



# U.S. Department of Health & Human Services

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**Food and Drug Administration**

## SAVE REQUEST

**USER:** (kml)

**FOLDER:** K110253 - 84 pages

**COMPANY:** DANA PRODUCTS, INC. (DANAPROD)

**PRODUCT:** INDICATOR, PHYSICAL/CHEMICAL STERILIZATION PROCESS (JOJ)

**SUMMARY:** Product: REUSABLE TEST PACK FOR DANA EMULATING INDICATORS

**DATE REQUESTED:** Jun 22, 2016

**DATE PRINTED:** Jun 22, 2016

**Note:** Printed





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

APR 29 2011

Re: K110253  
Trade/Device Name: Reusable Integrator Test Pack for Dana Emulating Indicator  
Regulation Number: 21 CFR 880.2800  
Regulation Name: Sterilization Process Indicator  
Regulatory Class: II  
Product Code: JOJ  
Dated: April 4, 2011  
Received: April 5, 2011

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.

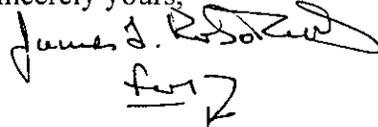
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further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

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,

A handwritten signature in black ink, appearing to read "James S. Watson" with a stylized flourish at the end. Below the signature is a handwritten number "12" with a checkmark-like symbol.

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





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

APR 29 2011

Re: K110253  
Trade/Device Name: Reusable Integrator Test Pack for Dana Emulating Indicator  
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Regulation Name: Sterilization Process Indicator  
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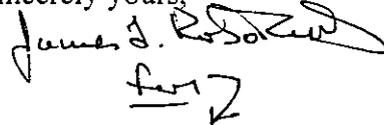
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If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office 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.

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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





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

April 05, 2011

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

510k Number: K110253

Product: REUSABLE TEST PACK FOR DANA

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



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

March 25, 2011

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

510k Number: K110253

Product: REUSABLE TEST PACK FOR DANA EM

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/MedicalDeviceProvisionsofFDAModernizationAct/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.

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

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

February 07, 2011

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

510k Number: K110253

Received: 1/31/2011

Product: REUSABLE TEST PACK FOR DANA EM

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) 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

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>.

**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.**

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 2 WO66-G609  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

January 28, 2011

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

510k Number: K110253  
Received: 1/28/2011  
User Fee ID Number: 6053958  
Product: REUSABLE TEST PACK FOR D

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

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 {ODE\_POS\_FAX\_NUMBER} 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](http://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](mailto:Diane.Garcia@fda.hhs.gov) or directly at (301)796-7200. 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

K110253

**510k NOTIFICATION**

**DANA REUSABLE TEST PACK FOR STEAM STERILIZATION  
FOR DANA EMULATING INDICATORS**

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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: <a href="http://www.fda.gov/oc/mdufma/coversheet.html">http://www.fda.gov/oc/mdufma/coversheet.html</a>		
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  1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) *****7868	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	
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: <a href="http://www.fda.gov/oc/mdufma">http://www.fda.gov/oc/mdufma</a> ) Select an application type:		
<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 Supplement Types: <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 checked="" type="checkbox"/> YES, I meet the small business criteria and have submitted the required qualifying documents to FDA <input type="checkbox"/> NO, I am not a small business 4.1 If Yes, please enter your Small Business Decision Number: (b)(4)		
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 <a href="http://www.fda.gov/cdrh/mdufma">http://www.fda.gov/cdrh/mdufma</a> 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"/> 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 sole purpose of the application is to support conditions of use for a pediatric population <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		
PAPERWORK REDUCTION ACT STATEMENT Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and 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 the address below.  Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 1350 Piccard Drive, 4th Floor Rockville, MD 20850 [Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]		
8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (b)(4)		27-Jan-2011

**CDRH PREMARKET REVIEW SUBMISSION COVER SHEET**

Form Approval  
OMB No. 0910-0120  
Expiration Date: December 31, 2013  
See OMB Statement on page 5.

Date of Submission 01-27-2011	User Fee Payment ID Number (b) [REDACTED]	FDA Submission Document Number (if known)
----------------------------------	--	---

**SECTION A TYPE OF SUBMISSION**

<b>PMA</b> <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	<b>PMA &amp; HDE Supplement</b> <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	<b>PDP</b> <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP	<b>510(k)</b> <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	<b>Meeting</b> <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):
<b>IDE</b> <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	<b>Humanitarian Device Exemption (HDE)</b> <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	<b>Class II Exemption Petition</b> <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	<b>Evaluation of Automatic Class III Designation (De Novo)</b> <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	<b>Other Submission</b> <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	

**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

Other Reason (*specify*):

**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		

Other Reason (*specify*):

**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> ):		

**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 <input type="checkbox"/> 510 (k) summary attached <input type="checkbox"/> 510 (k) statement
1	JOJ	2		3		4		
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	Attest 1296 Rapid Readout Test Pack	3M
2	K926364	Attest 1292 Rapid Readout BI	3M
3	K100891	Dana Emulating Indicator	Dana Products, Inc.
4	K092944	Reusable Biological and Integrator Test Pack for Steam Sterilization	Dana Products, Inc.
5	K102761	Reusable Test Pack for Steam Sterilization for SteriScan Integrators	Dana Products, Inc.
6			

**SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS**

Common or usual name or classification name

	Trade or Proprietary or Model Name for This Device	Model Number
1	Reusable Test Pack for Dana Emulating Indicators	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 JOJ	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)

**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

## 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	2008	01/01/2008
2	ST 79	ANSI AAMI	Comprehensive Guide to Steam Sterilization and Sterility 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 Chief Information Officer  
 1350 Piccard Drive, Room 400  
 Rockville, MD 20850

*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.*

Department of Health and Human Services  
Food and Drug Administration  
**STANDARDS DATA REPORT FOR 510(k)s**  
(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE<sup>1</sup>

Hospital Steam Sterilizers

*Please answer the following questions*

Yes    No

Is this standard recognized by FDA<sup>2</sup>? .....    

