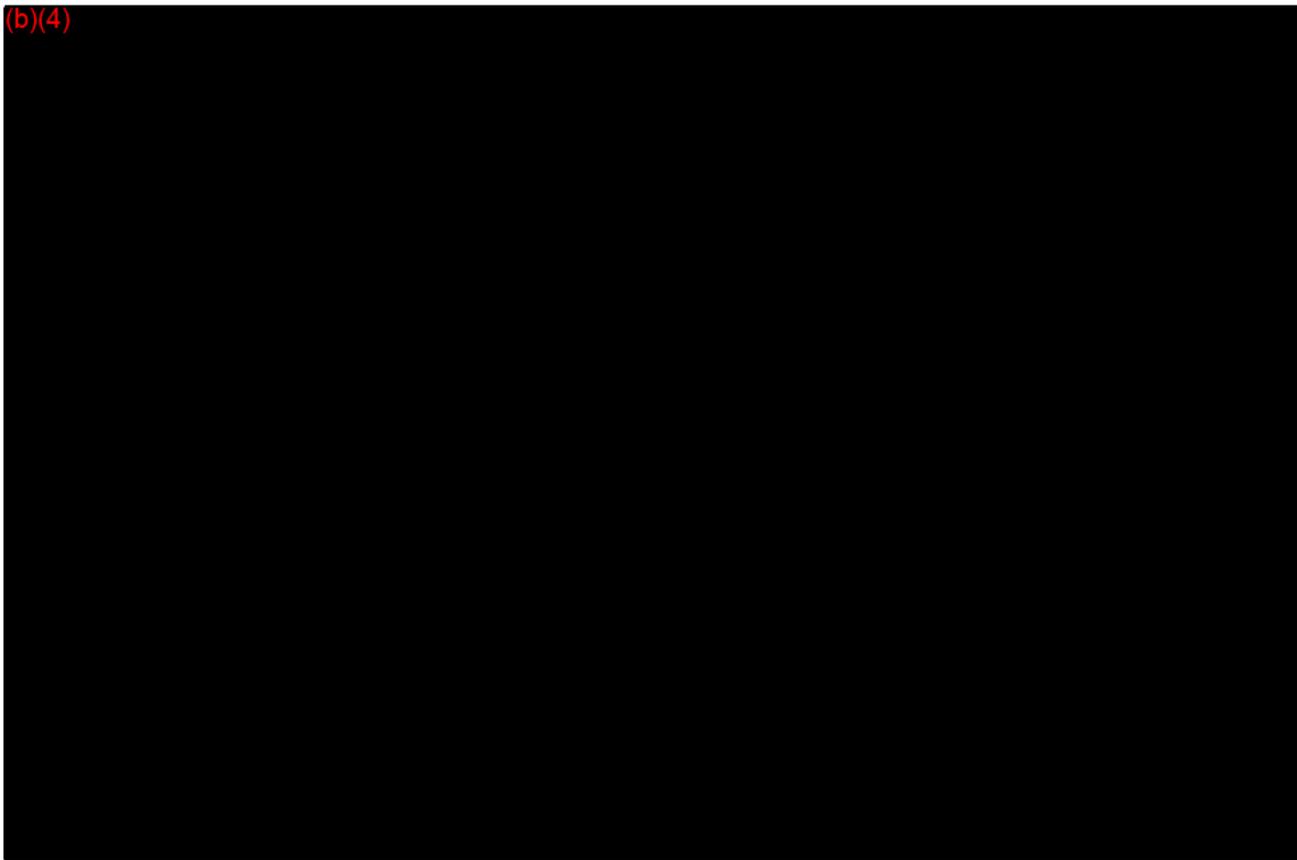
Detailed information is under the following Tabs:

(b)(4)



Performance Testing:

(b)(4)



JJA 00189

LABELING:

ITEM - 14:

(b)(4)



ITEM -15:

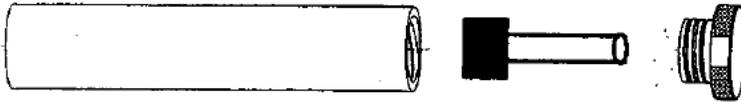
The following is the draft of the labeling that will be applied on each test pack.

Dana Reusable Test Pack

For 270° F 4minute Pre-Vacuum Cycles

For use with 3M Attest 1292 BI

With or without SteriScan Integrator



Insert first open end of BI in Test Pack
Insert first Pellet End of SteriScan Indicator

Discard after 100 Uses

Dana Products, Inc.
11457 Melrose St.
Franklin Park, IL

Serial Number:
Lot Number:
Exp.:

LABELING:

ITEM – 16 - 18:

The following is the draft of the instructions that would accompany the test packs:

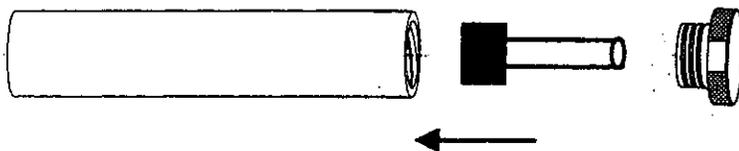
Dana Reusable Test Pack

Product Description:

Dana reusable test pack is designed to challenge steam sterilization process in healthcare facilities and for routine monitoring of pre-vacuum steam sterilization cycles. It is to be used in 4 minute 270°F pre-vacuum steam sterilization cycles with 3M's 1292 Rapid Readout Biological Indicators along with or without SteriScan Integrators. It can be used 100 times without the test pack losing its effectiveness.

Direction for Use:

1. Open the screw cap.
2. Insert 3M's 1292 Rapid Read out Biological open end first in the test pack as shown. SteriScan indicator can also be used in addition to the BI by inserting the pellet end first into the test pack.



**Insert first open end of BI in Test Pack
Insert first Pellet End of SteriScan Indicator**

3. Screw on the cap tight.
4. Place the test pack on the bottom shelf above the drain.
5. Process the load according to recommended practices.
6. After completion of the cycle open the sterilizer door and wait at least 5 minutes before removing the test pack.
7. Use gloves to remove the test pack from the sterilizer.
8. Do not open the test pack until it has sufficiently cooled off.
9. Open the screw cap.
10. Remove the 3M's Rapid Readout BI and the SteriScan indicator if it is used along with the BI.
11. Follow the instructions provided with the 1292 BI and the SteriScan indicator by their respective manufacturers to read and interpret the results.

DJA 00191

12. Enter the serial number of the test pack and the date of initial use in the card supplied along with the test pack. Track the number of uses by crossing off the numbers sequentially as shown below.

Dana Test Pack

Serial Number:

Date of initial use:

Discard test pack after 100 uses

1 2 3 4 5 6 7 8 9 10
11 12 13 14 15 16 17 18 19 20
21 22 23 24 25 26 27 28 29 30
31 32 33 34 35 36 37 38 39 40
41 42 43 44 45 46 47 48 49 50
51 52 53 54 55 56 57 58 59 60
61 62 63 64 65 66 67 68 69 70
71 72 73 74 75 76 77 78 79 80
81 82 83 84 85 86 87 88 89 90
91 92 93 94 95 96 97 98 99 100

13. Discard the test pack after 100 uses.
14. Store at normal room conditions: Temperature 60° to 85° F Humidity 30 –70%

Cleaning:

Clean the test pack only with alcohol. Wipe the outside and rinse the inside with alcohol.

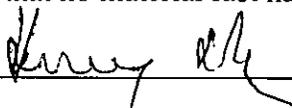
Precautions:

1. Use only with 270°F pre-vacuum steam sterilization cycles.
2. Use gloves to handle test pack after sterilization.
3. Wait until the test pack cools off before opening.
4. Discard after 100 uses.

Made in USA by
Dana Products
11457 Melrose Street
Franklin Park, IL 60131
847-455-2881

Premarket Notification Truthful and Accurate Statement:
[As Required by 21CFR 807.87(k)]

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

Signature: 

Harry Bala

Date 3/8/10

510k Number: K092944

K092944

510k NOTIFICATION

**DANA REUSABLE BIOLOGICAL INDICATOR AND INTEGRATOR
TEST PACK FOR STEAM STERILIZATION**

TABLE OF CONTENTS

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- 2. CDRH Premarket Review Submission Cover sheet
- 3. 510(k) Cover letter -----Pages 1 & 2
- 4. Indications For Use Statement -----Page 3
- 5. 510(k) Statement -----Page 4
- 6. Declaration of Conformity,
Executive Summary & Devise Description -----Pages 6 -29
Substantial Equivalence Discussion & Test Results
Proposed Labeling and Shelf Life
- 7. Truthful and Accuracy Statement -----Page 30
- 8. Attachment A ----- 11 Pages
- 9. Attachment B -----4 Pages

V3

DJA 00228

Form Approved: OMB No. 0910-511 Expiration Date: January 31, 2010. See Instructions for OMB Statement.

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.	
A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/cover sheet.html			
1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code) DANA PRODUCTS INC 7 Corey Dr. South Barrington IL 60010 US		2. CONTACT NAME Harry Bala 2.1 E-MAIL ADDRESS bala@voyager.net 2.2 TELEPHONE NUMBER (include Area code) 847-4552881 2.3 FACSIMILE (FAX) NUMBER (Include Area code) 847-4552886	
1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) 010647868			
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)			
<u>Select an application type:</u> <input checked="" type="checkbox"/> Premarket notification (510(k)); except for third party <input type="checkbox"/> 513(g) Request for Information <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR) <input type="checkbox"/> Annual Fee for Periodic Reporting (APR) <input type="checkbox"/> 30-Day Notice		3.1 Select a center <input checked="" type="checkbox"/> CDRH <input type="checkbox"/> CBER 3.2 Select one of the types below <input checked="" type="checkbox"/> Original Application <u>Supplement Types:</u> <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP)	
4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status) <input type="checkbox"/> YES, I meet the small business criteria and have submitted the required qualifying documents to FDA <input checked="" type="checkbox"/> NO, I am not a small business 4.1 If Yes, please enter your Small Business Decision Number:			
5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA? <input checked="" type="checkbox"/> YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.) <input type="checkbox"/> NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)			
6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION. <input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates <input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population <input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only <input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially			
7. 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).) <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO			
8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (b)(4)			

09-Jul-2009

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

DJA 00230

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION CDRH PREMARKET REVIEW SUBMISSION COVER SHEET	Form Approval OMB No. 0910-0120 Expiration Date: August 31, 2010. See OMB Statement on page 5.
--------------------------------------------------------------------------------------------------------------------------------	---------------------------------------------------------------------------------------------------------

Date of Submission 9-21-09	User Fee Payment ID Number (b)(4)	FDA Submission Document Number (if known)
-------------------------------	--------------------------------------	-------------------------------------------

SECTION A TYPE OF SUBMISSION				
PMA <input type="checkbox"/> Original Submission <input type="checkbox"/> Premarket Report <input type="checkbox"/> Modular Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment <input type="checkbox"/> Licensing Agreement	PMA & HDE Supplement <input type="checkbox"/> Regular (180 day) <input type="checkbox"/> Special <input type="checkbox"/> Panel Track (PMA Only) <input type="checkbox"/> 30-day Supplement <input type="checkbox"/> 30-day Notice <input type="checkbox"/> 135-day Supplement <input type="checkbox"/> Real-time Review <input type="checkbox"/> Amendment to PMA & HDE Supplement <input type="checkbox"/> Other	PDP <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP	510(k) <input checked="" type="checkbox"/> Original Submission: <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated (Complete section I, Page 5) <input type="checkbox"/> Additional Information <input type="checkbox"/> Third Party	Meeting <input type="checkbox"/> Pre-510(K) Meeting <input type="checkbox"/> Pre-IDE Meeting <input type="checkbox"/> Pre-PMA Meeting <input type="checkbox"/> Pre-PDP Meeting <input type="checkbox"/> Day 100 Meeting <input type="checkbox"/> Agreement Meeting <input type="checkbox"/> Determination Meeting <input type="checkbox"/> Other (specify):
IDE <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	Humanitarian Device Exemption (HDE) <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	Class II Exemption Petition <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Evaluation of Automatic Class III Designation (De Novo) <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Other Submission <input type="checkbox"/> 513(g) <input type="checkbox"/> Other (describe submission):

Have you used or cited Standards in your submission? Yes No (If Yes, please complete Section I, Page 5)

SECTION B SUBMITTER, APPLICANT OR SPONSOR			
Company / Institution Name Dana Products, Inc.		Establishment Registration Number (if known) 3007412809	
Division Name (if applicable)		Phone Number (including area code) 847-455-2881	
Street Address 7 Corey Drive		FAX Number (including area code) 847-455-2886	
City South Barrington	State / Province IL	ZIP/Postal Code 60010	Country USA
Contact Name Harry Bala			
Contact Title President		Contact E-mail Address bala@voyager.net	

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)			
Company / Institution Name			
Division Name (if applicable)		Phone Number (including area code)	
Street Address		FAX Number (including area code)	
City	State / Province	ZIP Code	Country
Contact Name			
Contact Title		Contact E-mail Address	

DJA 00231

SECTION D1			REASON FOR APPLICATION - PMA, PDP, OR HDE		
<input type="checkbox"/> New Device <input type="checkbox"/> Withdrawal <input type="checkbox"/> Additional or Expanded Indications <input type="checkbox"/> Request for Extension <input type="checkbox"/> Post-approval Study Protocol <input type="checkbox"/> Request for Applicant Hold <input type="checkbox"/> Request for Removal of Applicant Hold <input type="checkbox"/> Request to Remove or Add Manufacturing Site	<input type="checkbox"/> Change in design, component, or specification: <input type="checkbox"/> Software / Hardware <input type="checkbox"/> Color Additive <input type="checkbox"/> Material <input type="checkbox"/> Specifications <input type="checkbox"/> Other (<i>specify below</i>)	<input type="checkbox"/> Location change: <input type="checkbox"/> Manufacturer <input type="checkbox"/> Sterilizer <input type="checkbox"/> Packager			
<input type="checkbox"/> Process change: <input type="checkbox"/> Manufacturing <input type="checkbox"/> Packaging <input type="checkbox"/> Sterilization <input type="checkbox"/> Other (<i>specify below</i>)	<input type="checkbox"/> Labeling change: <input type="checkbox"/> Indications <input type="checkbox"/> Instructions <input type="checkbox"/> Performance Characteristics <input type="checkbox"/> Shelf Life <input type="checkbox"/> Trade Name <input type="checkbox"/> Other (<i>specify below</i>)	<input type="checkbox"/> Report Submission: <input type="checkbox"/> Annual or Periodic <input type="checkbox"/> Post-approval Study <input type="checkbox"/> Adverse Reaction <input type="checkbox"/> Device Defect <input type="checkbox"/> Amendment			
<input type="checkbox"/> Response to FDA correspondence:		<input type="checkbox"/> Change in Ownership <input type="checkbox"/> Change in Correspondent <input type="checkbox"/> Change of Applicant Address			
<input type="checkbox"/> Other Reason (<i>specify</i>):					

SECTION D2			REASON FOR APPLICATION - IDE		
<input type="checkbox"/> New Device <input type="checkbox"/> New Indication <input type="checkbox"/> Addition of Institution <input type="checkbox"/> Expansion / Extension of Study <input type="checkbox"/> IRB Certification <input type="checkbox"/> Termination of Study <input type="checkbox"/> Withdrawal of Application <input type="checkbox"/> Unanticipated Adverse Effect <input type="checkbox"/> Notification of Emergency Use <input type="checkbox"/> Compassionate Use Request <input type="checkbox"/> Treatment IDE <input type="checkbox"/> Continued Access	<input type="checkbox"/> Change in: <input type="checkbox"/> Correspondent / Applicant <input type="checkbox"/> Design / Device <input type="checkbox"/> Informed Consent <input type="checkbox"/> Manufacturer <input type="checkbox"/> Manufacturing Process <input type="checkbox"/> Protocol - Feasibility <input type="checkbox"/> Protocol - Other <input type="checkbox"/> Sponsor	<input type="checkbox"/> Response to FDA Letter Concerning: <input type="checkbox"/> Conditional Approval <input type="checkbox"/> Deemed Approved <input type="checkbox"/> Deficient Final Report <input type="checkbox"/> Deficient Progress Report <input type="checkbox"/> Deficient Investigator Report <input type="checkbox"/> Disapproval <input type="checkbox"/> Request Extension of Time to Respond to FDA <input type="checkbox"/> Request Meeting <input type="checkbox"/> Request Hearing			
<input type="checkbox"/> Report submission: <input type="checkbox"/> Current Investigator <input type="checkbox"/> Annual Progress Report <input type="checkbox"/> Site Waiver Report <input type="checkbox"/> Final					
<input type="checkbox"/> Other Reason (<i>specify</i>):					

SECTION D3			REASON FOR SUBMISSION - 510(k)		
<input checked="" type="checkbox"/> New Device	<input type="checkbox"/> Additional or Expanded Indications	<input type="checkbox"/> Change in Technology			
<input type="checkbox"/> Other Reason (<i>specify</i>):					

DJA 00232

SECTION E								ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS			
Product codes of devices to which substantial equivalence is claimed								Summary of, or statement concerning, safety and effectiveness information			
1	FRC	2		3		4		<input type="checkbox"/> 510 (k) summary attached		<input checked="" type="checkbox"/> 510 (k) statement	
5		6		7		8					

Information on devices to which substantial equivalence is claimed (if known)											
	510(k) Number		Trade or Proprietary or Model Name		Manufacturer						
1	K952408	1	Attest 1296 Rapid Readout test pack	1	3M						
2	k926364	2	Attest 1292 Rapid Readout BI	2	3M						
3	k012195	3	SteriScan Integrator	3	Dana Products, Inc.						
4		4		4							
5		5		5							
6		6		6							

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name
 Challenge Test Pack for steam sterilization.

	Trade or Proprietary or Model Name for This Device		Model Number
1	Dana Reusable Test pack for Steam Sterilization.	1	
2		2	
3		3	
4		4	
5		5	

FDA document numbers of all prior related submissions (regardless of outcome)					
1	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission
 Laboratory Testing Animal Trials Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code FRC	C.F.R. Section (if applicable) 880.2800	Device Class <input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified
Classification Panel		

Indications (from labeling)

DJA 00233

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.		FDA Document Number (if known)	
SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION			
<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	Facility Establishment Identifier (FEI) Number		<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler
Company / Institution Name Dana Products, Inc.		Establishment Registration Number 3007412809	
Division Name (if applicable)		Phone Number (including area code) 847-455-2881	
Street Address 11457 Melrose Street		FAX Number (including area code) 847-455-2886	
City Franklin Park		State / Province IL	ZIP Code 60131 Country usa
Contact Name Harry Bala	Contact Title President	Contact E-mail Address bala@voyager.net	
<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	Facility Establishment Identifier (FEI) Number		<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name (if applicable)		Phone Number (including area code)	
Street Address		FAX Number (including area code)	
City		State / Province	ZIP Code Country
Contact Name	Contact Title	Contact E-mail Address	
<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	Facility Establishment Identifier (FEI) Number		<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name (if applicable)		Phone Number (including area code)	
Street Address		FAX Number (including area code)	
City		State / Province	ZIP Code Country
Contact Name	Contact Title	Contact E-mail Address	

DJA 00234

SECTION I UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a "Declaration of Conformity to a Recognized Standard" statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1	ST8	ANSI AAMI	Hospital Steam Sterilizers	2001	01/01/2001
2	ST 79	ANSI AAMI	Comprehensive Guide to steam sterilization and sterility assurance in health care facilities	2006	01/01/2006
3					
4					
5					
6					
7					

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
 Food and Drug Administration
 Office of the Chief Information Officer (HFA-710)
 5600 Fishers Lane
 Rockville, Maryland 20857

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.