FDA Recognition number<sup>3</sup> ..... # 14-264

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? .....    

Is a summary report<sup>4</sup> describing the extent of conformance of the standard used included in the 510(k)? .....       
If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? .....    

Does this standard include acceptance criteria? .....       
If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests? .....       
If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard? .....       
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)<sup>5</sup>? .....    

Were deviations or adaptations made beyond what is specified in the FDA SIS? .....       
If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard? .....       
If yes, report these exclusions in the summary report table.

Is there an FDA guidance<sup>6</sup> that is associated with this standard? .....       
If yes, was the guidance document followed in preparation of this 510k? .....    

Title of guidance: premarket notification submissions for chemical indicators

<sup>1</sup> The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

<sup>2</sup> Authority [21 U.S.C. 360d], [www.fda.gov/cdrh/stdsprog.html](http://www.fda.gov/cdrh/stdsprog.html)

<sup>3</sup> <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

<sup>4</sup> The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or

certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

<sup>5</sup> The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

<sup>6</sup> The online search for CDRH Guidance Documents can be found at [www.fda.gov/cdrh/guidance.html](http://www.fda.gov/cdrh/guidance.html)

Department of Health and Human Services  
Food and Drug Administration  
**STANDARDS DATA REPORT FOR 510(k)s**  
(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE <sup>1</sup>

Comprehensive guide to steam sterilization and sterility assurance in health care facilities

**Please answer the following questions**

Yes    No

Is this standard recognized by FDA <sup>2</sup>? .....    

FDA Recognition number <sup>3</sup> ..... # 14-280

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? .....    

Is a summary report <sup>4</sup> describing the extent of conformance of the standard used included in the 510(k)? .....       
If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? .....    

Does this standard include acceptance criteria? .....       
If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests? .....       
If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard? .....       
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) <sup>5</sup>? .....    

Were deviations or adaptations made beyond what is specified in the FDA SIS? .....       
If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard? .....       
If yes, report these exclusions in the summary report table.

Is there an FDA guidance <sup>6</sup> that is associated with this standard? .....       
If yes, was the guidance document followed in preparation of this 510k? .....    

Title of guidance: premarket notification submissions for chemical indicators

<sup>1</sup> The formatting convention for the title is: [SDO] {numeric identifier} (title of standard) [date of publication]

<sup>2</sup> Authority [21 U.S.C. 360d]. [www.fda.gov/cdrh/stdsprog.html](http://www.fda.gov/cdrh/stdsprog.html)

<sup>3</sup> <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

<sup>4</sup> The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or

certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

<sup>5</sup> The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

<sup>6</sup> The online search for CDRH Guidance Documents can be found at [www.fda.gov/cdrh/guidance.html](http://www.fda.gov/cdrh/guidance.html)

K110253

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

January 27, 2011

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

JAN 28 2011

Dear Sir or Madam:

Received K9

**510K Notification ( 21CFR 807.90 (e) )**  
**Traditional Submission**  
**Reusable Test Pack for Steam Sterilization**  
**For Dana Emulating Indicators**

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

- Device Name: Reusable Test Pack for Dana Emulating Indicators
- Device Classification Name: Indicator, Physical/Chemical Sterilization Process
- Product Code: JOJ
- Regulation Number: 880.2800
- Review Panel: General Hospital
- Device Class: 2

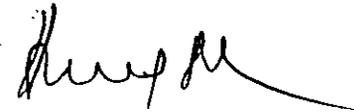
- Proprietary Name: Dana Reusable Test Pack
- Establishment Registration Number: 3007412809
- Owner Operator Number: 9054259
- Performance Standard: ANSI/AAMI ST 79: 2006 (Sec. 10.7.2.1), ANSI/AAMI ST 8: 2008 (Sec. 5.5.2.2)
- Predicate Device 510 k: 3M -1296 Test pack – K952408 & 1292 Rapid Readout BI K926364; Dana Emulating Indicator – K100891; Reusable Biological and Integrator Test Pack for Steam Sterilization K092944; Reusable Test Pack for Steam Sterilization for SteriScan Integrators – K102761.

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](mailto:bala@voyager.net)

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

Sincerely,

A handwritten signature in black ink, appearing to read 'Harry Bala', with a long horizontal flourish extending to the right.

Harry Bala  
President

## Indications for Use

510(k) Number (if known):

Device Name: Reusable Integrator Test Pack for Dana Emulating Indicator.

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 Dana Emulating Indicators.