DANA PRODUCTS, INC.
7 COREY DRIVE
SOUTH BARRINGTON, IL 60010
TEL. 847-455-2881 FAX. 847-455-2886

September 22, 2009

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center –W066-0609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

FDA CDRH DMC

SEP 24 2009

Received

Dear Sir or Madam:

510K Notification (21CFR 807.90 (e))
Traditional Submission
Reusable Challenge Test Pack for Steam Sterilization

I request marketing clearance for our reusable challenge test pack for Biological Indicators and Integrators to be used in steam sterilization. The information on the test pack is as follows:

Device Name: Reusable Biological Indicator and Integrator Test Pack for
Steam Sterilization

Device Classification Name: Indicator, Biological Sterilization Process

Product Code: FRC

Regulation Number: 880.2800

Review Panel: General Hospital

Device Class: 2

Propriety Name: Dana Reusable Test Pack

Establishment Registration Number: 3007412809

Owner Operator Number: 9054259

Performance Standard: ANSI/AAMI ST 79: 2006 (Sec. 10.7.2.1),
ANSI/AAMI ST 8: 2001 (Sec. 5.5.2.2)

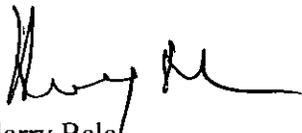
Predicate Device 510 k: 3M -1296 Test pack- k 952408 & 1292 Rapid Readout BI k926364
SteriScan Integrator – k 012195

This submission is prepared in duplicate and it includes adequate information to show substantial equivalence to the predicate device. Our manufacturing facility is located at 11457 Melrose Street, Franklin Park, IL 60131. If you have any questions concerning this submission, please contact:

Harry Bala
Dana Products, Inc.
7 Corey Drive
South Barrington, IL 60010
Tel.: 847-455-2881, Fax: 847-455-2886
Email: bala@voyager.net

Dana Products, Inc. considers this submission confidential and requests that the FDA consider it as such.

Sincerely yours,



Harry Bala
President

DJA 00237

Indications for Use

510(k) Number (if known):

Device Name: Reusable Biological Indicator and Integrator Test Pack for Steam Sterilization.

Indications For Use:

Dana reusable challenge test pack is designed to challenge steam sterilization process in healthcare facilities. It is intended to be used for routine monitoring of pre-vacuum steam sterilization cycles. It is validated to be used in 4 minute 270°F pre-vacuum steam sterilization cycles with 3M's 1292 Rapid Readout Biological Indicators, SteriScan Integrators or both. The microorganism used in this validation is *Geobacillus Stearothermophilus* ATCC 7953 with a population of 3.0 to 4.7 million and with a D-value(121°C) of 1.5 to 1.8. Using the Dana disposable sleeve, it can also be used to monitor extended 270°F pre-vacuum steam sterilization 10-minute cycles

Prescription Use _____ AND/OR
(Part 21 CFR 801 Subpart D)

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

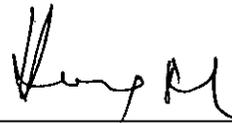
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

DJA 00238

510k STATEMENT
(As required by 21 CFR 807.93)

I certify that, in my capacity as the President of Dana Products, 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: 

Harry Bala

Date: 2/22/09

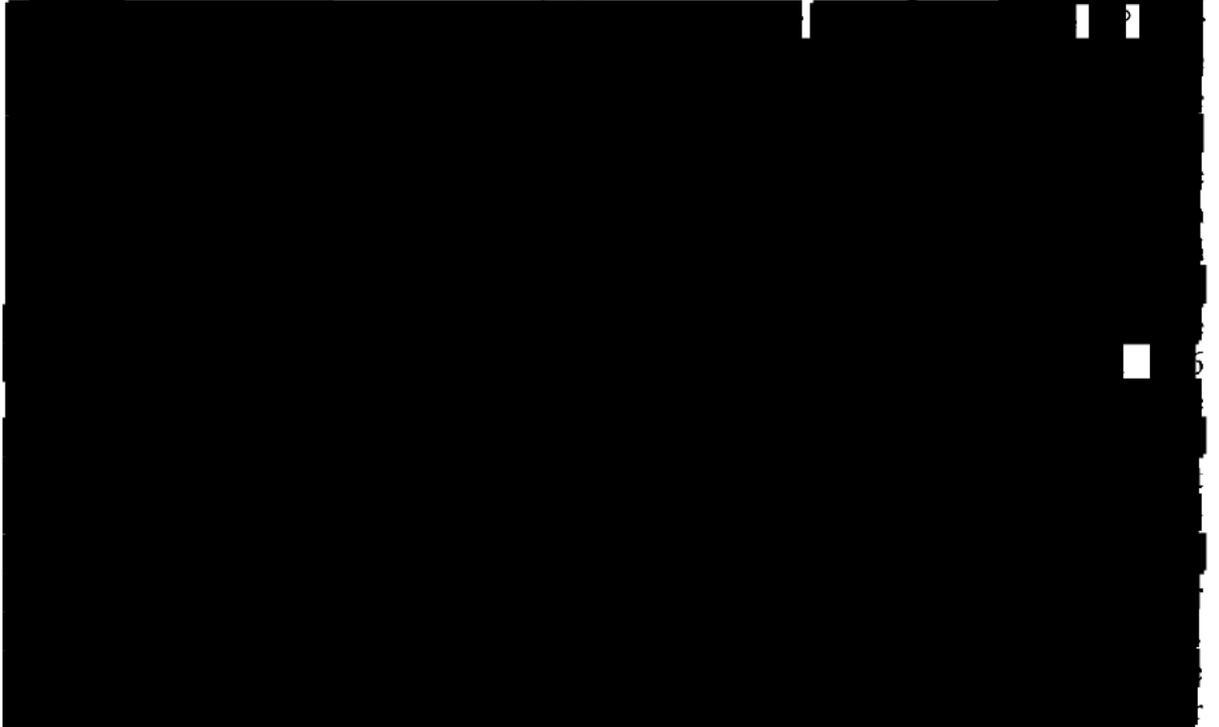
510k Number: _____

DJA 00239

Declaration of conformity: The Dana Reusable Test Pack, when used with 3M's 1292 rapid readout BI's, conforms to the Standard set for a BI challenge test pack (b)(4)

Executive Summary: Dana Reusable Test Pack consists of an (b)(4) chamber that can be sealed at one end using a removable (b)(4) plug. The other end has a permanently pressed in (b)(4) cap with a precision machined spiral that provides the (b)(4) chamber is large enough to accommodate BI and SteriScan Integrator. We used for testing (b)(4) (b)(4)(b)(4)

Device Description: The device consists of an (b)(4) tube (attachment A, fig.1). One end of the tube has internal thread to receive a removable (b)(4) plug (attachment A, fig.2). Between item A, knurled (b)(4) disc, and item B, (b)(4) threaded plug, is sandwiched a (b)(4) disc (shown in attachment A, fig.3). All three are bolted together. (b)(4)



DJA 00240

(b)(4)

(b)(4)

All drawings submitted are fully dimensioned with tolerances specified for manufacturing. The critical dimensions are internal diameter of the tube for press fitting the cap, outer diameter and the depth of the spiral of the press cap. These are inspected (b)(4)

(b)(4)

Tolerance on dimensions specified to third decimal is ± 0.005 inches, to second decimal is ± 0.01 inches and on fractions is $\pm 1/64$ inches (these are specified in each drawing). With these drawings any manufacturing facility can make the parts.

The device is individually packaged in a plastic bag and there are six devices per case, along with instructions for use as follows:

Clean the test pack with alcohol, only. Use an alcohol wipe to clean the outside and rinse out the inside with alcohol.

Information on items used in this study (attached in Attachment B)

510k Numbers and other relevant data:

Steam Sterilizer used: Our brand new AMSCO CENTURY

Chamber size: 20"x20"x38"

Cycle: Prevac at 270°F (132°C)

510k : K030789

BI: 3M's 1292 Attest Rapid Readout BI

510K: K 926364

Determination by the FDA that we could use 1292 BI in Dana Test Pack. (copy enclosed)

1296 Attest Rapid Readout Test Pack

Uses 3M's 1292 Attest Rapid Readout BI

510K: K 952408

Copy of clarification that this is the correct 510k is enclosed.

3M 290 Auto Reader
For Incubating 1292 BIs
510K: K004009

SteriScan Integrator 510 K: K012195

1296 test packs and 1292 BIs used in this study:
Organism: Geobacillus Stearothermophilus ATCC 7953

Lot: 2010-04 DA
Population (mean/strip): 4.7x1, 000,000
Test D-Value (121°C): 1.5 Min.
Survival Time: 7.01 Min.
Kill Time: 16.01 Min.
Z-Value: 10.7°C

Lot: 2010-05 DA
Population (mean/strip): 4.0x1, 000,000
Test D-Value (121°C): 1.6 Min.
Survival Time: 7.36 Min.
Kill Time: 16.96 Min.
Z-Value: 11.0°C

Lot: 2010-05 DB
Population (mean/strip): 3.2 x1, 000,000
Test D-Value (121°C): 1.6 Min.
Survival Time: 7.21 Min.
Kill Time: 16.81 Min.
Z-Value: 10.0°C

Lot: 2010-12 DA
Population (mean/strip): 3x1, 000,000
Test D-Value (121°C): 1.6 Min.
Survival Time: 7.16 Min.
Kill Time: 16.76 Min.
Z-Value: 11°C

Lot: 2011-01 DI
Population (mean/strip): 4.4x1, 000,000
Test D-Value (121°C): 1.8
Survival Time: 8.36 Min.
Kill Time: 19.16 Min.
Z-Value: 12°C

DJA 00242

Lot: 2011-01 DX
Population (mean/strip): 4.2x1, 000,000
Test D-Value (121°C): 1.7
Survival Time: 7.86 Min.
Kill Time: 18.06 Min.
Z-Value: 12°C

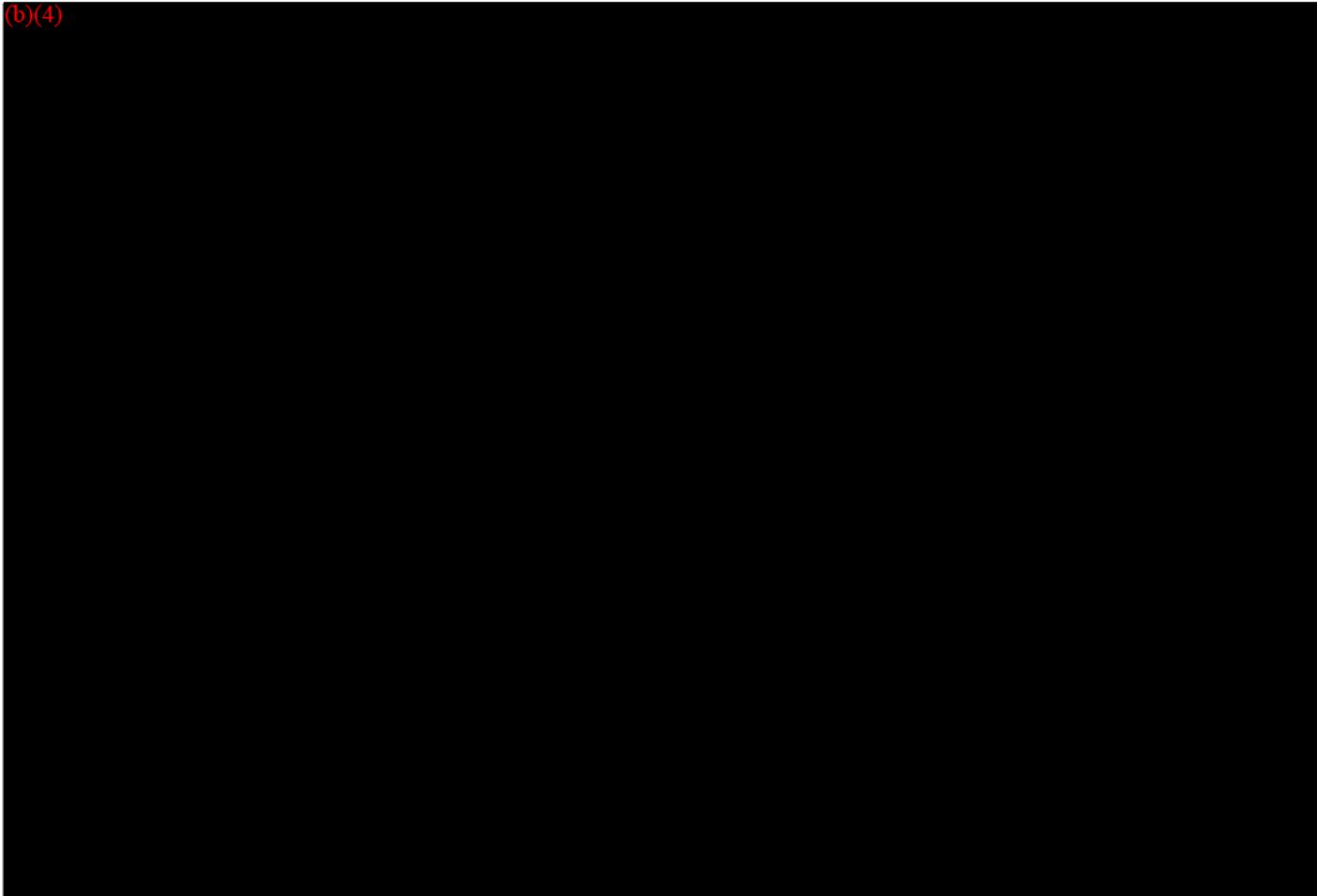
Performance Testing:

Predicate device: 3M's 1296 Test pack with 1292 Rapid Readout BI.

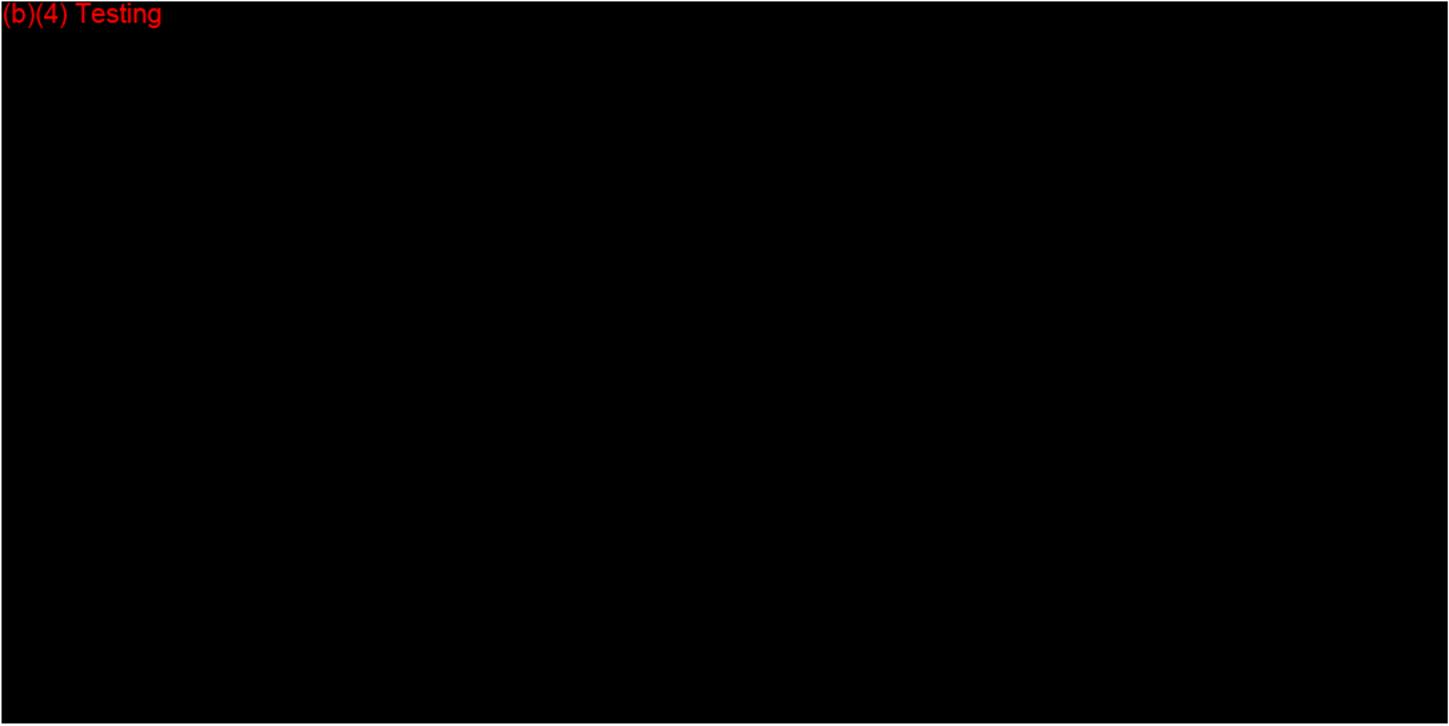
Object: To show that Dana Test Pack is more resistant in a 4minute 270°F prevac cycle when compared to 3M's 1296. Both test packs use 1292 BIs from the same lot. Also to show that the Dana Test Pack with 3M's 1292 BI in the single use plastic sleeve can be used effectively to challenge 10 minute 270°F prevac sterilization cycles.

Test Parameters:

(b)(4)



(b)(4) Testing



Shelf and Reuse Life: The individual parts for Dana Test Pack were manufactured four years ago. The finished assemblies are nine months old. It will at least be one year from the assembly date before the packaging is finalized and is cleared for marketing by the FDA. At the end of one year, we will (b)(4)

(b)(4)



We will claim reuse life of 200 times. We have enclosed test data to substantiate our claim. We will continue to test to validate the reuse life with the retained samples.

Labeling:

Each test pack has a serial number that is unique to the test pack. The Serial Number of the test pack is to be entered in the record card supplied with the test pack. The number of uses can be tracked by crossing off numbers sequentially on the record card. The card also contains a section to record date of initial use. After the permitted number of uses the test pack is to be discarded.

Dana Reusable Test Pack

For Routine Monitoring of 4 min. 270°F pre vacuum cycles .

Serial Number: Expiration Date: Lot Number

For use with 3M Attest 1292 BI and or SteriScan Integrator.

Clean with alcohol only.

Discard after 200 uses.

Track number of uses with the enclosed card.

DJA 00262

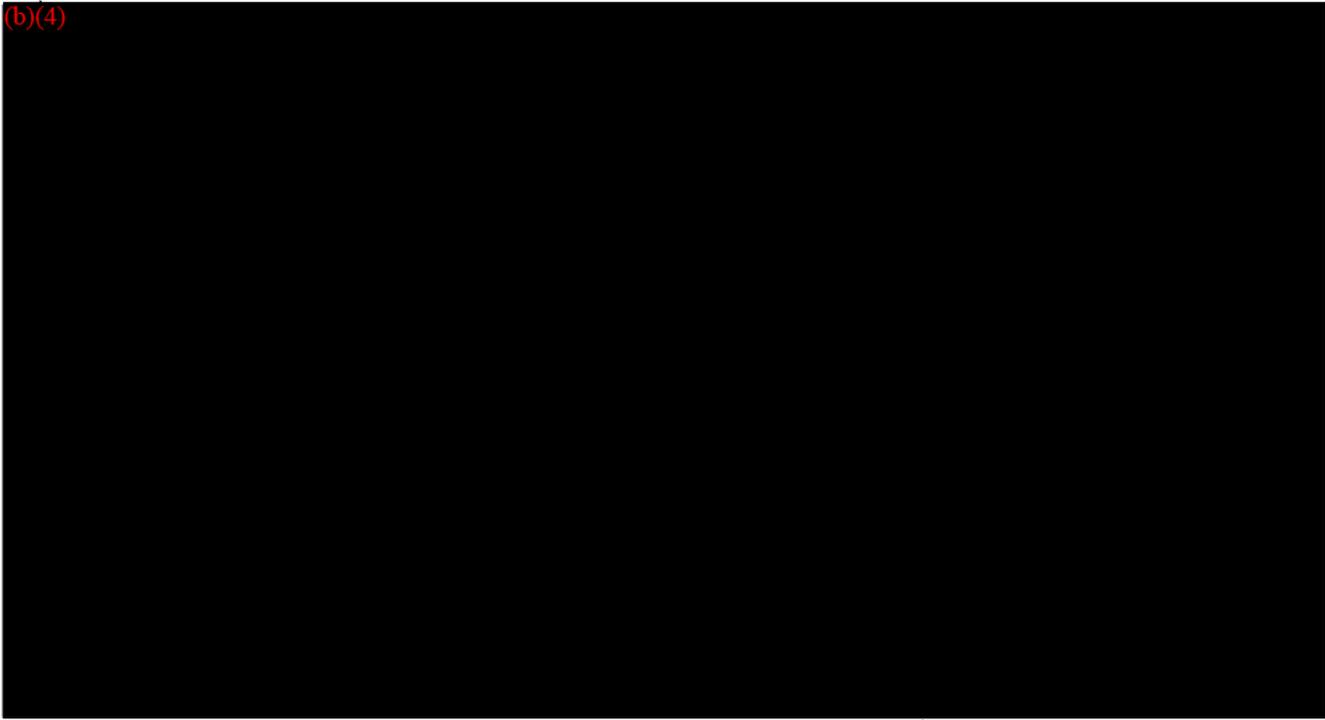
Instructions for use:

Dana Reusable Test Pack is designed for routine monitoring of 270°F vacuum assisted steam sterilization cycles. It is validated for use with 3M Attest 1292 Rapid Readout BI's for use in 4 minute 270°F pre-vacuum steam sterilization cycles. (b)(4)

(b)(4). Dana test pack is substantially equivalent to 3M's 1296 test pack. Dana test pack represents the challenge and resistance of a 16-towel pack recommended by AAMI. 3M's self contained 1292 BI's use *Geobacillus stearothermophilus*. The D-value of 1292 BI is reproducible only under the exact conditions under which it was determined and can not be duplicated in the healthcare facility. Determine the suitability of the 1292 BI for the process before using it. Use the Dana Test Pack with only one BI at a time.

For 4 minute pre vacuum cycles: Open the screw cap and insert the Attest 1292 BI with the open end first in the Dana test pack as shown in Attachment A, Fig. 8. In addition to the BI a SteriScan integrator can be placed in the test pack. It can also be used only with the SteriScan integrator. In both cases, insert the pellet end of the integrator first. Screw the cap back on tightly. Place the test pack on the bottom shelf above the drain. Process the load. After completion of the cycle, allow the test pack to cool. Open the screw cap and remove the BI and/or the integrator. Press the cap of BI down. Crush the glass ampule of the BI in the crusher well of the Attest Auto-Reader. Incubate the sterilized Attest 1292 BI in the Auto Reader for 3 hours at 60°C ± 2°C. A positive (red light or +) result means sterilization process failure may have occurred. A negative reading (green light or -) indicates acceptable sterilization process. The final reading of visual pH color change can be made in 48 hours. The color change from purple to yellow indicates growth. Each facility must establish final readout time in its policy and procedures. Sterilization parameters are met if the migrating dye of SteriScan integrator reaches the accept window.

(b)(4)



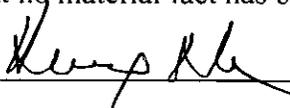
Enter the Serial Number of the test pack and the date of initial use in the enclosed record card and track the use by crossing off of numbers sequentially. After the permitted number of uses discard the test pack.

Clean the test pack only with alcohol. Use an alcohol wipe to clean the outside and rinse out the inside with alcohol.

DJA 00264

Premarket Notification Truthful and Accurate Statement:
[As Required by 21CFR 807.87(k)]

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

Signature: 

Harry Bala

Date 9/22/09

510k Number: _____

ATTACHMENT - A

DJA 00273

STOCKCAP

About StockCap | Products | Online Store | Custom Capabilities | Quote/Sample Request | News

Home | Contact Us | Locations | Information Center | Careers | Other S & R Companies

Styles

[Caps](#)

[Plugs](#)

[Other](#)

Materials

[Vinyl](#)

[Rubber](#)

[Plastic](#)

Markets

[Automotive](#)

[Finishing](#)

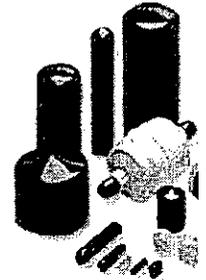
[HVAC](#)

[Custom](#)

Products

Hi-Temp Short Caps

Vinyl Short Caps are the most economic choice for masking products during most liquid painting and plating processes. The flexible vinyl stretches to form a tight seal over threads, beaded tubes, and odd shapes. Vinyl short caps also possess excellent chemical resistance to withstand most washing processes.



FREE

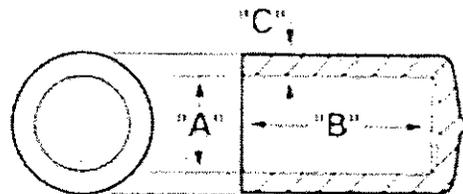
ID: Because Short Caps are soft and flexible, we suggest an undersized diameter for a tight fit. For example: if your outside diameter is .500" (12.70 mm), use a .437" (11.10 mm) Short Cap.

Length: Production Short Caps are available in any length, in .062" (1.57 mm). Minimum length is .187" (4.75 mm). Maximum length is stated in chart. tolerance is ± .062" (1.57 mm). Inside length is measured along the side the closed end, not down the center. For stock lengths, please go to Stock lengths, please go to Long Caps.

Wall thickness: Wall Thickness "C" is measured .250" (6.35 mm) from

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**Attachment A – Fig. 11
High Temperature Vinyl Cap
0.625 ID, 0.016 Wall, 0.625 long**

ATTACHMENT - B

DJA 00275

Subject: RE: K070959 - Clarification on using 3M's RRBI for Dana reusable BI test pack
From: "Jayan, Geetha C" <geetha.jayan@fda.hhs.gov>
Date: Thu, 17 Jan 2008 16:01:57 -0500
To: "Harry Bala" <bala@voyager.net>
CC: "Murphey, Sheila A" <sheila.murphey@fda.hhs.gov>, "Lin, Chiu S." <chiu.lin@fda.hhs.gov>, "Jayan, Geetha C" <geetha.jayan@fda.hhs.gov>

Dear Mr. Bala:

Thank you for the information you provided on your predicate device

(b)(4)

Based on the information you provided, today I discussed your submission with Dr. Chiu Lin (DAGID Division Director) and Dr. Sheila Murphey (INCB Branch Chief). We concur with (b)(4)

(b)(4)

Now that this issue has been resolved, I am not sure if you are still interested in having a face-to-face meeting with Drs. Lin and Murphey, the purpose of which, as you indicated to me, was to discuss this (b)(4) Please let me know.

(b)(4)

Please consider the following points when using the 3M RRBI for your test pack:

(b)(4)

In addition to the above points, you should provide your response to all (b)(4) deficiencies we communicated to you on 11/16/2007. FDA would like to mention to you that in your S001 response, (b)(4)

(b)(4)

The upcoming S002 review will be your final review cycle before we make a determination on your device. Therefore, please ensure that you (b)(4) deficiencies - you should provide your item-wise response to each deficiency.

(b)(4)

Please contact me if you have additional questions in this regard.

Thank you,
Geetha Jayan

=====
Geetha C. Jayan, Ph. D.



COVER SHEET MEMORANDUM

From: Reviewer Name Geetha C. Jayan
Subject: 510(k) Number K092944/S1
To: The Record

- Please list CTS decision code SE
- Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)
 - Hold (Additional Information or Telephone Hold).
 - Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	Attach IFU	✓	
510(k) Summary/510(k) Statement	Attach Summary	✓	
Truthful and Accurate Statement.	Must be present for a Final Decision	✓	
Is the device Class III?			✓
If yes, does firm include Class III Summary?	Must be present for a Final Decision		✓
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			✓
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC)			✓
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			✓
Is this device intended for pediatric use only?			✓
Is this a prescription device? (If both prescription & OTC, check both boxes.)			✓
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			✓
Is clinical data necessary to support the review of this 510(k)?			✓
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank? (If not, then applicant must be contacted to obtain completed form.)			✓
Does this device include an Animal Tissue Source?			✓
All Pediatric Patients age ≤ 21			✓
Neonate/Newborn (Birth to 28 days)			✓
Infant (29 days - < 2 years old)			✓
Child (2 years - < 12 years old)			✓
Adolescent (12 years - < 18 years old)			✓
Transitional Adolescent A (18 - < 21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			✓

DJA 00005

Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)	-
Nanotechnology	-
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	Contact OC. -

Regulation Number	Class*	Product Code
21 CFR 880.2800	II	FRC.
(*If unclassified, see 510(k) Staff)		

Additional Product Codes: _____

Review: <u>Elaine S. Maghall (acting)</u>	<u>INCB</u>	<u>3-18-10</u>
(Branch Chief)	(Branch Code)	(Date)

Final Review: <u>[Signature]</u>	<u>3/18/10</u>
(Division Director)	(Date)

DJA 00007



DEPARTMENT OF HEALTH AND HUMAN SERVICES MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

**PRE-MARKET NOTIFICATION [510(K)] REVIEW
TRADITIONAL
K092944 / S001**

Date: March 18, 2010
To: The Record
From: Geetha C. Jayan

Office: ODE
Division: DAGID

510(k) Holder: Dana Products Inc., 7 Corey Dr., South Barrington IL 60010.
Device Name: Dana reusable test pack for steam sterilization.
Contact: Mr. Harry Bala
Phone: (847) 455-2881
FAX: (847) 455-2886
e-mail: bala@voyager.net

*ESM
3-18-10*

I. PURPOSE AND SUBMISSION SUMMARY:

Dana Products Inc intends to introduce "Dana reusable test pack for steam sterilization" into interstate commerce; and has submitted a pre-market notification (PMN) for the device.

Proposed classification: Class II. FRC. 21 CFR 880.2800.

Predicate devices cited:

K952408 – 3M Attest 1296 Rapid Readout Test Pack (3M).

K926364 – 3M Attest 1292 Rapid Readout B1 (3M).

K012195 – SteriScan Integrator (Dana Products Inc).

The firm has not provided sufficient information for FDA to make a final determination on the subject device for the indicated use. An additional information letter was sent to the firm on 12/07/09, and the submission was placed on hold (TH).

The firm has now submitted and S001 response. Information pertaining to the S001 response is on page 18, in the section "S001 review".

II. ADMINISTRATIVE REQUIREMENTS:

	Yes	No	N/A
Indications for Use page (OTC)	√		
Truthful and Accuracy Statement	√		
510(k) Statement: on page 4	√		

DCA 00008

	Yes	No	N/A
Standards Form			√

III. DEVICE DESCRIPTION:

	Yes	No	N/A
Is the device life-supporting or life sustaining?		√	
Is the device an implant (implanted longer than 30 days)?		√	
Does the device design use software?		√	
Is the device sterile?		√	
Is the device reusable (not reprocessed single use)?	√		
Are "cleaning" instructions included for the end user?			

The device description is provided on page 5 of the submission is as follows.

(b)(4)
 The reusable test pack consists of an AI tube. One end of the tube (b)(4)
 (b)(4)
 (b)(4) The AI chamber is large enough to accommodate the BI and SteriScan integrator.

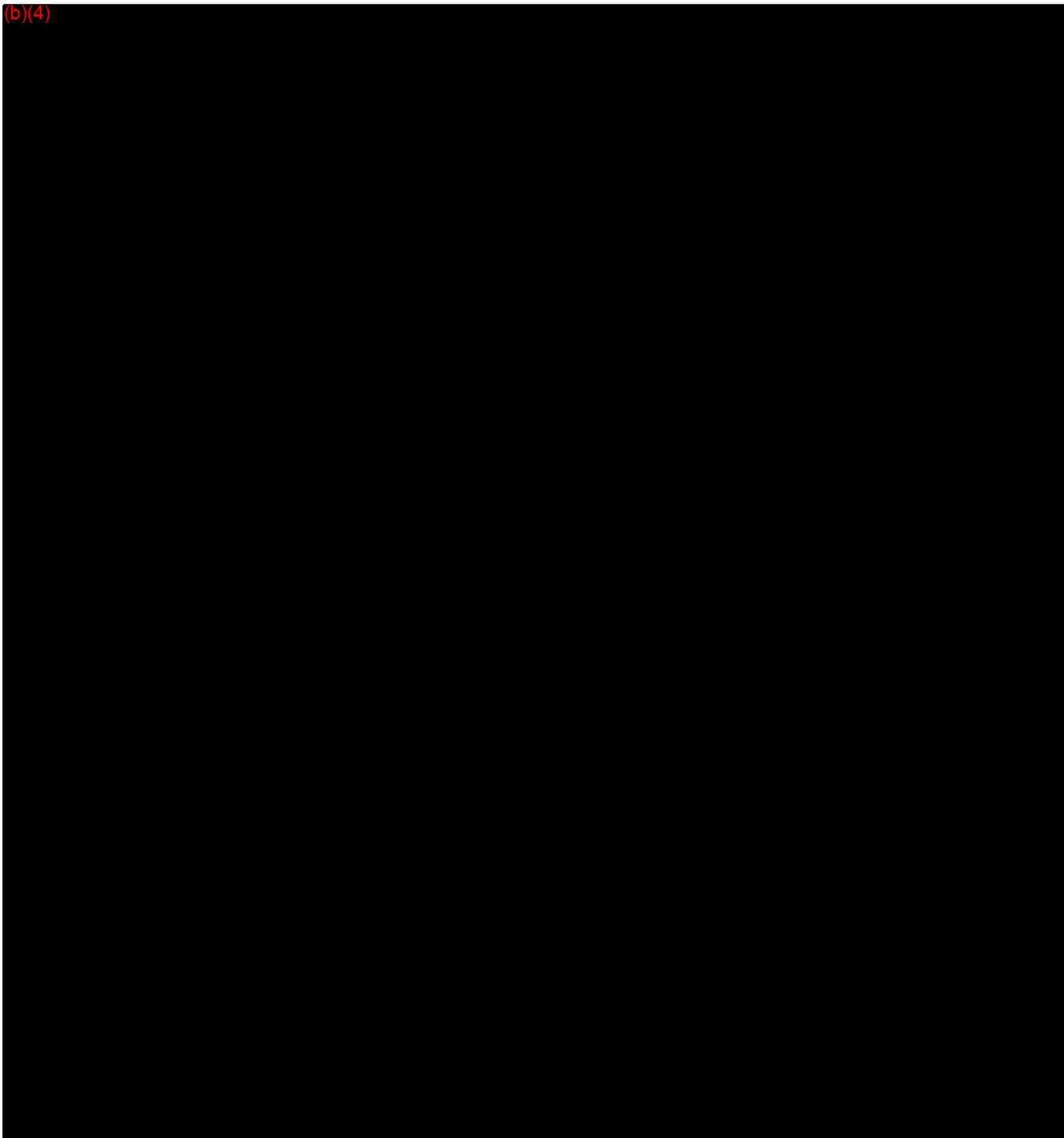
(b)(4)

(b)(4)

(b)(4)

DJA 00009

(b)(4)



IV. INDICATIONS FOR USE (IFU) STATEMENT:

The IFU statement on page 3 of the submission is as follows. Device name: Reusable BI and Integrator test pack for steam sterilization.

Dana reusable challenge test pack is designed to challenge steam sterilization process in health care facilities. It is intended to be used for routine monitoring of pre-vacuum steam sterilization cycles. It is validated to be used in 4 minute 270°F pre-vacuum steam sterilization cycles with 3M's 1292 Rapid Readout Biological Indicators, SteriScan Integrators or both. The

(b)(4)

(b)(4)

(b)(4)

(b)(4)

V. PREDICATE DEVICE COMPARISON:

Predicate devices cited:

K926364 – 3M Attest 1292 Rapid Readout BI (3M).

K952408 – 3M Attest 1296 Rapid Readout Test Pack (3M).

K012195 – SteriScan Integrator (Dana Products Inc).

Information on CDRH IMAGE2000 is as follows:

K926364 is for Attest Brand Rapid Readout Biological Indicator (BI).

The Attest Rapid Readout Biological Indicators are used to monitor the efficacy of sterilization cycles. The indicator is a self-contained unit with a dry spore strip and ampouled medium.

K952408 is for "ATI Disposable Test Pack" for steam sterilization. It contains a BI and a process indicator (PI). The review memo indicates the following:

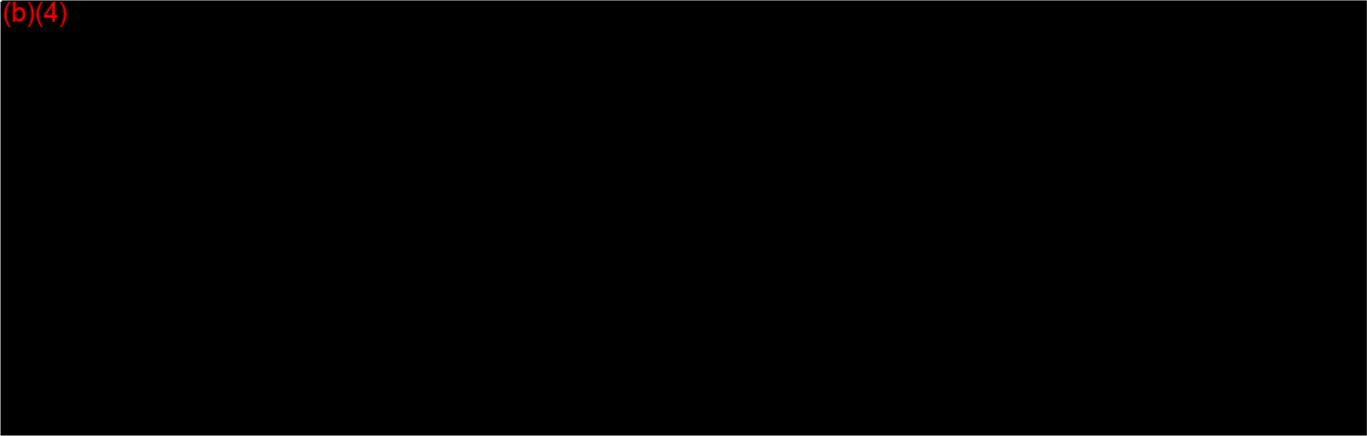
DJA 00011

(b)(4)

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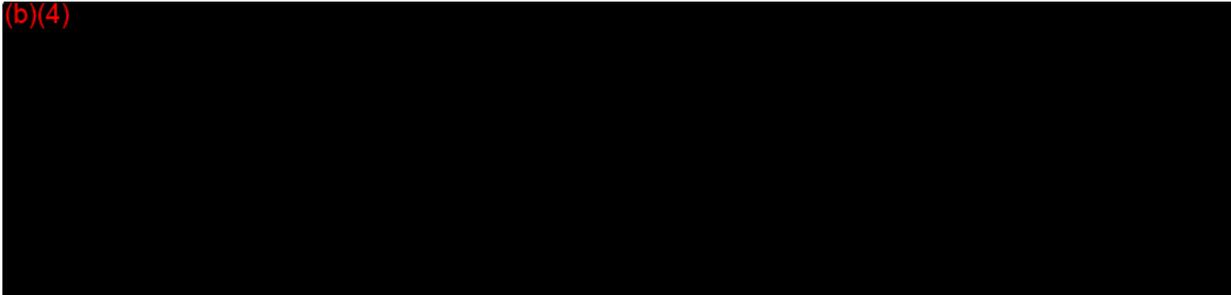
Sterilization indicator:

(b)(4)

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K012195 is for SteriScan Steam Sterilization Integrator.