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)

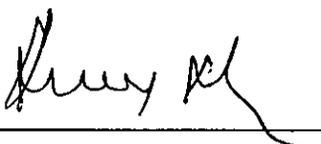
---

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1

**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: 1/27/2011

510k Number: \_\_\_\_\_

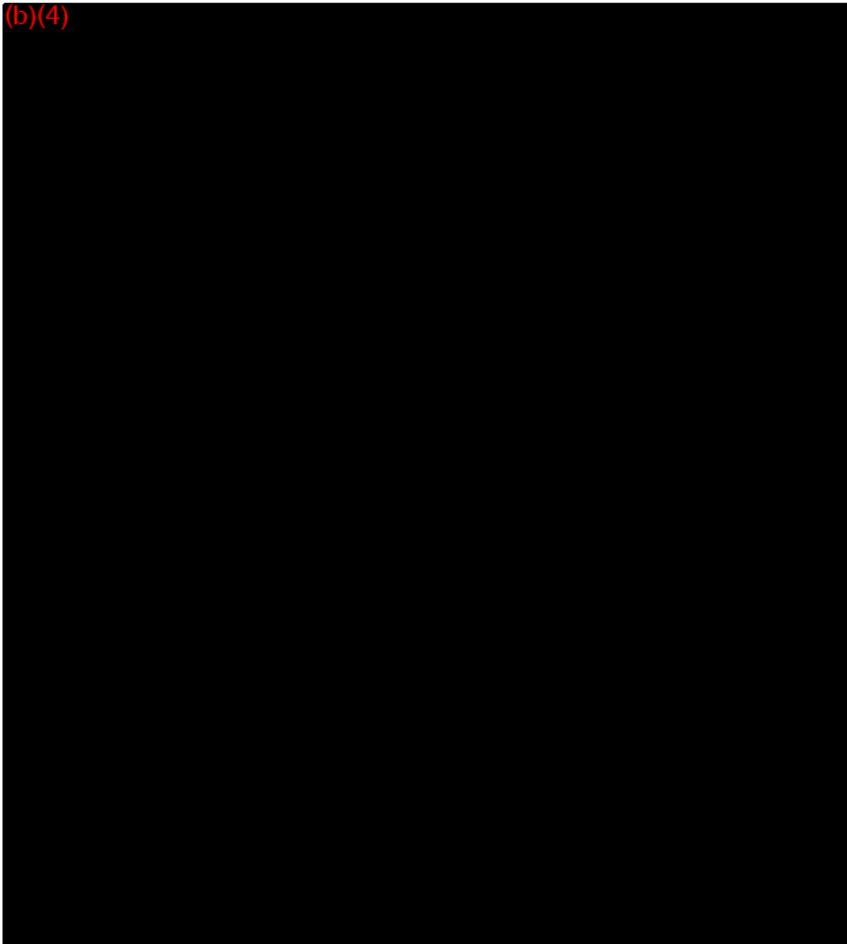
**Declaration of conformity:** The Dana Reusable Test Pack, when used with Dana Emulating Indicators conforms to the Standard set test pack using 16 surgical towels in section 10.7.2.1 of ANSI/AAMI ST79: 2006. 3 M's 1296 test pack was validated against the 16 towel packs. The Dana Reusable Test Pack was more resistant than 3M's 1296 test packs when tested in an FDA approved Steam Sterilizer and 270°F Prevac cycle for use in healthcare facilities. Comparative testing was done with the Dana Reusable Test Pack with Dana Emulating Indicators, 3M 1296 test packs, and with Dana Emulating Indicators on an open tray, placed directly over the drain but otherwise empty sterilizer. This is the worst sterilizer load condition. (Per sec. 5.5.2.2 of ANSI/AAMI ST-8)

**Device Description:**

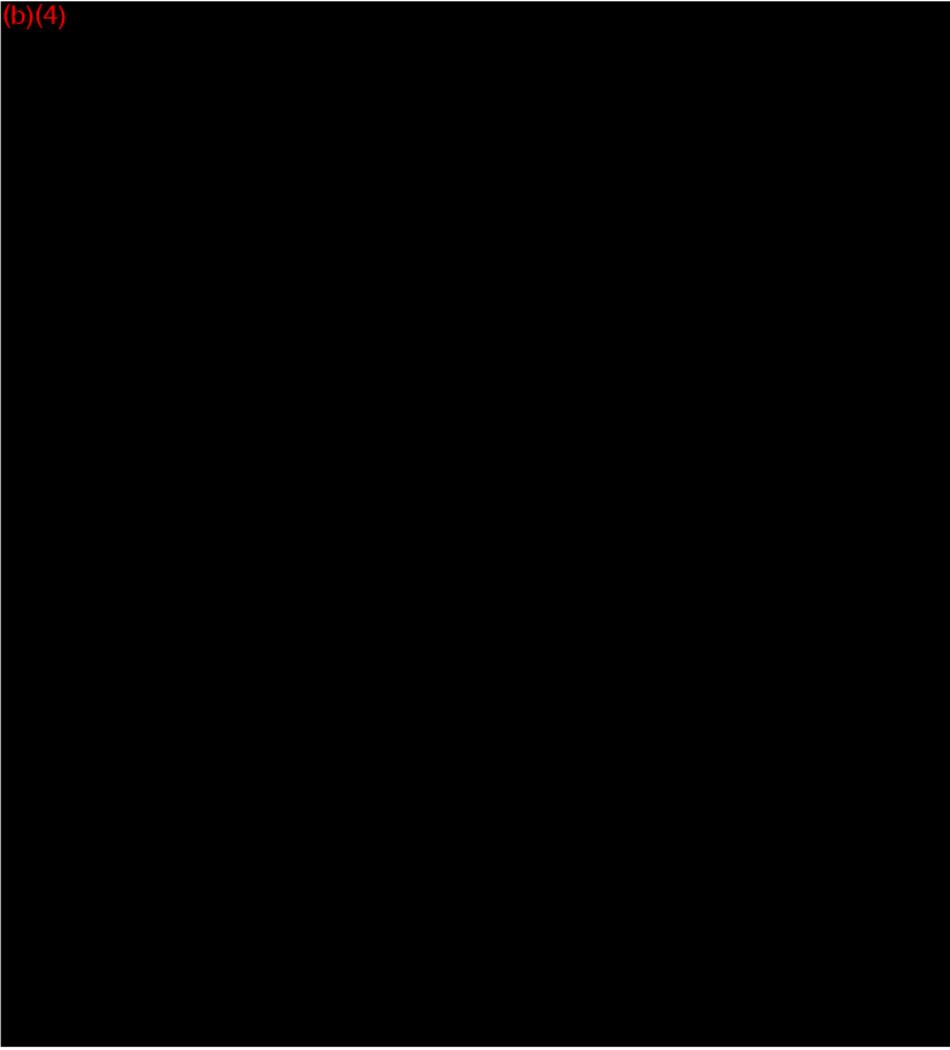
Dana Reusable Test Pack was validated (510k: K 092944) for use with 3M's 1292 Rapid Readout Biological indicators along with or without SteriScan Integrators (510k: K 012195). The Dana Reusable Test Pack was also approved for use with only the SteriScan Integrator (510k: K 102761). In this submission I am submitting the data to validate the Dana Reusable Test Pack for use with the Dana Emulating Indicator.