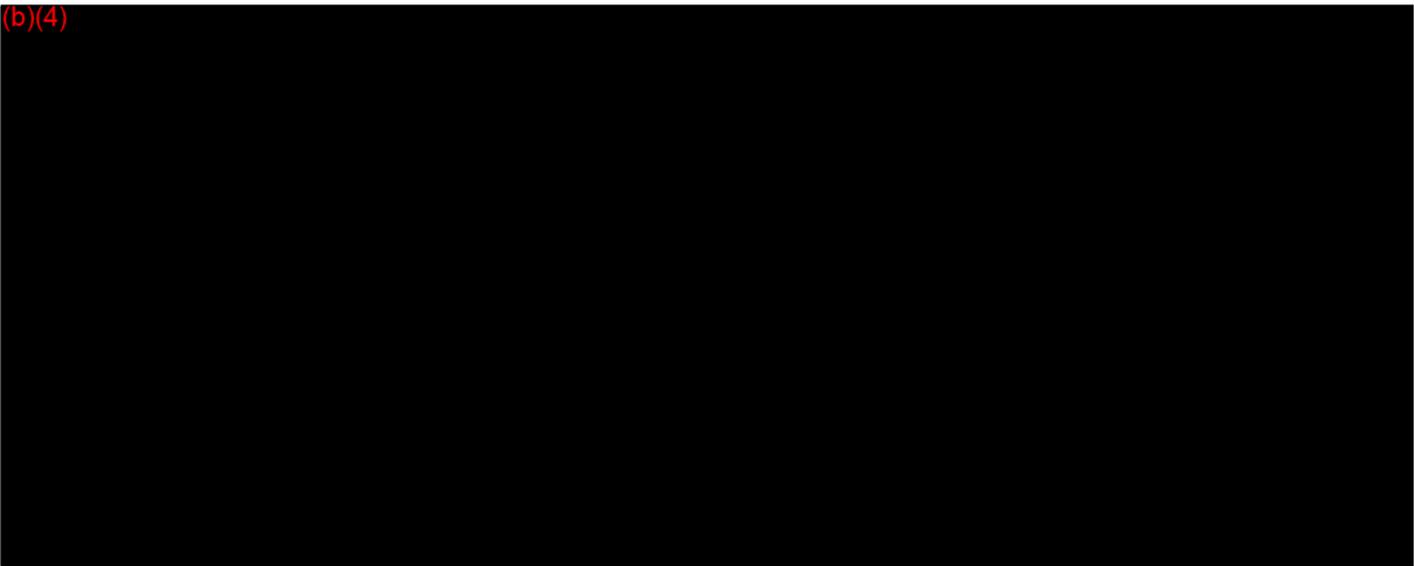
(b)(4)

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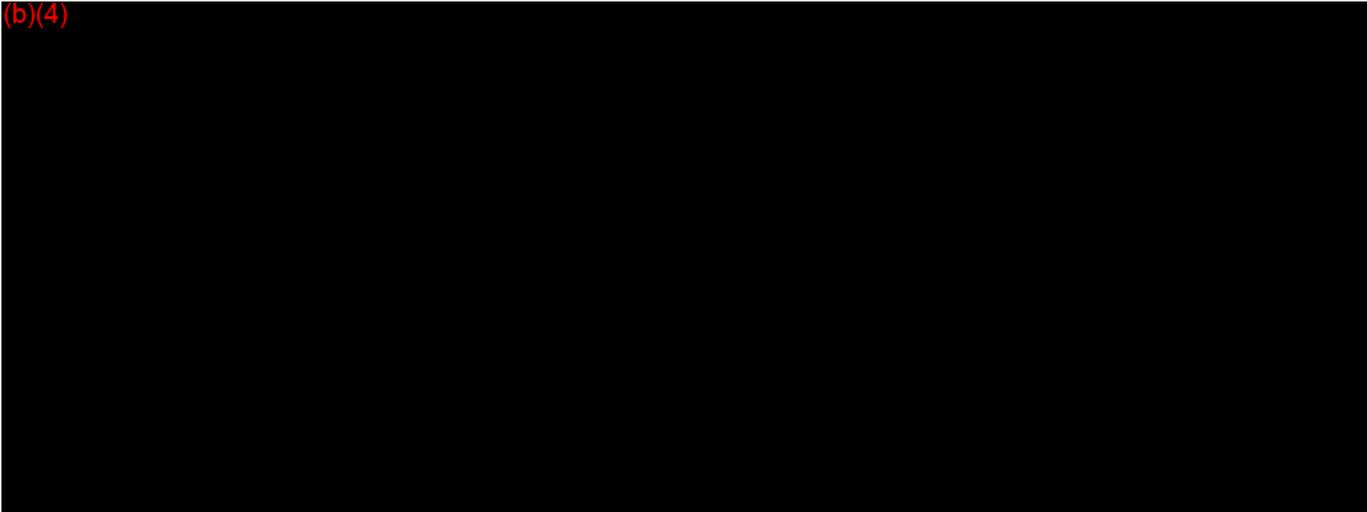
VI. LABELING: (PAGE 27)

The firm should address the following comments:

(b)(4)

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(b)(4)



VII. SHELF LIFE/REUSE: (PAGE 27)

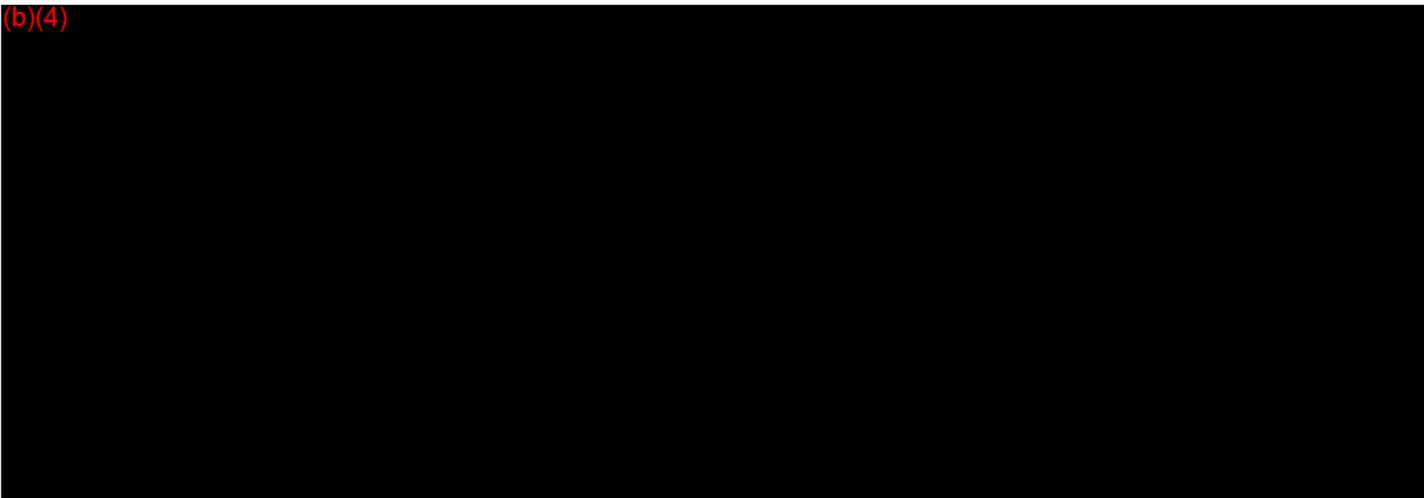
Shelf life: 1 year at this time; it will be updated as more test data is obtained.

The individual parts for Dana test pack were manufactured four years ago. The finished assemblies are nine months old. It will at least be one year from the assembly date before the packaging is finalized and cleared for marketing. At the end of one year Dana will test to validate the performance of the retained samples.

Reuse life: 200 times. Data is provided in performance testing, to support reuse of 200 times.

VIII. BIOCOMPATIBILITY:

(b)(4)



IX. SOFTWARE:

The device has no software. This section is not applicable.

X. ELECTROMAGNETIC COMPATIBILITY AND ELECTRICAL, MECHANICAL AND THERMAL SAFETY:

The device has no electrical components. This section is not applicable.

XI. PERFORMANCE TESTING – BENCH:

Performance testing information is provided on pages 8 – 29.

DJA 00020

The Attest Rapid Readout Biological Indicators are used to monitor the efficacy of sterilization cycles. The indicator is a self-contained unit with a (b)(4)

(b)(4)

The Attest Rapid Readout Biological Indicator are intended for use by health care providers to accompany products being sterilized through a sterilization procedure and to monitor adequacy of said sterilization cycle.

K952408:

Device Description: The ATI Disposable Test Pack for steam sterilization is a disposable test pack for the installation and routine monitoring of both gravity displacement and pre-vacuum steam sterilizers. The test pack is comprised of 21 blank sheets of index paper, 40 sheets of index paper with an oval die cut in the middle (nominally 7 1/2 x 4 3/4 in.), and two sheets of index paper laminated on one side with a (b)(4) film. The entire contents of the pack are wrapped with a 15 x 15 inch (b) Wrap. The wrap is held together by a printed label with a pressure sensitive adhesive. Any legally marketed sterilization indicator (chemical and/or biological) can be placed inside the cavity formed by the 40 die cut sheets. The test pack will be supplied fully assembled with a legally marketed sterilization indicator.

(b)(4)

(b)(4)

(b)(4) testing.

(b)(4)

(b)(4)

(b)(4) testing (b)(4)

(b)(4)

XII. PERFORMANCE TESTING – ANIMAL:

Not applicable.

XIII. PERFORMANCE TESTING – CLINICAL:

Not applicable to this device.

XIV. SUBSTANTIAL EQUIVALENCE (SE) DISCUSSION:

Discussion of SE has been deferred until all performance and labeling issues are resolved.

DJA 00021

	Yes	No	
1. Same Indication Statement?	√		If YES = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If YES = Stop NSE
3. Same Technological Characteristics?		√	If YES = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?		√	If YES = Go To 6
5. Descriptive Characteristics Precise Enough?		√	If NO = Go To 8 If YES = Stop SE
6. New Types Of Safety Or Effectiveness Questions?		√	If YES = Stop NSE
7. Accepted Scientific Methods Exist?		√	If NO = Stop NSE
8. Performance Data Available?	√		If NO = Request Data
9. Data Demonstrate Equivalence?	√		On TH after S000 review.

XV. DEFICIENCIES:

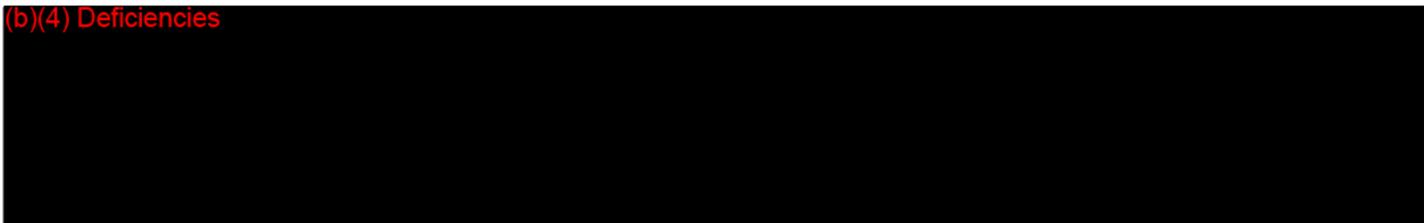
The following deficiencies were communicated to the firm on 12/07/2009.

To complete the review of this submission, please provide additional information and clarification as detailed below. Please provide an item-wise response to each deficiency.



DJA 00024

(b)(4) Deficiencies

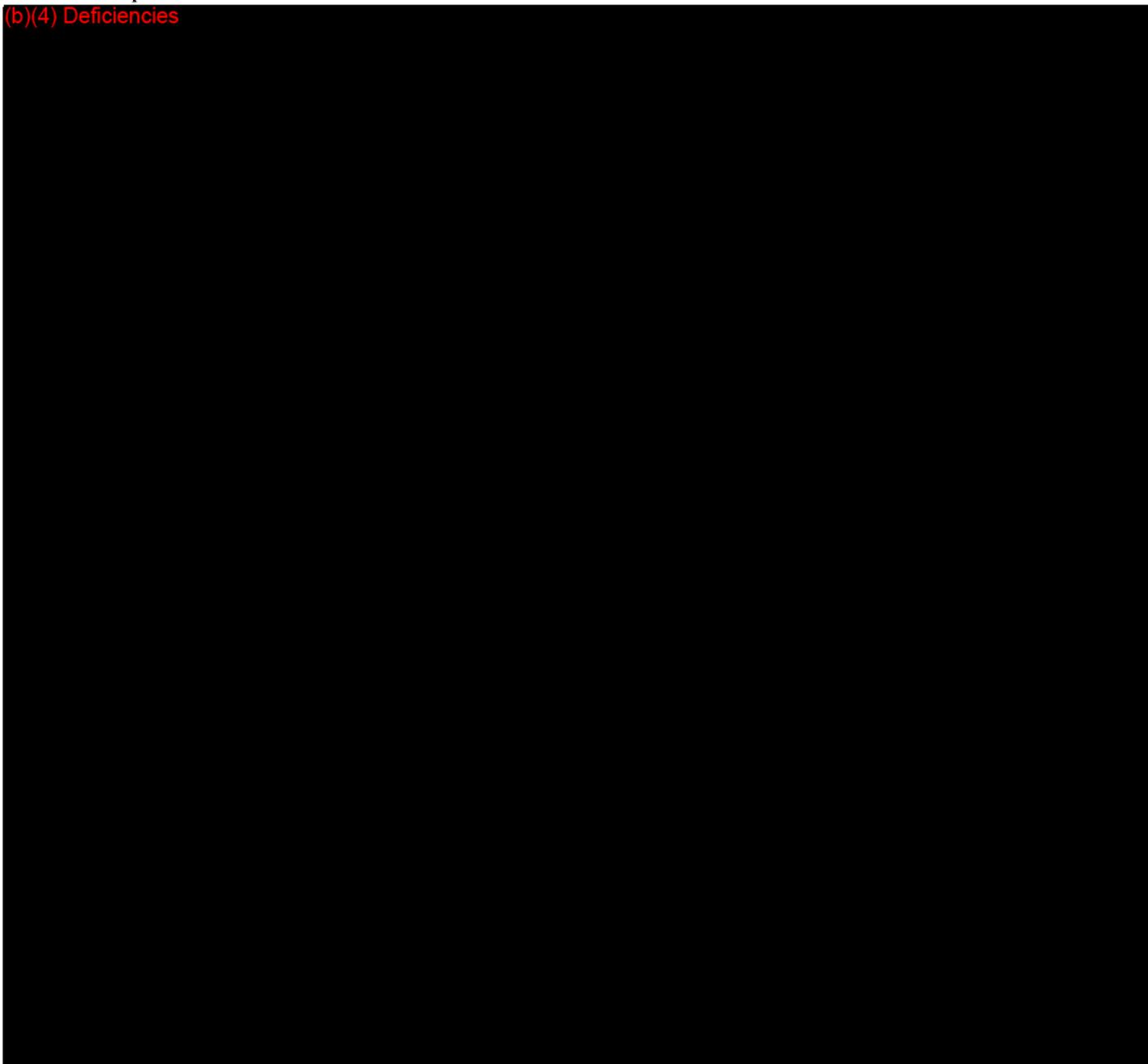
A large black rectangular redaction box covers the majority of the page's upper section, starting below the header and ending above the reviewer comment.

Reviewer comment: This submission was assigned to me and I received this submission for S000 review on 11/23/2009, which is FDA-day 59 on the submission. I have completed the S000 review on 12/07/2009, which is FDA-day 73.

S001 REVIEW

In this section, FDA's 12/07/2009 deficiencies to the firm are stated, followed by the firm's S001 response and FDA comments.

(b)(4) Deficiencies

A very large black rectangular redaction box covers the entire lower half of the page, starting below the S001 REVIEW section and extending to the footer.

(b)(4) Deficiencies

XVI. CONTACT HISTORY:

12/07/2009: FAXed deficiencies, after S000 review, to the firm (attention Mr. Harry Bala, 847-455-2886).

03/12/10: Phone and e-mail communication with the sponsor to resolve concerns in the IFU statement and labeling.

XVII. RECOMMENDATION: SE (03/18/2010)

Regulation Number: 21 CFR 880.2800

Regulation Name: Sterilization process indicator

Regulatory Class: II

Product Code: FRC



Reviewer: Geetha C. Jayan

Date: 03/18/2010



Acting Branch Chief: Dr. Elaine Mayhall, Ph. D.

Date: 3-18-10

DJA 00029

Indications for Use

510(k) Number (if known): K092944

Device Name: Reusable Biological Indicator and Integrator Test Pack for Steam Sterilization.

Indications For Use:

Dana reusable test pack is designed to challenge steam sterilization process in healthcare facilities. It is intended to be used for routine monitoring of pre-vacuum steam sterilization cycles. It is validated to be used in 4 minute 270°F pre-vacuum steam sterilization cycles with 3M's 1292 Rapid Readout Biological Indicators along with or without SteriScan Integrators.

Prescription Use _____ AND/OR
(Part 21 CFR 801 Subpart D)

Over-The-Counter Use X
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

DJA 00030

LABELING:

ITEM - 14:

(b)(4)

ITEM -15:

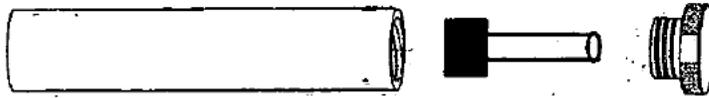
The following is the draft of the labeling that will be applied on each test pack.

Dana Reusable Test Pack

For 270° F 4minute Pre-Vacuum Cycles

For use with 3M Attest 1292 BI

With or without SteriScan Integrator



Insert first open end of BI in Test Pack

Insert first Pellet End of SteriScan Indicator

Discard after 100 Uses

**Dana Products, Inc.
11457 Melrose St.
Franklin Park, IL**

**Serial Number:
Lot Number:
Exp.:**

LABELING:

ITEM - 16 - 18:

The following is the draft of the instructions that would accompany the test packs:

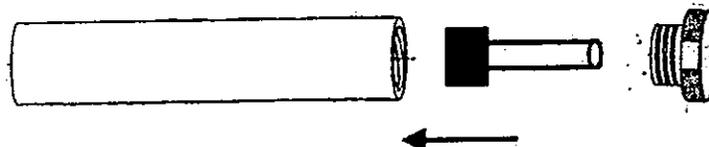
Dana Reusable Test Pack

Product Description:

Dana reusable test pack is designed to challenge steam sterilization process in healthcare facilities and for routine monitoring of pre-vacuum steam sterilization cycles. It is to be used in 4 minute 270°F pre-vacuum steam sterilization cycles with 3M's 1292 Rapid Readout Biological Indicators along with or without SteriScan Integrators. It can be used 100 times without the test pack losing its effectiveness.

Direction for Use:

1. Open the screw cap.
2. Insert 3M's 1292 Rapid Read out Biological open end first in the test pack as shown. SteriScan indicator can also be used in addition to the BI by inserting the pellet end first into the test pack.



**Insert first open end of BI in Test Pack
Insert first Pellet End of SteriScan Indicator**

3. Screw on the cap tight.
4. Place the test pack on the bottom shelf above the drain.
5. Process the load according to recommended practices.
6. After completion of the cycle open the sterilizer door and wait at least 5 minutes before removing the test pack.
7. Use gloves to remove the test pack from the sterilizer.
8. Do not open the test pack until it has sufficiently cooled off.
9. Open the screw cap.
10. Remove the 3M's Rapid Readout BI and the SteriScan indicator if it is used along with the BI.
11. Follow the instructions provided with the 1292 BI and the SteriScan indicator by their respective manufacturers to read and interpret the results.

12. Both SteriScan and 1292 BIs are single use devices. Dispose these devices after one use per manufacturer's directions.
13. Enter the serial number of the test pack and the date of initial use in the card supplied along with the test pack. Track the number of uses by crossing off the numbers sequentially as shown below.

Dana Test Pack

Serial Number:

Date of initial use:

Discard test pack after 100 uses

1 2 3 4 5 6 7 8 9 10
11 12 13 14 15 16 17 18 19 20
21 22 23 24 25 26 27 28 29 30
31 32 33 34 35 36 37 38 39 40
41 42 43 44 45 46 47 48 49 50
51 52 53 54 55 56 57 58 59 60
61 62 63 64 65 66 67 68 69 70
71 72 73 74 75 76 77 78 79 80
81 82 83 84 85 86 87 88 89 90
91 92 93 94 95 96 97 98 99 100

14. Discard the test pack after 100 uses.
15. Store at normal room conditions: Temperature 60° to 85° F Humidity 30 –70%

Cleaning:

Clean the test pack only with alcohol. Wipe the outside and rinse the inside with alcohol.

Precautions:

1. Use only with 270°F pre-vacuum steam sterilization cycles.
2. Use gloves to handle test pack after sterilization.
3. Wait until the test pack cools off before opening.
4. Discard after 100 uses.
5. Both SteriScan and 1292 BIs are single use devices. Dispose these devices after one use per manufacturer's directions.

Made in USA by
Dana Products
11457 Melrose Street
Franklin Park, IL 60131
847-455-2881



Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Geetha C. Jayan
Subject: 510(k) Number K092944
To: The Record

Please list CTS decision code TH
 Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/D_5631/Screening%20Checklist%207%202%2007.doc)
 Hold (Additional Information or Telephone Hold)
 Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.)

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	Attach IFU		
510(k) Summary / 510(k) Statement	Attach Summary	✓	
Truthful and Accurate Statement.	Must be present for a Final Decision	✓	
Is the device Class III?			
If yes, does firm include Class III Summary?	Must be present for a Final Decision		✓
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			✓
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/D_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC)			✓
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			✓
Is this device intended for pediatric use only?			✓
Is this a prescription device? (If both prescription & OTC, check both boxes.)			✓
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			✓
Is clinical data necessary to support the review of this 510(k)?			✓
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank? (If not, then applicant must be contacted to obtain completed form.)			✓
Does this device include an Animal Tissue Source?			✓
All Pediatric Patients age <= 21			✓
Neonate/Newborn (Birth to 28 days)			✓
Infant (29 days -< 2 years old)			✓
Child (2 years -< 12 years old)			✓
Adolescent (12 years -< 18 years old)			✓
Transitional Adolescent A (18 - < 21 years old) Special considerations are being given to this group; different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			✓

DJA 00198

DJA 00199

Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)			
Nanotechnology			
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)		Contact OC.	
Regulation Number	Class*	Product Code	

21 CFR 880.2800

II

FRC

Additional Product Codes: (*If unclassified, see 510(k) Staff)

Review: *Elizabeth F. Claverie-Webb*
 (Branch Chief)

INCB
 (Branch Code)

12-7-09
 (Date)

Final Review: _____
 (Division Director)

(Date)



DEPARTMENT OF HEALTH AND HUMAN SERVICES MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

**PRE-MARKET NOTIFICATION [510(K)] REVIEW
TRADITIONAL
K092944**

*Edyett 8. (Comment) will
12-7-09*

Date: Dec.07, 2009
To: The Record
From: Geetha C. Jayan

Office: ODE
Division: DAGID

510(k) Holder: Dana Products Inc., 7 Corey Dr., South Barrington IL 60010.
Device Name: Dana reusable test pack for steam sterilization.
Contact: Mr. Harry Bala
Phone: (847) 455-2881
FAX: (847) 455-2886
e-mail: bala@voyager.net

I. PURPOSE AND SUBMISSION SUMMARY:

Dana Products Inc intends to introduce "Dana reusable test pack for steam sterilization" into interstate commerce; and has submitted a pre-market notification (PMN) for the device.

Proposed classification: Class II. FRC. 21 CFR 880.2800.

Predicate devices cited:

- K952408 – 3M Attest 1296 Rapid Readout Test Pack (3M).
- K926364 – 3M Attest 1292 Rapid Readout BI (3M).
- K012195 – SteriScan Integrator (Dana Products Inc).

The firm has not provided sufficient information for FDA to make a final determination on the subject device for the indicated use. An additional information letter was sent to the firm on 12/07/09, and the submission was placed on hold (TH).

II. ADMINISTRATIVE REQUIREMENTS:

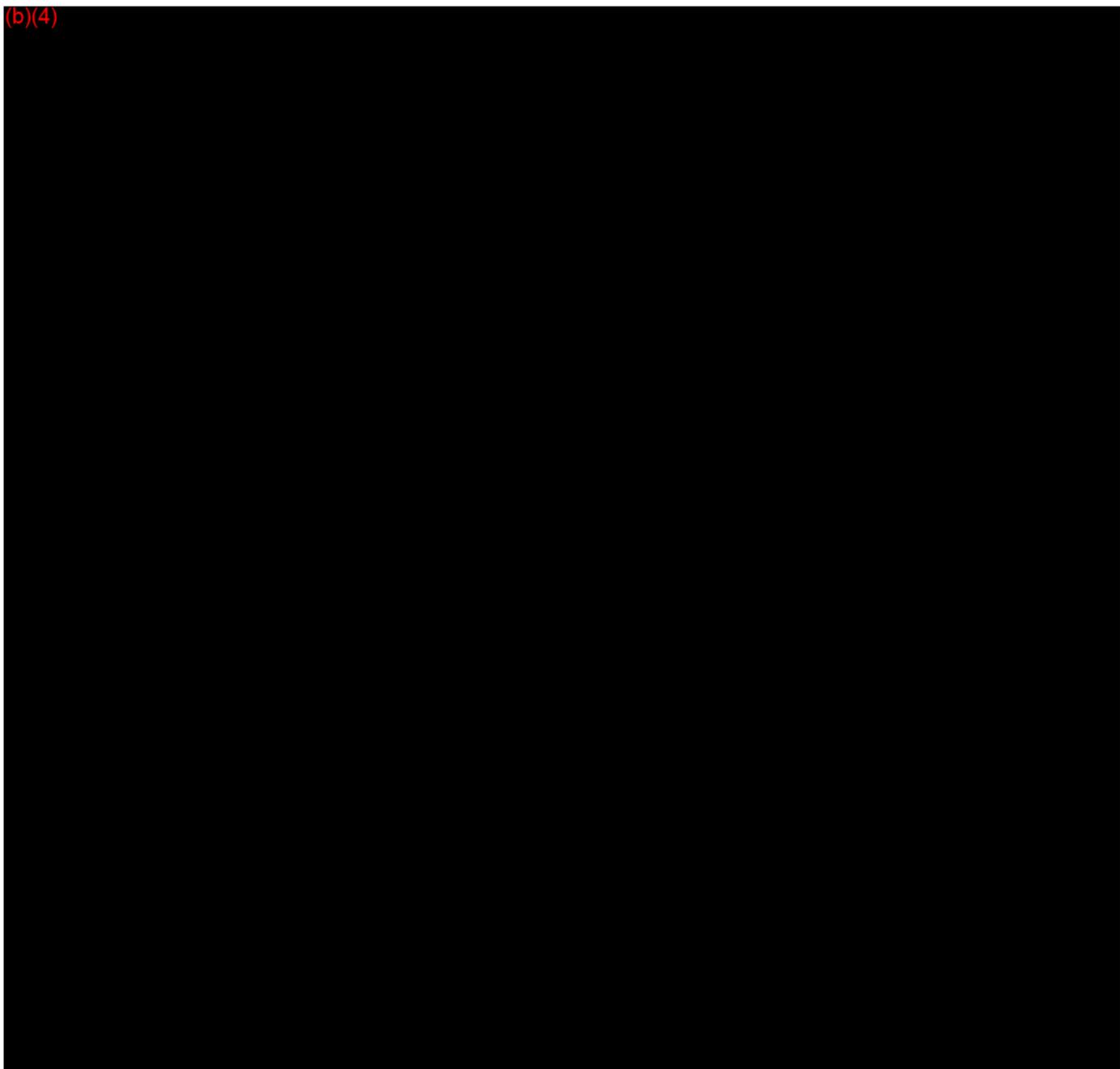
	Yes	No	N/A
Indications for Use page (OTC): on page 3 is inadequate			
Truthful and Accuracy Statement: on page 30	√		
510(k) Statement: on page 4	√		
Standards Form			√

DJA 00201

III. DEVICE DESCRIPTION:

	Yes	No	N/A
Is the device life-supporting or life sustaining?		√	
Is the device an implant (implanted longer than 30 days)?		√	
Does the device design use software?		√	
Is the device sterile?		√	
Is the device reusable (not reprocessed single use)? Are "cleaning" instructions included for the end user?	√		

The device description is provided on page 5 of the submission is as follows.



DJA 00202

(b)(4)

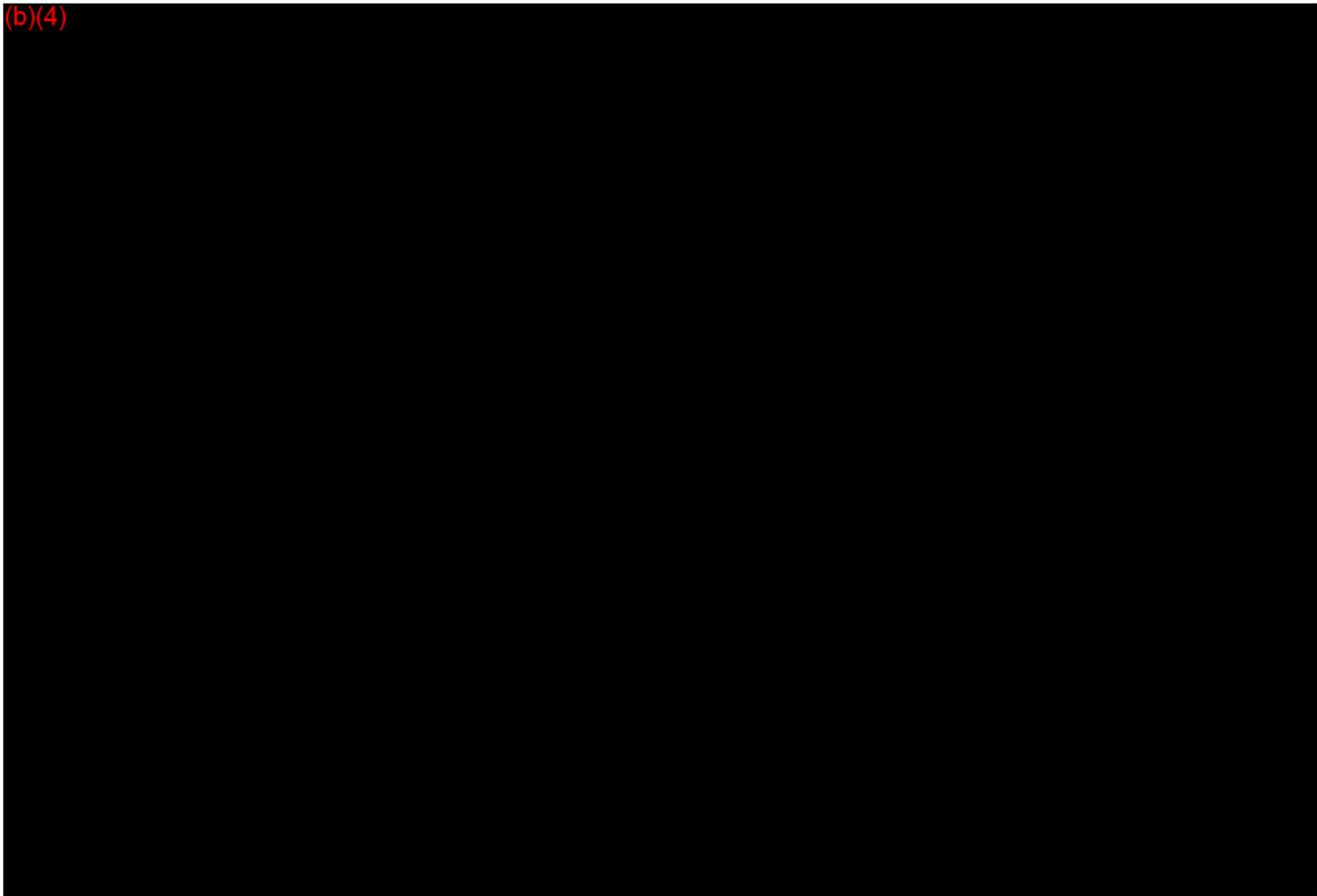


IV. INDICATIONS FOR USE (IFU) STATEMENT:

The IFU statement on page 3 of the submission is as follows. Device name: Reusable BI and Integrator test pack for steam sterilization.

Dana reusable challenge test pack is designed to challenge steam sterilization process in health care facilities. It is intended to be used for routine monitoring of pre-vacuum steam sterilization cycles. It is validated to be used in 4 minute 270°F pre-vacuum steam sterilization cycles with 3M's 1292 Rapid Readout Biological Indicators, SteriScan Integrators or both. The

(b)(4)



V. PREDICATE DEVICE COMPARISON:

Predicate devices cited:

K926364 – 3M Attest 1292 Rapid Readout BI (3M).

K952408 – 3M Attest 1296 Rapid Readout Test Pack (3M).

K012195 – SteriScan Integrator (Dana Products Inc).

Information on CDRH IMAGE2000 is as follows:

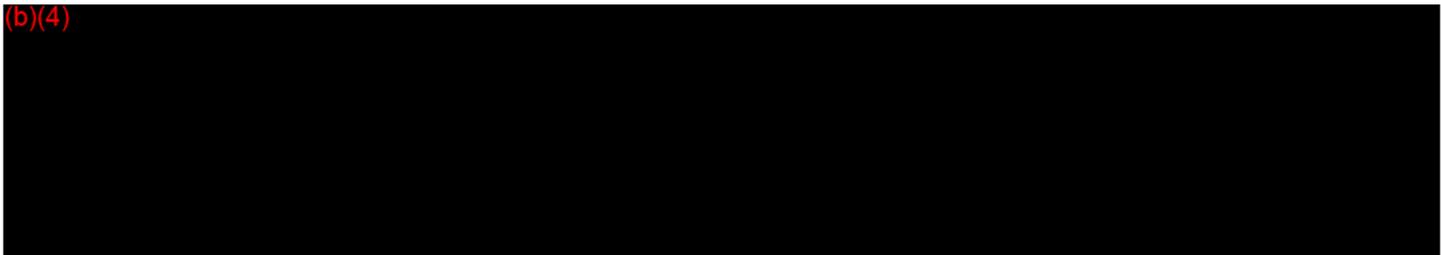
K926364 is for Attest Brand Rapid Readout Biological Indicator (BI).

The Attest Rapid Readout Biological Indicator, are used to monitor the efficacy of sterilization cycles. The indicator is a self-contained unit with a dry spore strip and ampouled medium.

K952408 is for “ATI Disposable Test Pack” for steam sterilization. It contains a BI and a process indicator (PI). The review memo indicates the following:

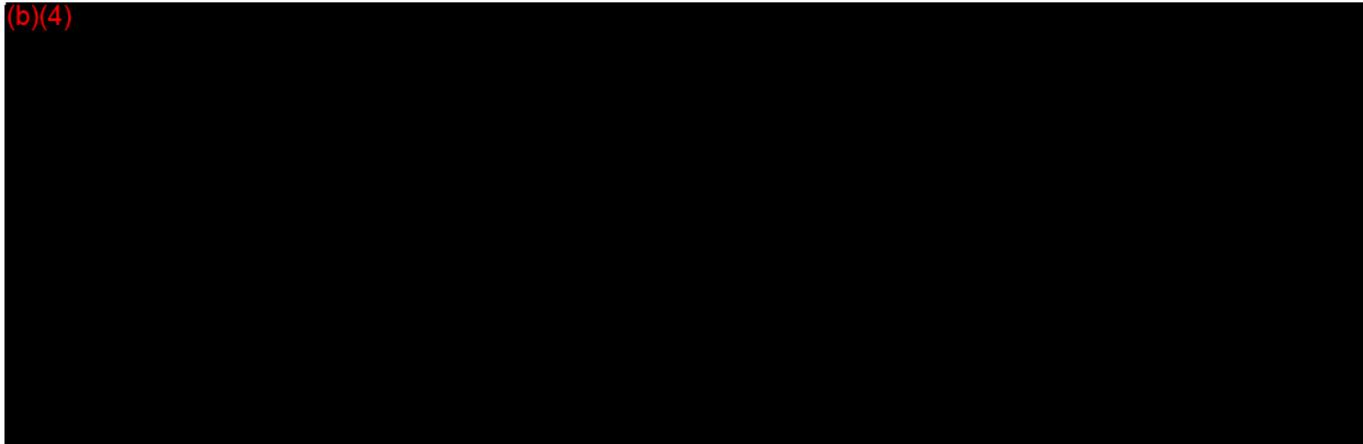
DJA 00204

(b)(4)



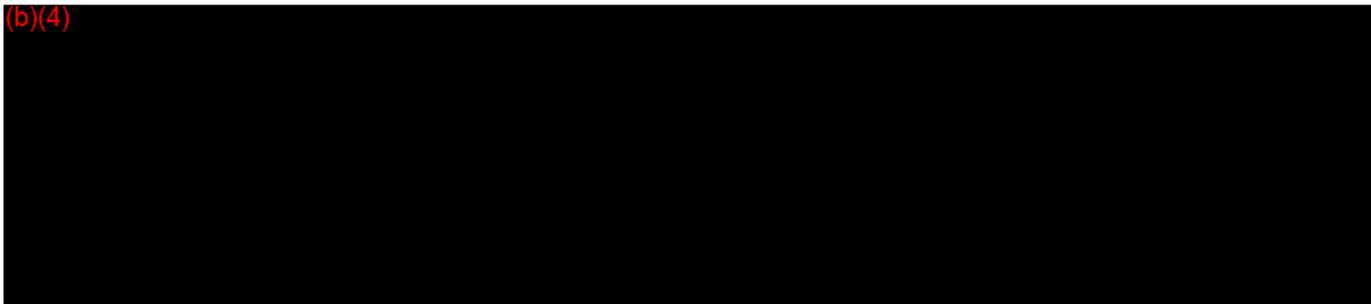
Sterilization indicator:

(b)(4)



K012195 is for SteriScan Steam Sterilization Integrator.