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

(b)(4)

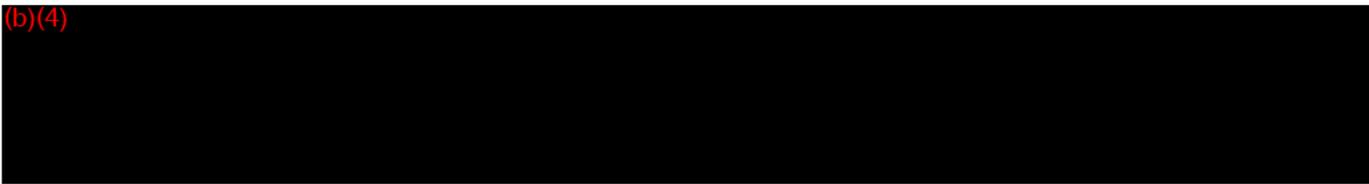


(b)(4)



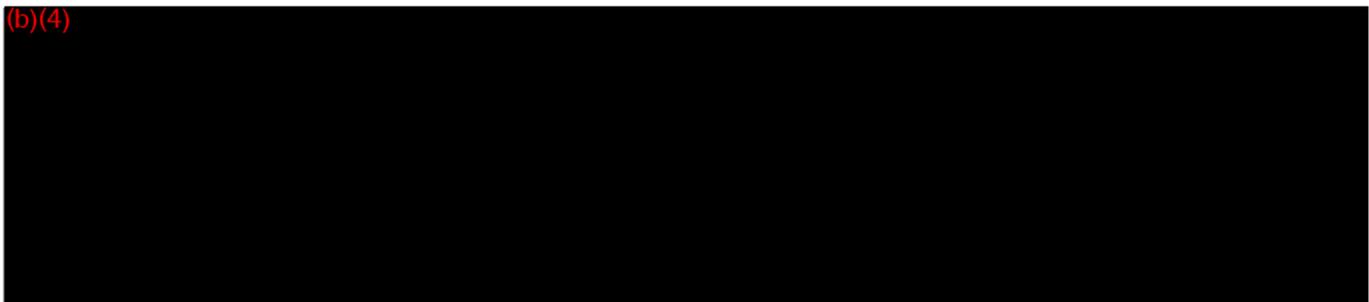
**Performance Testing:**

(b)(4)



**Test Parameters:**

(b)(4)



(b)(4)

### **Statement of Purpose/ Objective of Studies**

The object of the study is to show that, in 270°F prevac cycles, (1) Dana Emulating Indicators in the Dana Reusable Test Pack are more resistant than Dana Emulating Indicators outside of the Dana Reusable Test Pack (acceptance criterion is that Dana Emulating Indicators in the Dana Reusable Test Pack should be more resistant than those outside) and (2) Dana Emulating Indicators in Dana Reusable Test Packs are more resistant (b)(4)

### **STUDY:**

(b)(4)

### **Performance of Dana Emulating Indicator:**

Acceptance Criterion: Dana Emulating Indicator in Dana Reusable Test Pack should be more resistant than (1) the Dana Emulating Indicator placed outside of the Dana Reusable Test Pack and (2) (b)(4)







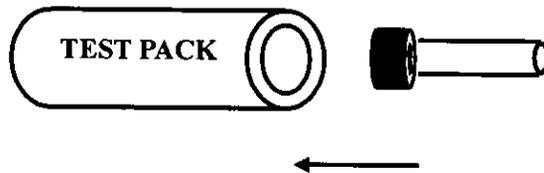




**LABELING:**

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**  
**or with SteriScan Integrator or both**  
**Also for use with the Dana Emulating Indicator**



**Insert first open end of BI in Test Pack**  
**Insert first Pellet end of SteriScan Indicator**  
**Insert first Pellet end of Dana Emulating Indicator**  
**Discard after 100 uses**

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

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

## **LABELING:**

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

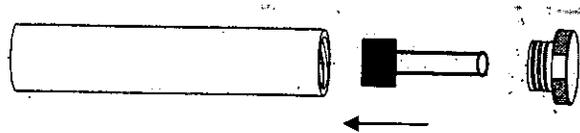
### **Dana Reusable Test Pack**

#### **Product Description:**

Dana Reusable Test Pack is designed to challenge the 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 also be used in 4 minute 270°F pre-vacuum steam sterilization cycles with the Dana Emulating Indicator. The Dana Reusable Test Pack can be used 100 times without 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 by itself or with the BI by inserting the pellet end first into the test pack. Dana Emulating Indicator can be used by itself 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  
Insert first Pellet End of Dana Emulating 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, the SteriScan indicator, and/or Dana Emulating Indicator, as applicable.
11. Follow the instructions provided with the 1292 BI, the SteriScan indicator or Dana Emulating Indicator by their respective manufacturers to read and interpret the results.
12. The SteriScan Integrators, Dana Emulating Indicators 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 Reusable 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.