(b)(4)

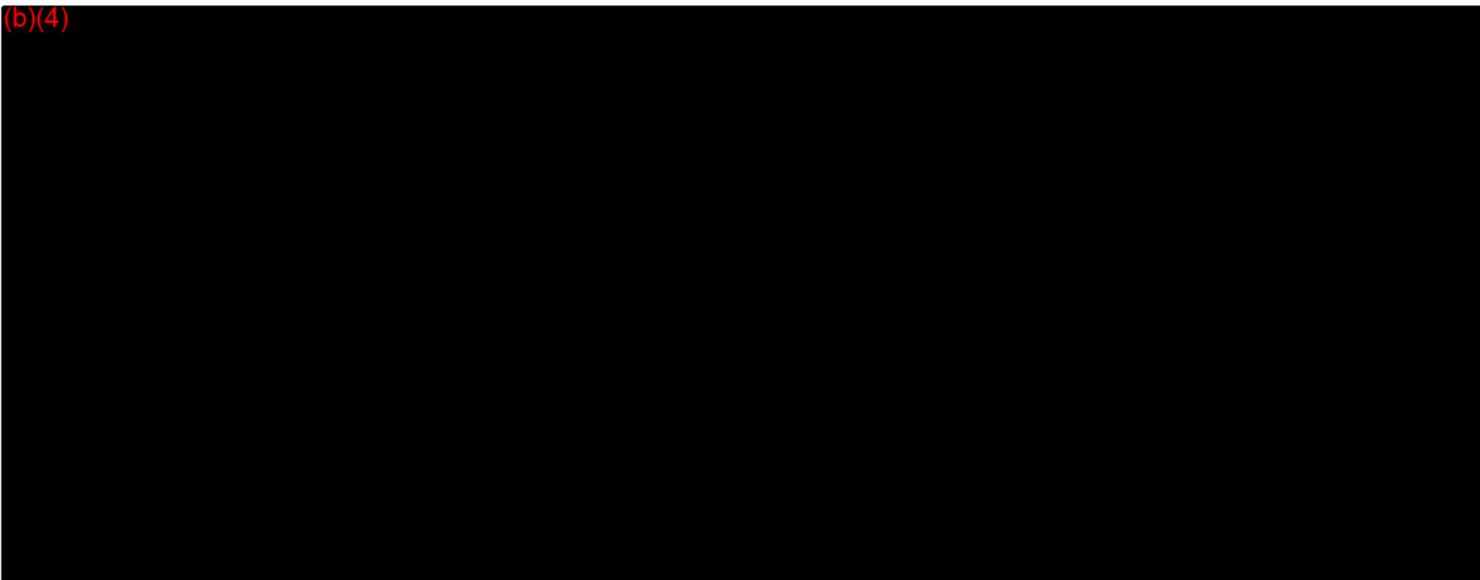


(b)(4)



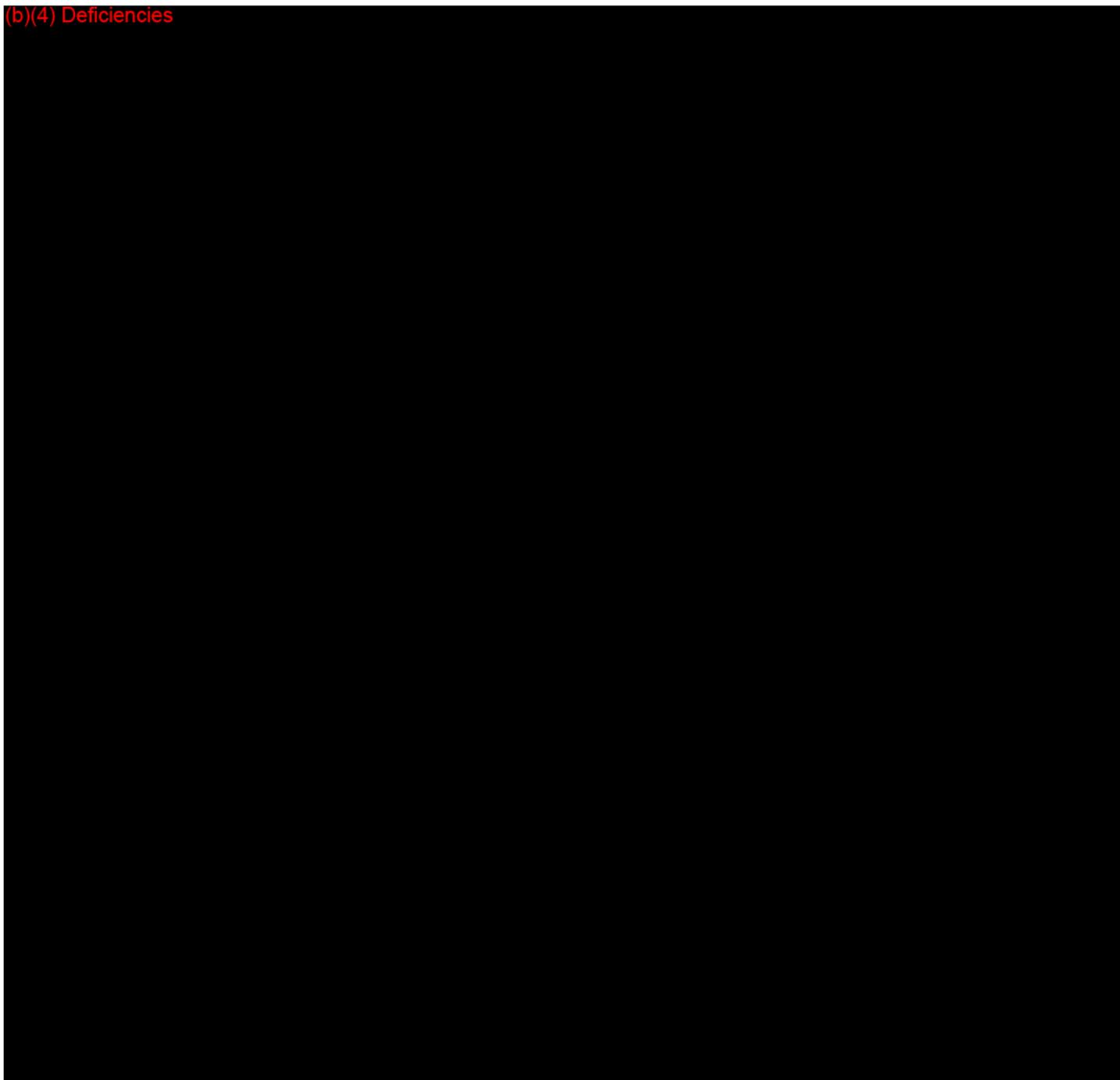
The firm should address the following comments:

(b)(4)



DJA 00205

(b)(4) Deficiencies



IX. SOFTWARE:

The device has no software. This section is not applicable.

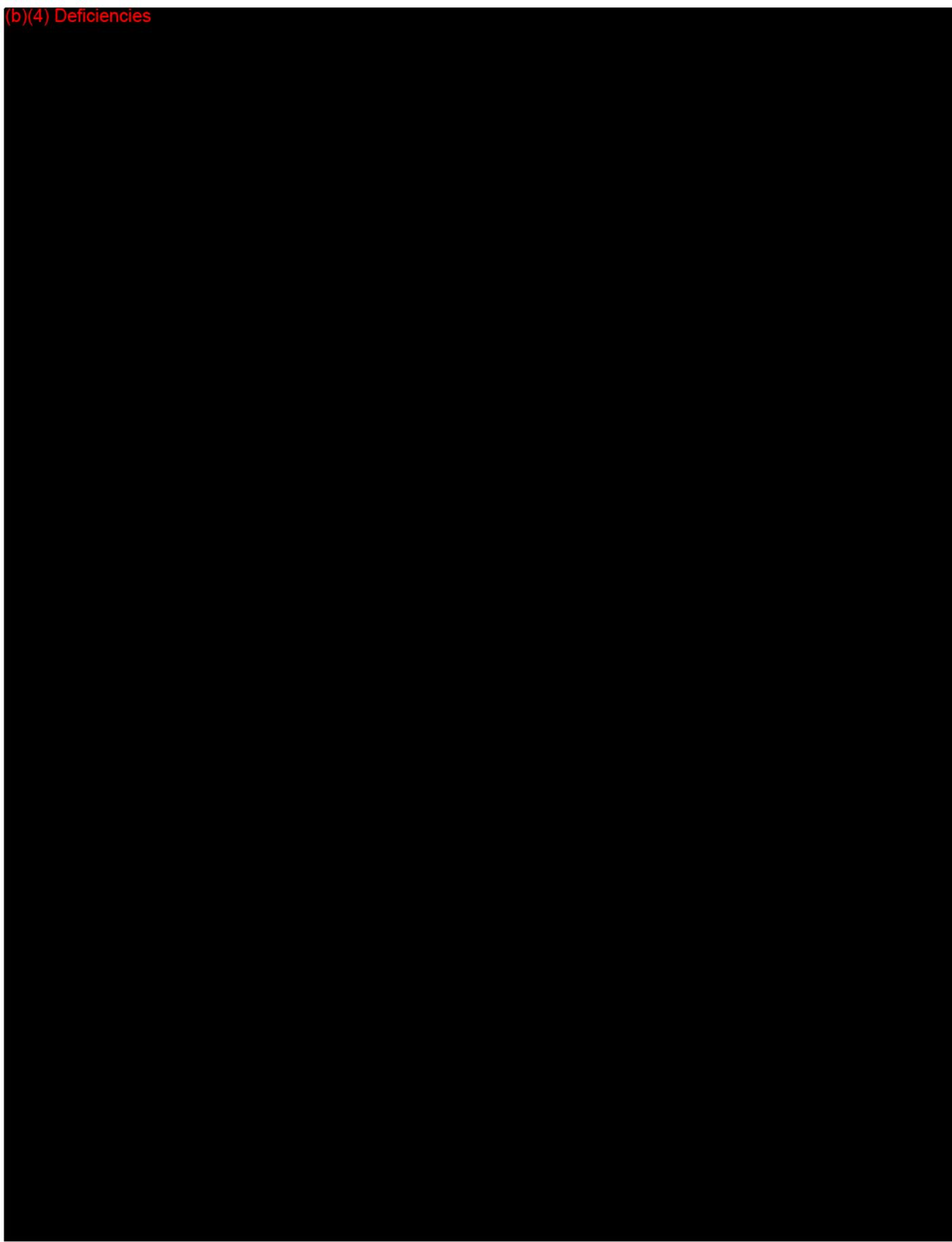
X. ELECTROMAGNETIC COMPATIBILITY AND ELECTRICAL, MECHANICAL AND THERMAL SAFETY:

The device has no electrical components. This section is not applicable.

XI. PERFORMANCE TESTING – BENCH:

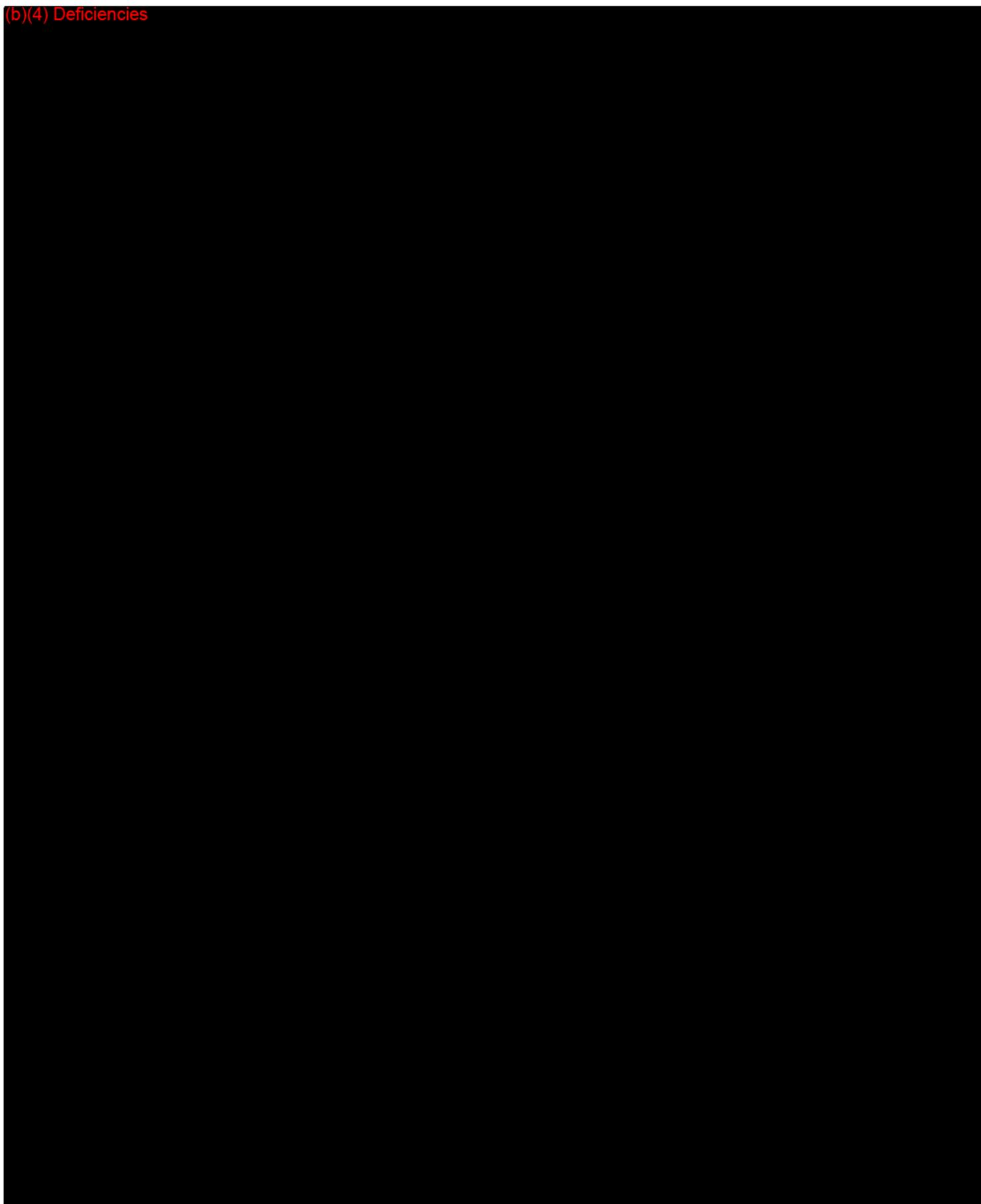
Performance testing information is provided on pages 8 – 29.

(b)(4) Deficiencies



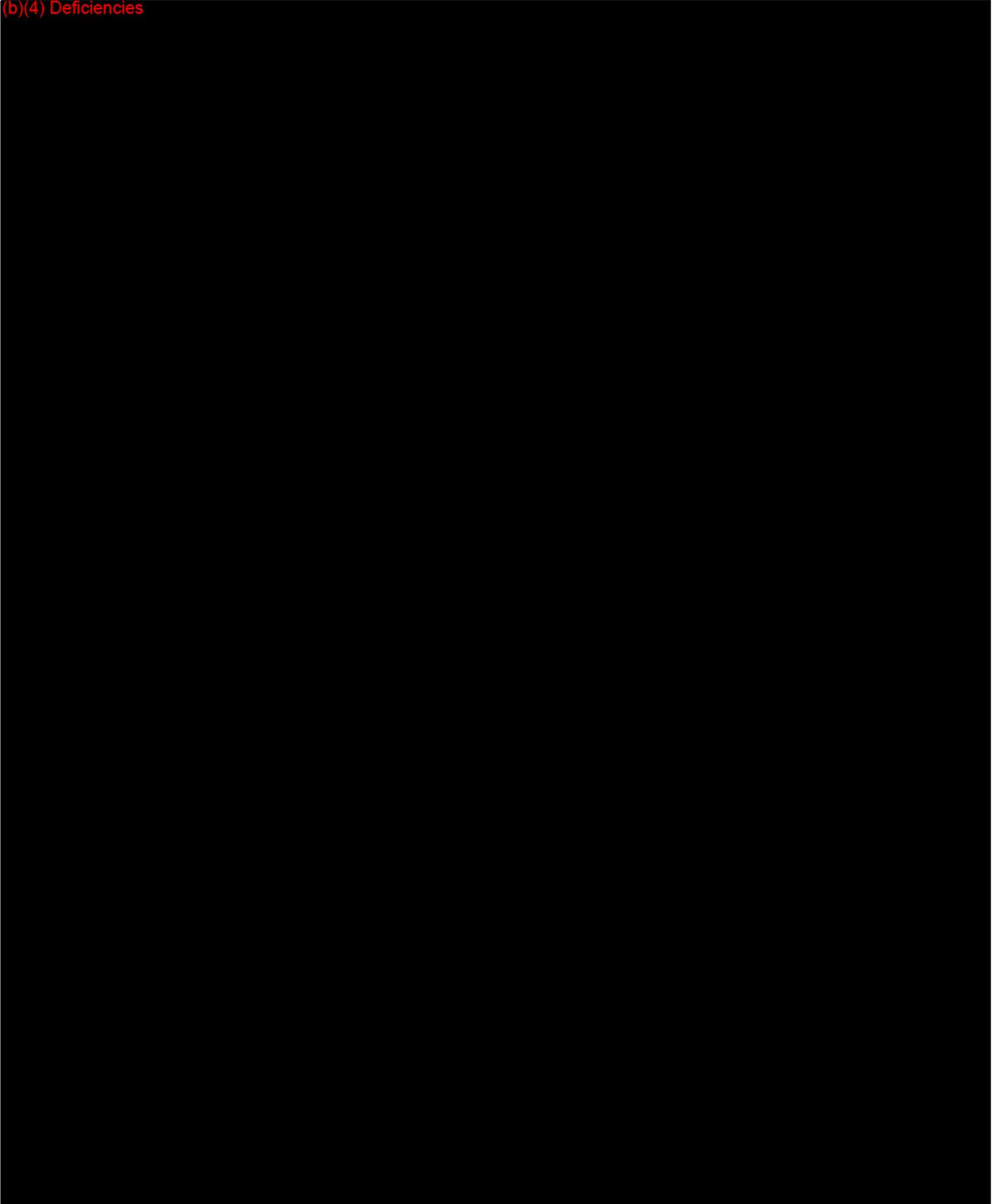
DJA 00207

(b)(4) Deficiencies



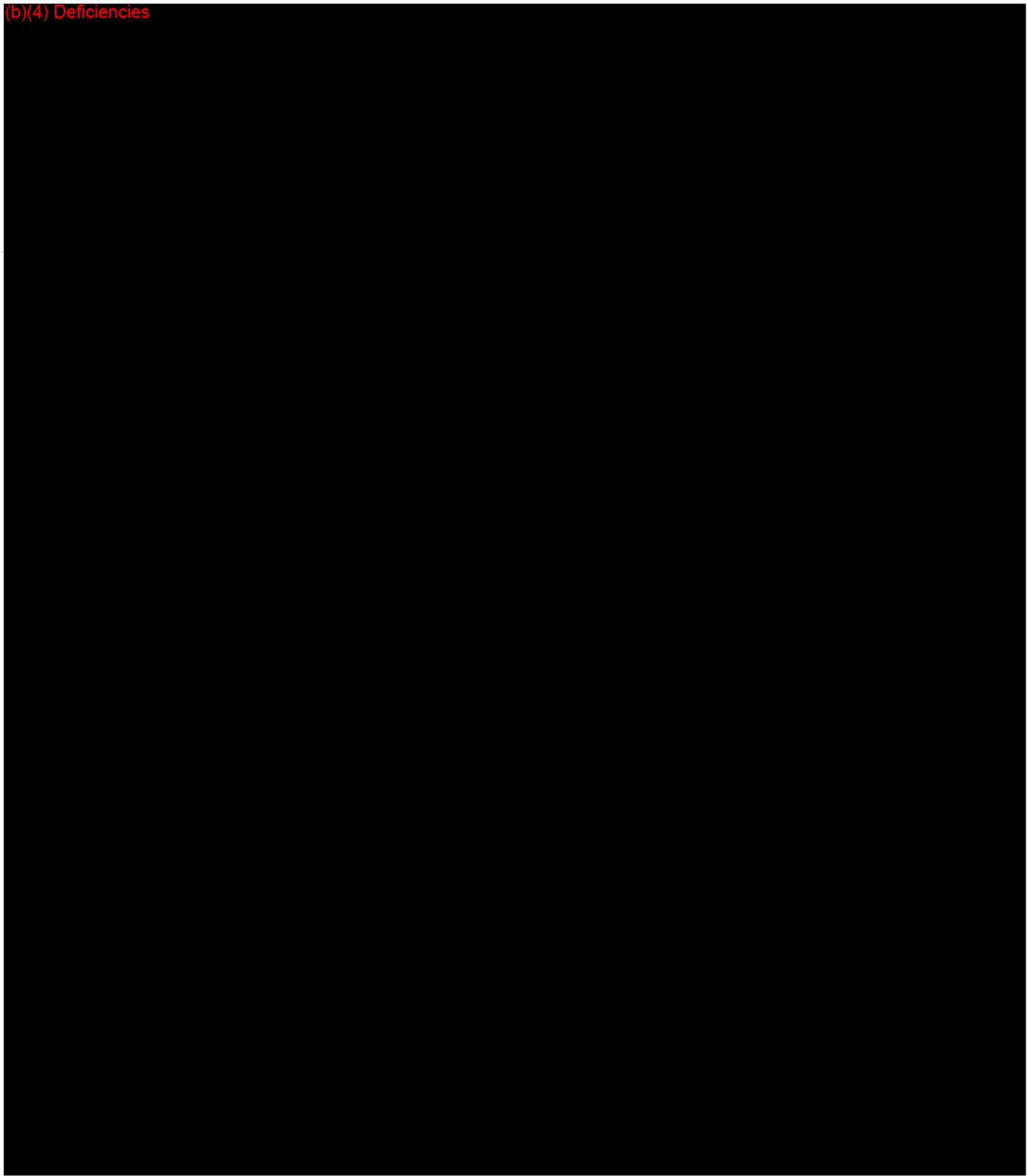
DJA 00208

(b)(4) Deficiencies



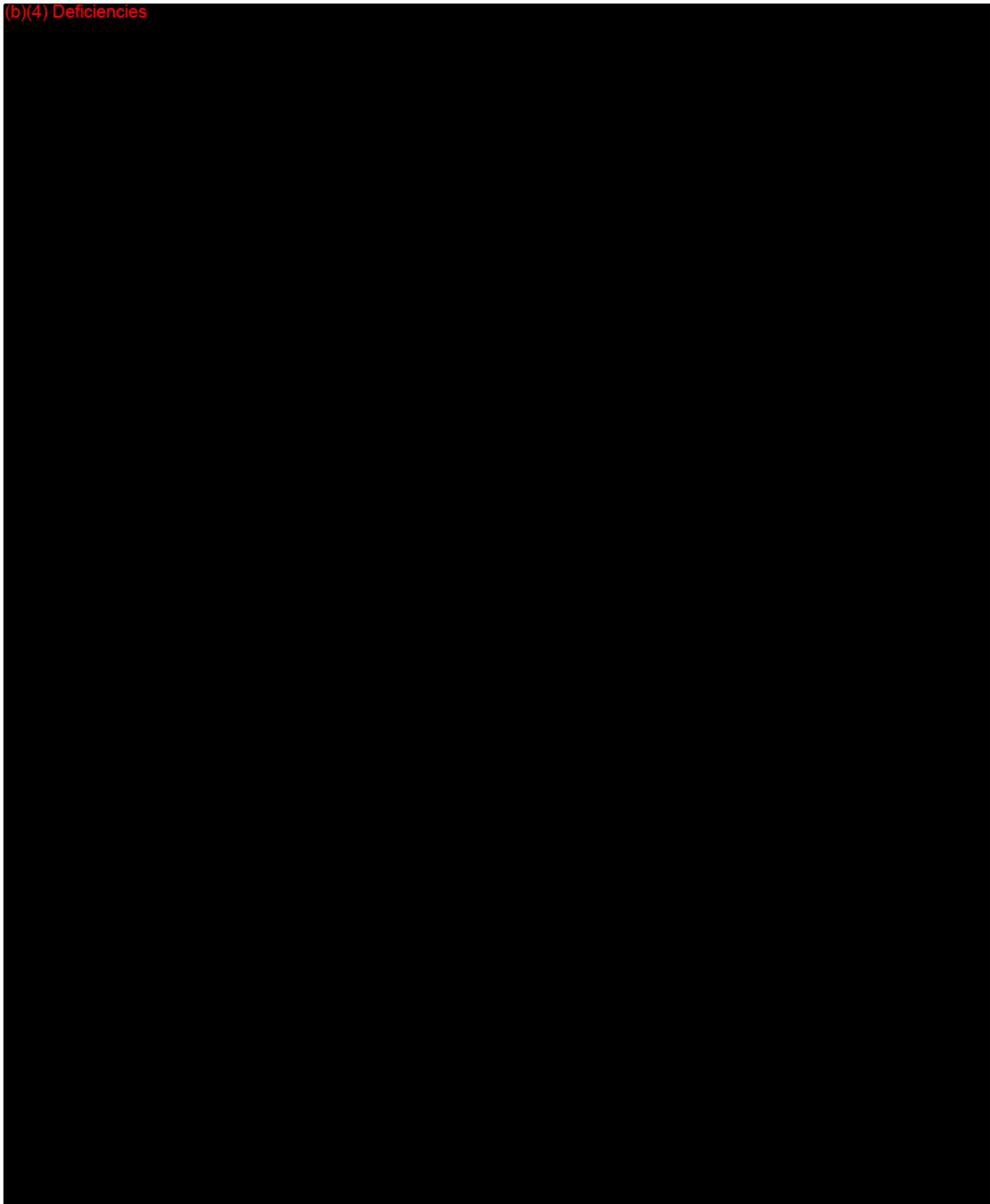
DJA 00209

(b)(4) Deficiencies



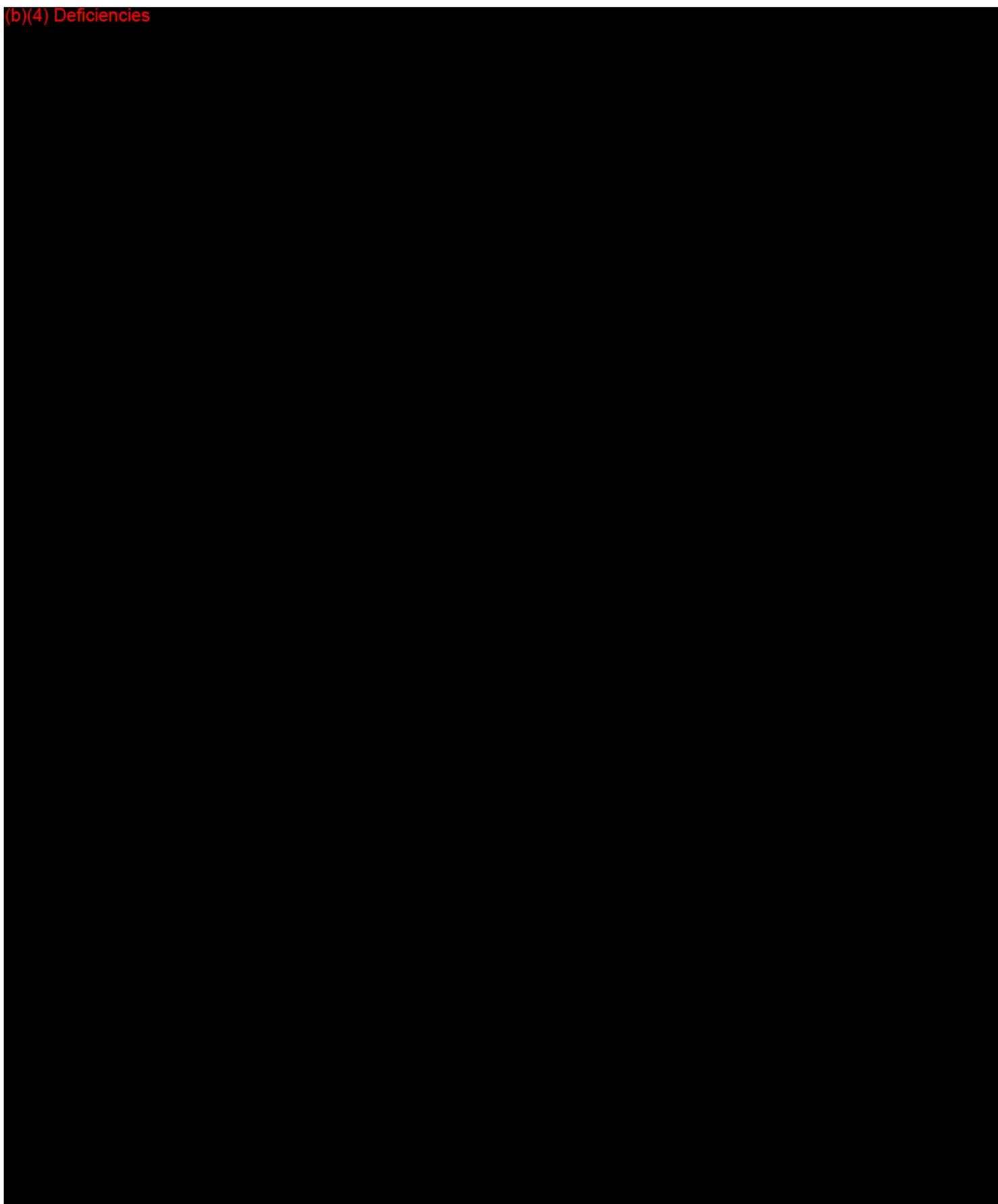
DJA 00210

(b)(4) Deficiencies



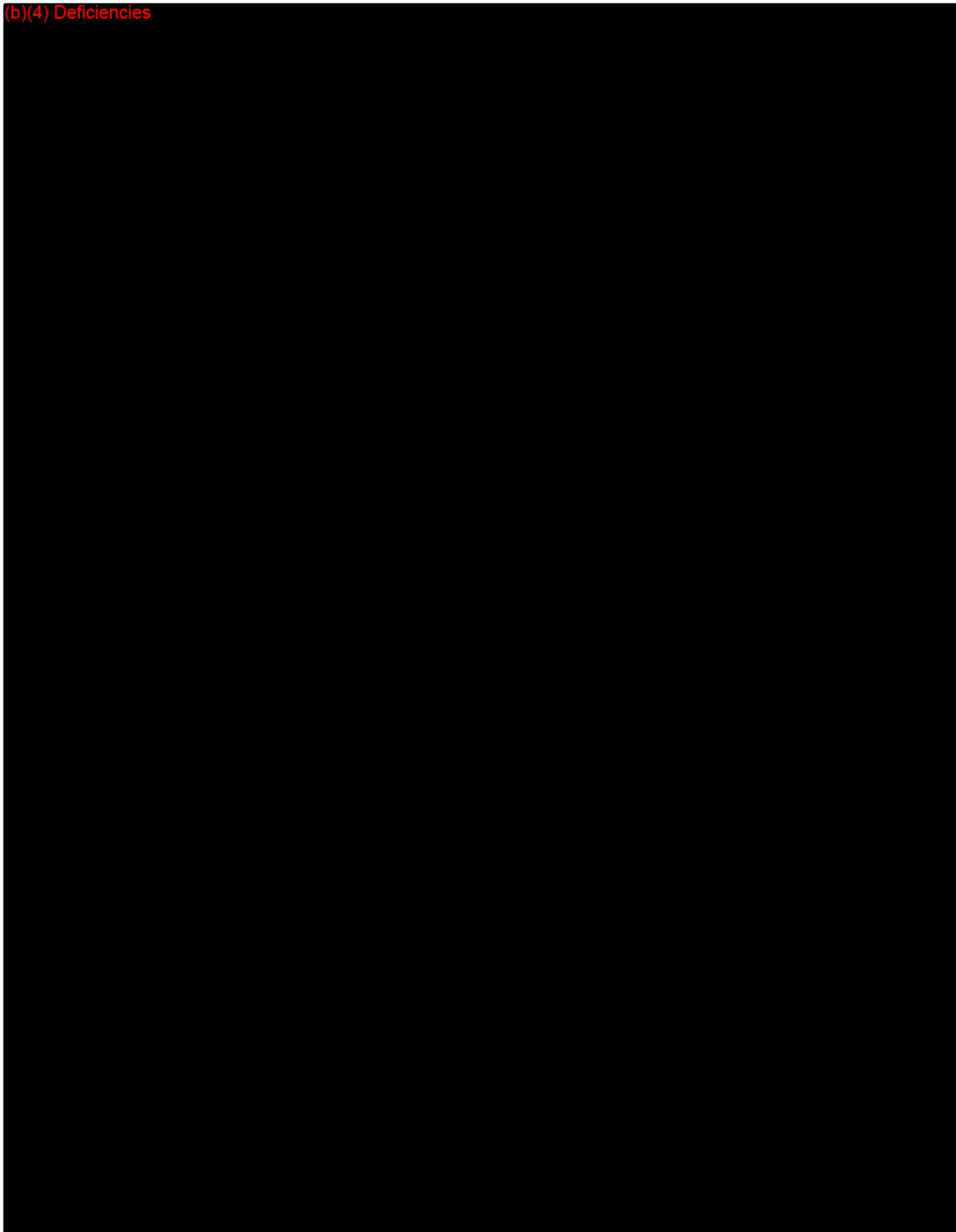
DJA 00211

(b)(4) Deficiencies

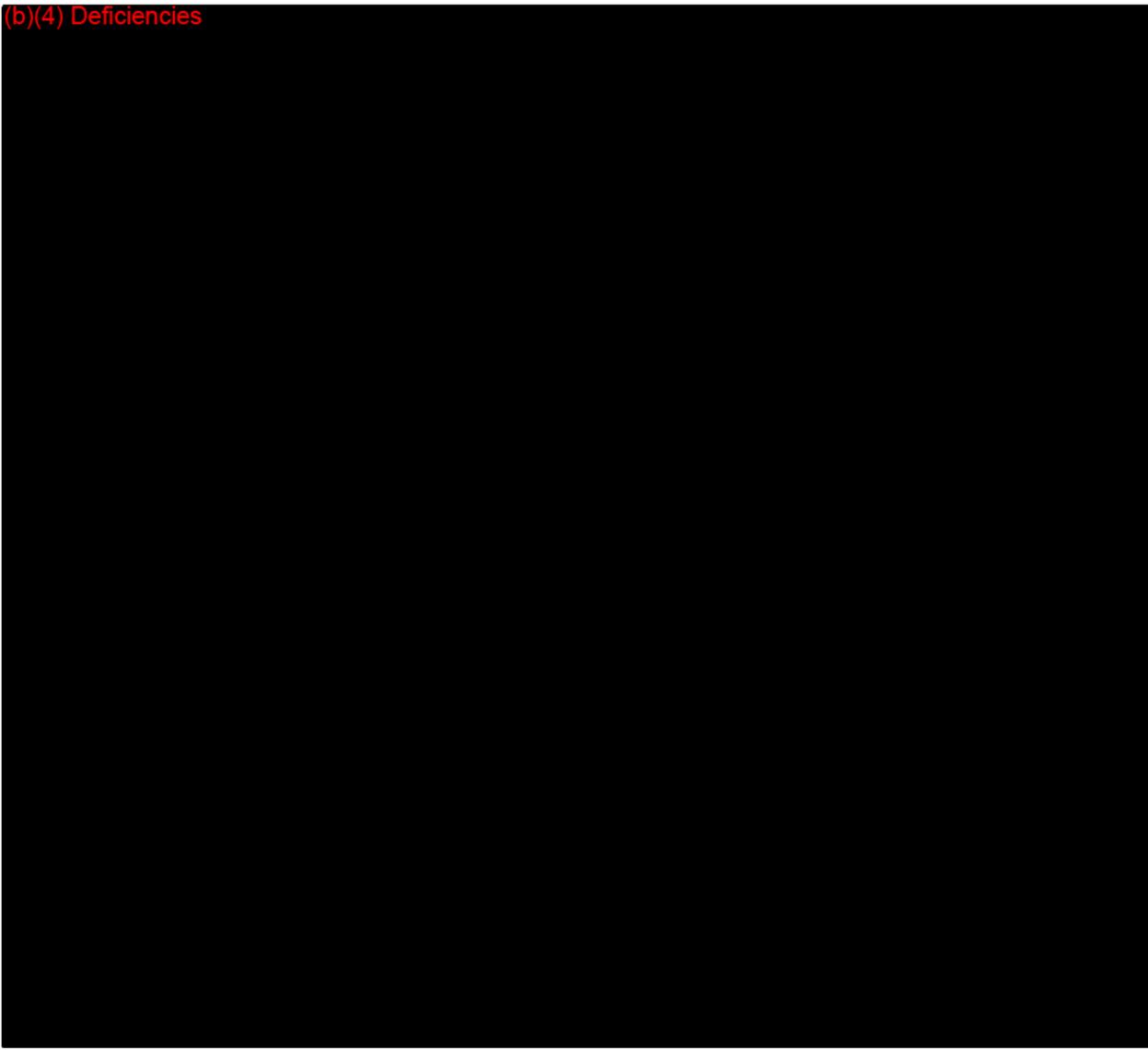


DJA 00212

(b)(4) Deficiencies



(b)(4) Deficiencies



XII. PERFORMANCE TESTING – ANIMAL:

Not applicable.

XIII. PERFORMANCE TESTING – CLINICAL:

Not applicable to this device.

XIV. SUBSTANTIAL EQUIVALENCE (SE) DISCUSSION:

Discussion of SE has been deferred until all performance and labeling issues are resolved.