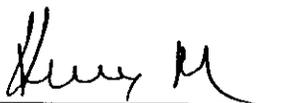
**Precautions:**

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.

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 01/27/2011

510k Number: \_\_\_\_\_



**COVER SHEET MEMORANDUM**

From: Reviewer Name Steven Elliott  
 Subject: 510(k) Number K110253/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](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 <u>510(k) Statement</u>	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 <a href="http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf">http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf</a> )		✓	
Is this a combination product? (Please specify category <u>NA</u> , see <a href="http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC">http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC</a> )			✓
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, <a href="http://www.fda.gov/cdrh/ode/guidance/1216.html">http://www.fda.gov/cdrh/ode/guidance/1216.html</a> )			✓
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.)			✓

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

880.2800

II

JOJ

(\*If unclassified, see 510(k) Staff)

Additional Product Codes:

Review:

*[Signature]*  
(Branch Chief)

1N2B

(Branch Code)

4/29/2011

(Date)

Final Review:

*[Signature]*  
Depy (Division Director)

04/29/2011

(Date)



**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**MEMORANDUM**

Food and Drug Administration  
 10903 New Hampshire Avenue  
 Document Mail Center – WO66-G609  
 Silver Spring, MD 20993-0002

**Premarket Notification [510(k)] Review  
 Traditional  
 K110253/S001**

*Capitol*  
*4/29/2011*

Date: April 26, 2011  
 To: The Record  
 From: Steven Elliott, M.S., Scientific Reviewer  
 Through: Dr. Kapil Panguluri, PhD. – Team leader  
 Through: Elizabeth Claverie-Williams, M.S.; Branch Chief, INCB  
 Device Name: Reusable Integrator Test Pack for Dana Emulating Indicator  
 510(k) Holder: Dana Products, Inc.  
 Address: 7 Corey Drive, South Barrington, Illinois 60010, United States  
 Contact: Harry Bala.  
 Phone: (847) 455 2881  
 Fax: (847) 455 2886  
 Email: [bala@voyager.net](mailto:bala@voyager.net)

Office: ODE  
 Division: DAGID

**I. Purpose and Submission Summary**

The 510(k) holder, Dana Products, Inc. would like to introduce the “Reusable Integrator Test Pack for Dana Emulating Indicator” into interstate commerce. The sponsor has submitted a pre-market notification (PMN) [510(K)] for the device.  
 The sponsor claims that the “Reusable Integrator Test Pack for Dana Emulating Indicator” is a class II Chemical indicator test pack under 21CFR § 880.2800. Product Code JOJ.

**II. Administrative Requirements**

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription or <b>OTC</b> )	√		
Truthful and Accuracy Statement – signed by Harry Bala	√		
510(k) Summary or <b>510(k) Statement</b>	√		
Standards Data Report Form – Form 3654		√	

**STANDARDS REFERENCED:**

- ANSI/AAMI ST8: 2008: Hospital Steam Sterilizers.
- ANSI/AAMI ST79: 2006: Comprehensive Guide to Steam Sterilization and Sterility in Health Care Facilities.

The sponsor has provided their 510(k) Statement:

	YES	NO	N/A
<b>Required Elements for 510(k) Summary (21 CFR 807.92)</b>			
Clearly labeled “510(k) Summary”			√
Submitter’s name, address, phone #; a contact person			√
Date the summary was prepared			√
The name of the device/trade name/common name/classification			√

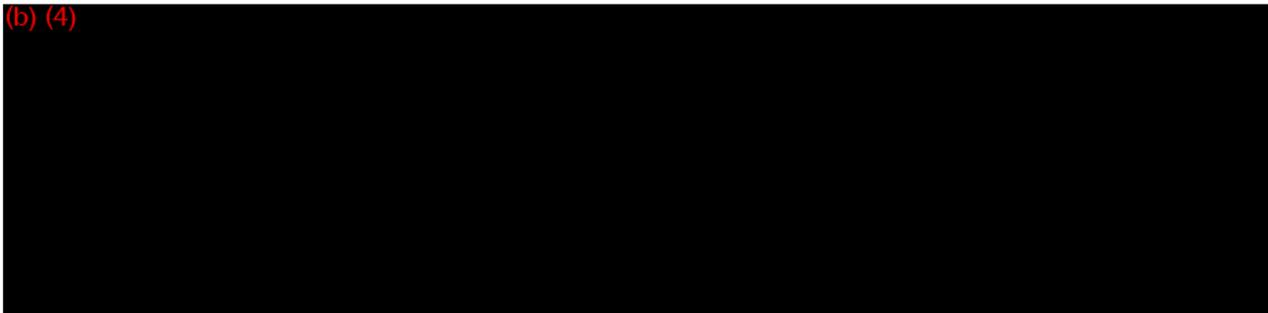
		YES	NO	N/A
name				
An identification of the legally marketed Predicate				√
Description of the subject device				√
Statement of intended use(identical to indications for use)				√
Technological characteristics	if same, a summary of comparison of technological characters			
	If different, a summary of how do they compare to the Predicate			√
Performance Data	Brief discussion of non-clinical data submitted, referenced, or relied on			
	Brief discussion of clinical data submitted, referenced, or relied on, including: <ul style="list-style-type: none"> <li>▪ Description upon whom the device was tested,</li> <li>▪ Data obtained from the tests and especially:</li> <li>▪ Adverse events and complications</li> <li>▪ Other information for SE determination</li> </ul>			√
	Conclusion that data demonstrate SE			√
<b>Required Elements for <u>510(k) Statement</u> (21 CFR 807.93)</b>				
Signed verbatim statement		√		