DJA 00214

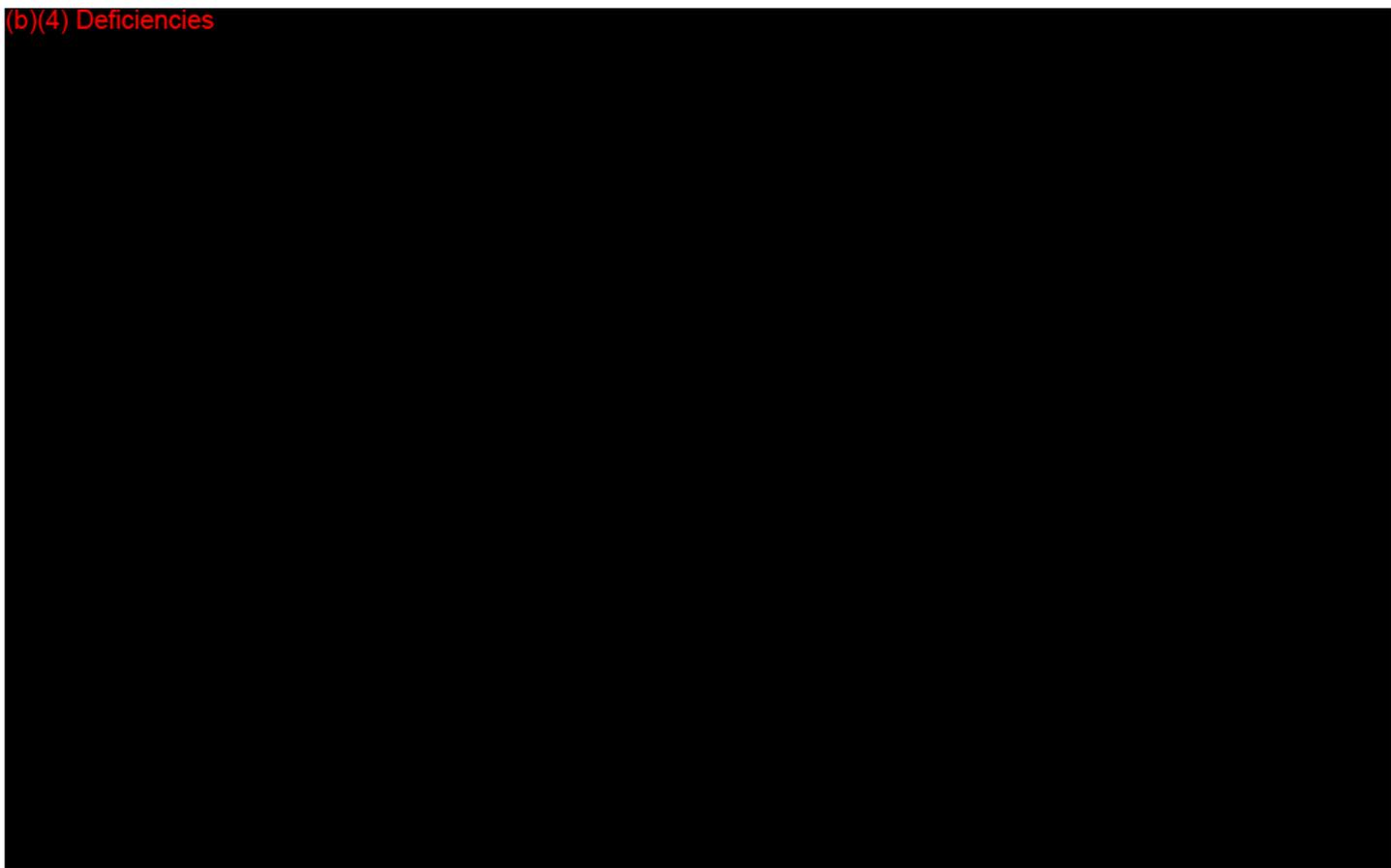
	Yes	No	
1. Same Indication Statement?	√		If YES = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If YES = Stop NSE
3. Same Technological Characteristics?		√	If YES = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 6
5. Descriptive Characteristics Precise Enough?		√	If NO = Go To 8 If YES = Stop SE
6. New Types Of Safety Or Effectiveness Questions?			If YES = Stop NSE
7. Accepted Scientific Methods Exist?			If NO = Stop NSE
8. Performance Data Available?		√	If NO = Request Data
9. Data Demonstrate Equivalence?			On TH after S000 review.

XV. DEFICIENCIES:

The following deficiencies were communicated to the firm on 12/07/2009.

To complete the review of this submission, please provide additional information and clarification as detailed below. Please provide an item-wise response to each deficiency.

(b)(4) Deficiencies



XVI. CONTACT HISTORY:

12/07/2009: FAXed deficiencies, after S000 review, to the firm (attention Mr. Harry Bala, 847-455-2886).

XVII. RECOMMENDATION:

Regulation Number: 21 CFR 880.2800

Regulation Name: Sterilization process indicator

Regulatory Class: II

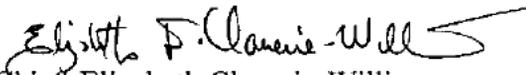
Product Code: FRC

Reviewer comment: This submission was assigned to me and I received this submission for S000 review on 11/23/2009, which is FDA-day 59 on the submission. I have completed the S000 review on 12/07/2009, which is FDA-day 73.



Reviewer: Geetha C. Jayan

Date: 12/07/2009



Acting Branch Chief: Elizabeth Claverie-Williams

Date: 12/7/09

* * * COMMUNICATION RESULT REPORT (DEC. 7. 2009 3:21PM) * * *

FAX HEADER 1: FAD-CDRH-ODE-DAGID
FAX HEADER 2:

TRANSMITTED/STORED MODE	DEC. 7. 2009 3:18PM	OPTION	ADDRESS	RESULT	PAGE
3742 MEMORY TX			8474552886	OK	5/5

REASON FOR ERROR
E-1) HANG UP OR LINE FAIL
E-3) NO ANSWER

E-2) BUSY
E-4) NO FACSIMILE CONNECTION

K092944



**DEPARTMENT OF HEALTH & HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
CDRH / ODE / DAGID / INCB**

DATE: December 07, 2009

FROM: Geetha C. Jayan, Ph. D., Scientific Reviewer & Network Liaison, INCB / DAGID / ODE / CDRH / FDA, Room 2504, Bldg WO#66, 10903 New Hampshire Ave., Silver Spring, MD 20903, U.S.A.
Tel: (301) 796-6300
FAX: (301) 847-8109
e-mail: geetha.jayan@fda.hhs.gov

TO: Mr. Harry Bala
Tel: (847) 455-2881
FAX: (847) 455-2886

SUBJECT: K092944 – Request for Additional information
of pages: 05 (including this cover sheet)

PLEASE ACKNOWLEDGE THE RECEIPT OF THIS FAX.
Please review the attached memo and mail your responses to the Document Mail Center, within 30 days from today. If you need additional time to provide your response, you may request for an extension up to 180 days from the date of this letter, by sending a written request to the Document Mail Center.

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 or other action based on the content of the 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.

DJA 00217

DJA 00218



**DEPARTMENT OF HEALTH & HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
CDRH / ODE / DAGID / INCB**

DATE: December 07, 2009

FROM: Geetha C. Jayan, Ph. D., Scientific Reviewer & Network Liaison, INCB /
DAGID / ODE / CDRH / FDA, Room 2504, Bldg WO#66, 10903 New
Hampshire Ave., Silver Spring, MD 20903, U.S.A.
Tel: (301) 796-6300
FAX: (301) 847-8109
e-mail: geetha.jayan@fda.hhs.gov

TO: Mr. Harry Bala
Tel: (847) 455-2881
FAX: (847) 455-2886

SUBJECT: K092944 – Request for Additional information
of pages: 05 (including this cover sheet)

PLEASE ACKNOWLEDGE THE RECEIPT OF THIS FAX.
Please review the attached memo and mail your responses to the Document Mail Center,
within 30 days from today. If you need additional time to provide your response, you
may request for an extension up to 180 days from the date of this letter, by sending a
written request to the Document Mail Center.

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any review, disclosure, dissemination or other action based on the content of the
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.**

MEMORANDUM

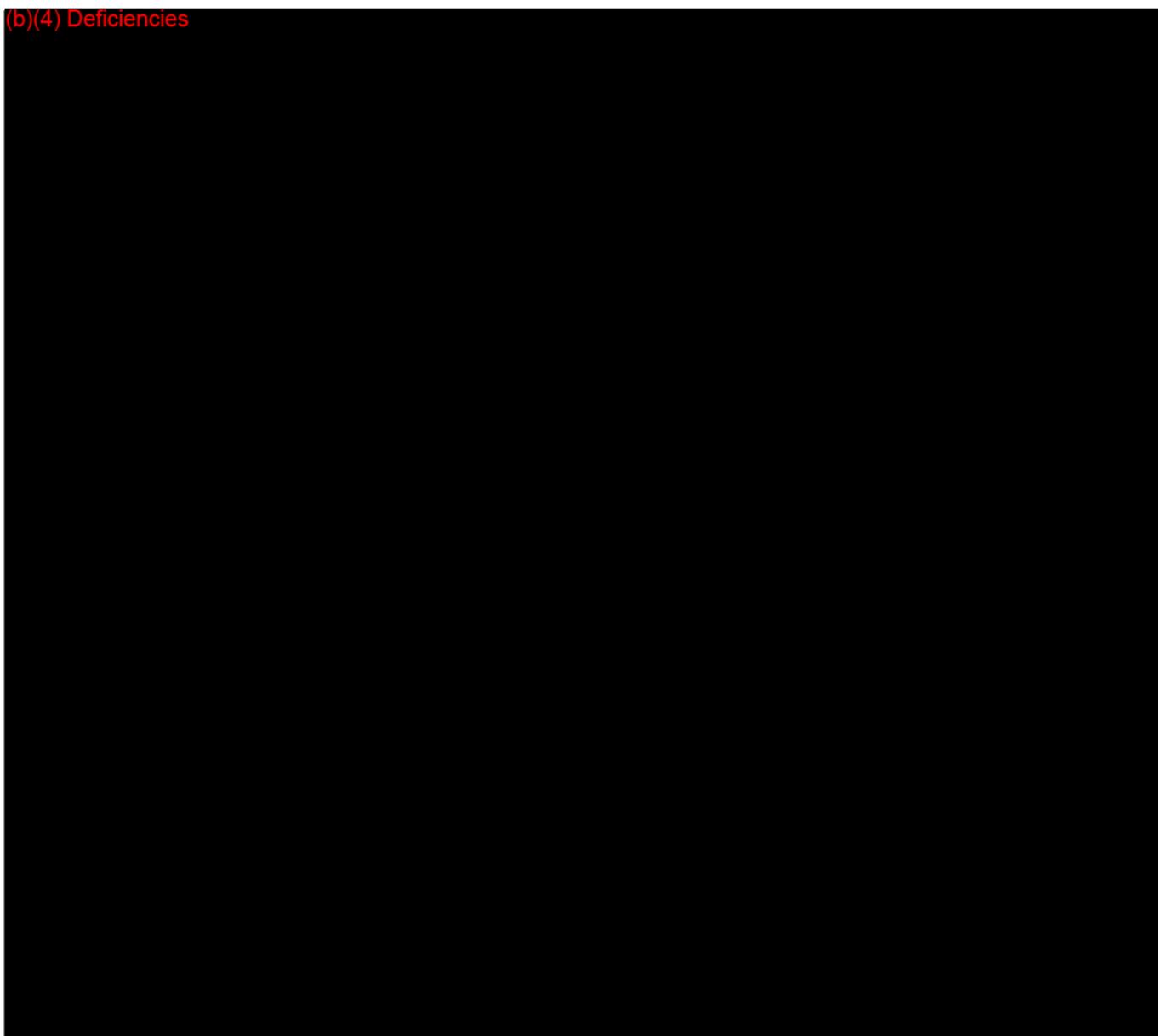
DATE: December 07, 2009
FROM: Geetha C. Jayan
TO: Mr. Harry Bala
SUBJECT: K092944 – Request for additional information

Dear Mr. Bala:

FDA has reviewed the information you provided in your pre-market notification (PMN), # K092944, for Dana Reusable Test Pack for steam sterilization. Based on the information you provided, we are unable to make a final determination on the submission.

To complete the review of this submission, please provide additional information and clarification as detailed below. Please provide an item-wise response to each deficiency.

(b)(4) Deficiencies



(b)(4) Deficiencies



Your submission has been placed on telephone hold (TH). Within 30 days from the date of this letter, please send your responses by mail to the Document Mail Center (DMC). If you require more than 30 days for sending your response, please submit your request for extension to the DMC. You can request for an extension up to 180 days, from the date of this letter. Your submission will be on TH until the DMC's receipt of your complete response to this letter.

The address for the DMC is: U.S. Food and Drug Administration, Center for Devices and Radiological Health, Document Mail Center – WO66-0609, 10903 New Hampshire Avenue, Silver Spring, MD 20993-0002.

Please contact me by phone or e-mail if you have questions regarding the contents of this letter. My contact information is on page 01 of this message.

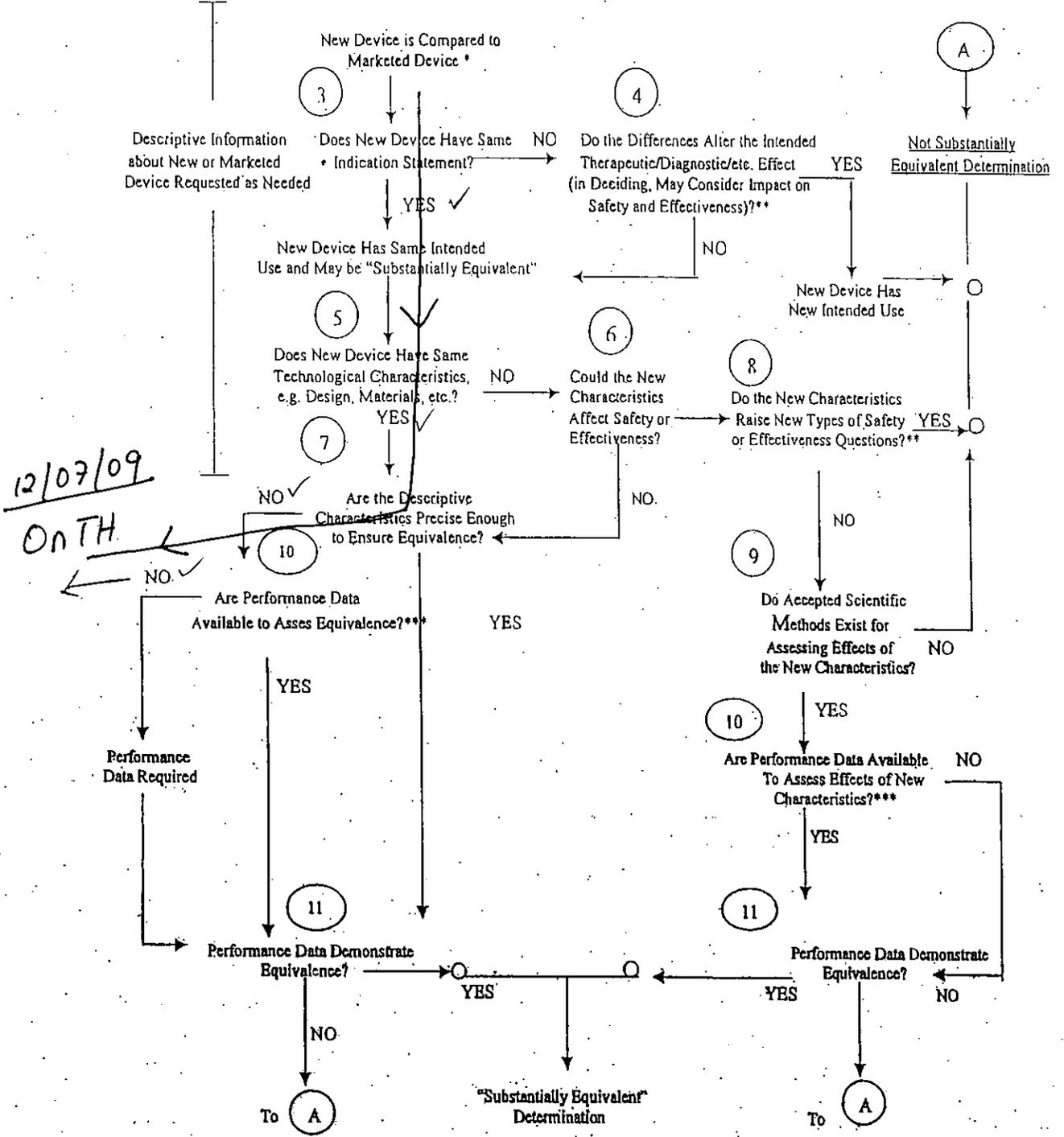
Sincerely,



Geetha C. Jayan

DJA 00223

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



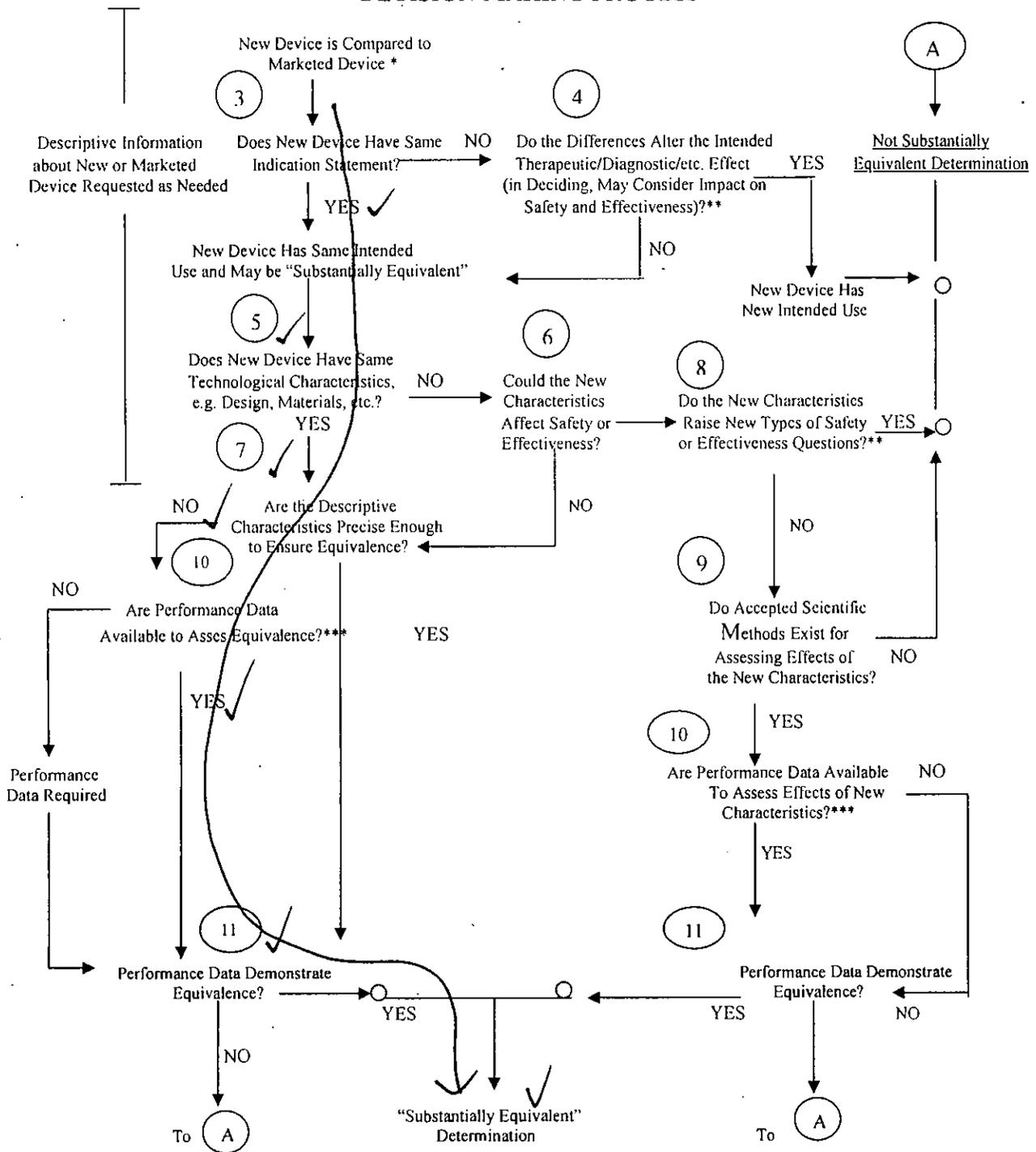
510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

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

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

DJA 00006

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 maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.