**III. Device Description**

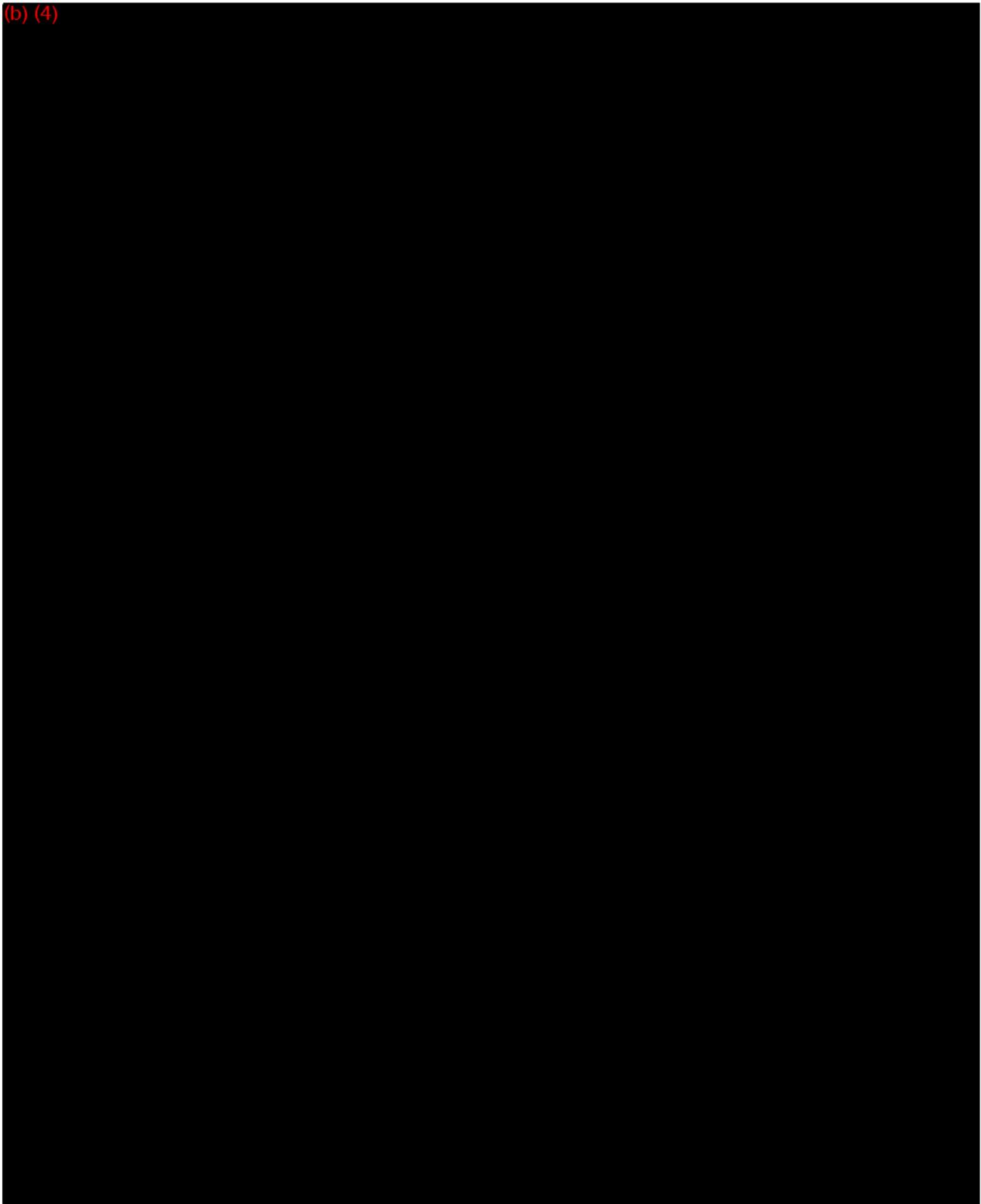
	Yes	No	N/A
Is the device life-supporting or life sustaining?		√	
Is the device an implant (implanted longer than 30 days)?		√	
Does the device design use software?		√	
Is the device sterile?		√	
Is the device reusable (not reprocessed single use)?		√	
Are "cleaning" instructions included for the end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

The sponsor indicated that the subject device is a reusable test pack that was previously cleared for use with 3M's 1292 Rapid Readout Biological Indicators (K092944). The sponsor is seeking clearance of the device for use with the Dana Emulating Indicator (K100891).

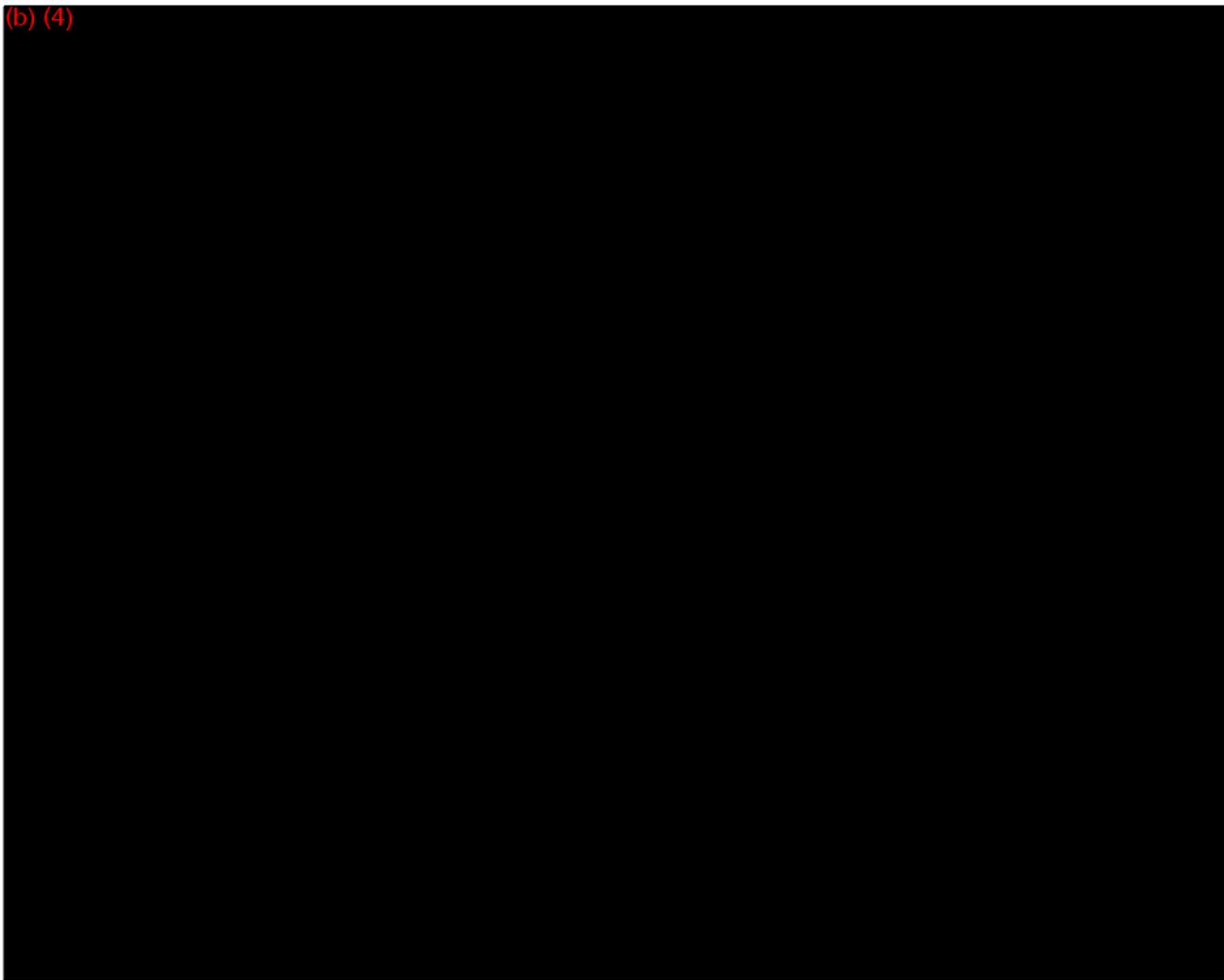
(b) (4)



(b) (4)



(b) (4)



**IV. Indications for Use**

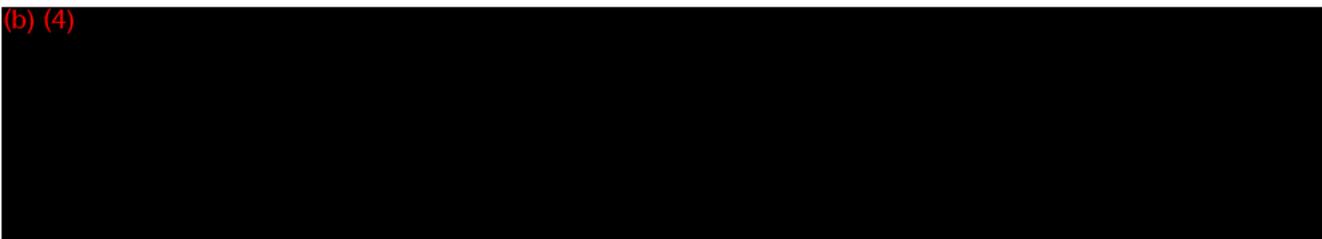
Device Name: Reusable Integrator Test Pack for Dana Emulating Indicator.

The sponsor states that the indication for use for the device is as follows:

Dana Reusable Test Pack is designed to challenge steam sterilization process in healthcare facilities. It is intended to be used for routine monitoring of prevacuum steam sterilization cycles. It is validated to be used in 4 minute 270°F prevacuum steam sterilization cycles with Dana Emulating Indicators.

The sponsor has indicated Over the Counter Use.

(b) (4)



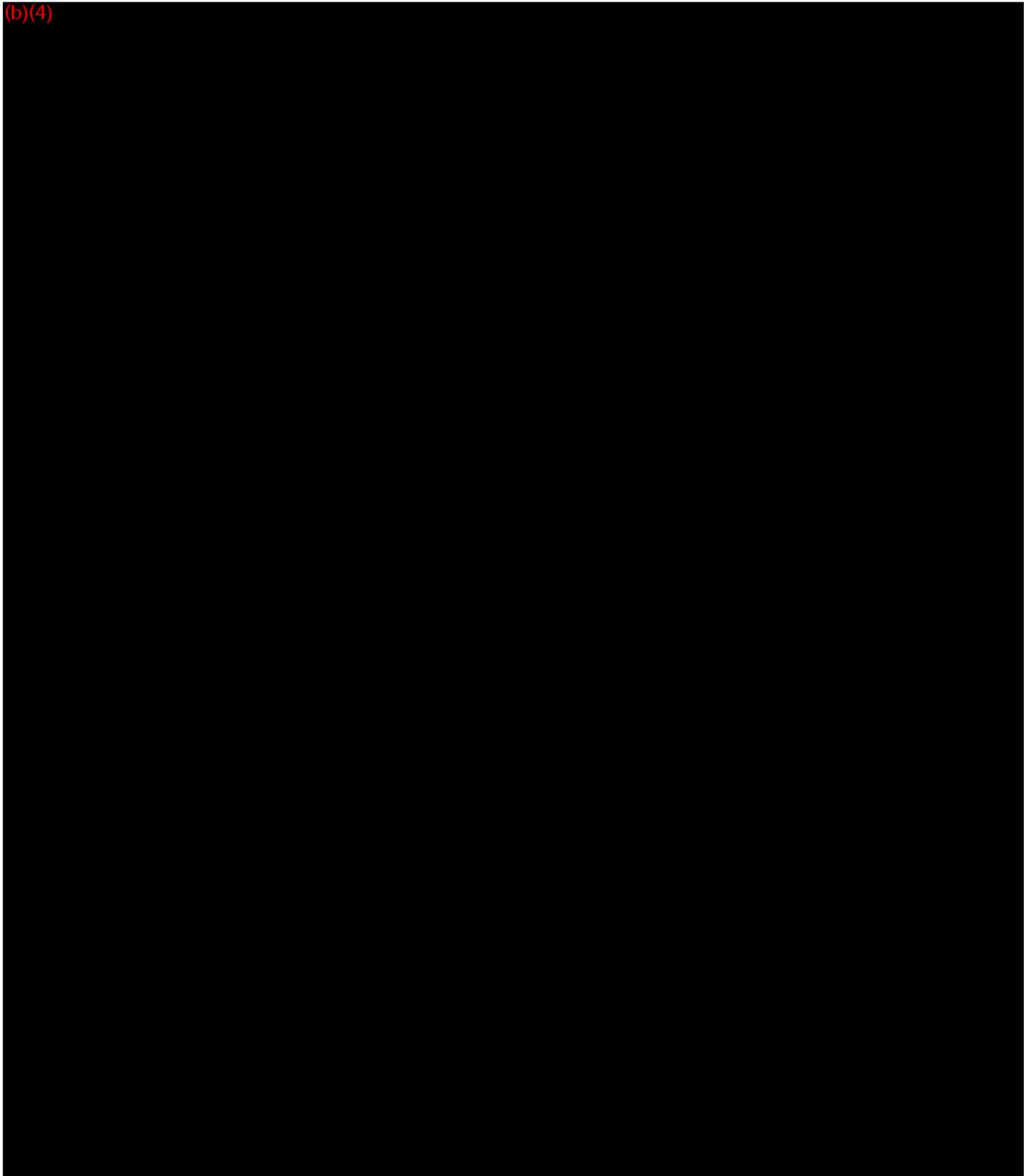
**V. Predicate Device Comparison**

The sponsor has identified the following predicate devices:

K952408 Attest 1296 Rapid Readout test pack (3M)

K926364 Attest 1292 Rapid Readout BI (3M)

(b)(4)



**VI. Labeling**

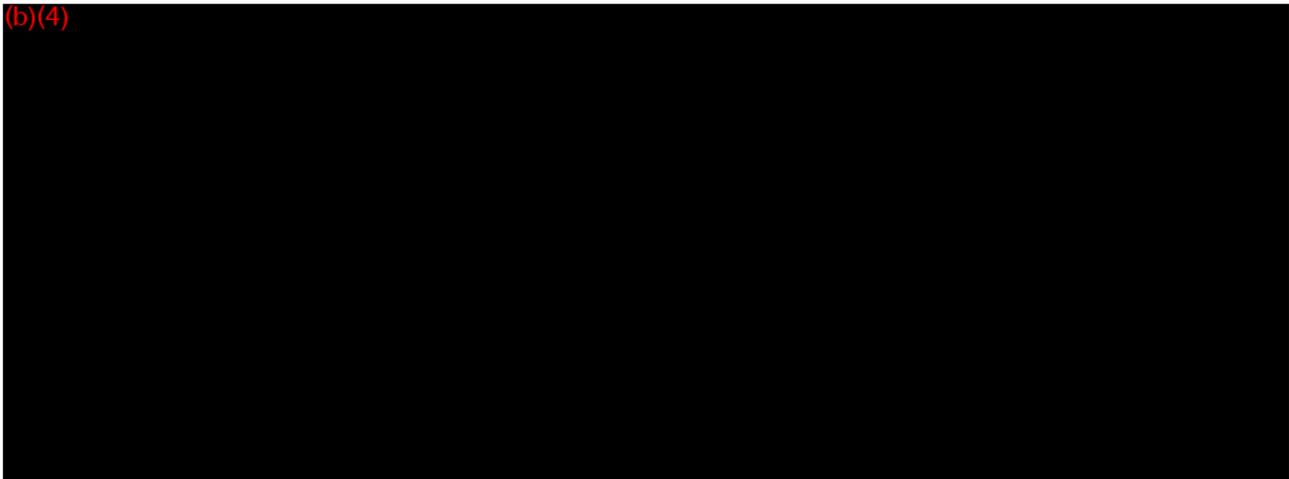
The sponsor provided a product insert that was stated to be included with the subject device. This insert contains instructions for the use of the device.

This insert indicates the use life of the device: 100 cycles

Step by step directions for use.

Cleaning: Use alcohol – wipe the outside and rinse the inside of the device with alcohol.

(b)(4)



**VII. Sterilization/Shelf Life/Reuse:**

The sponsor has indicated that the subject device is a non-sterile, reusable device. The use-life of the device is for 100 cycles. The device has been previously cleared for use with the claimed cycle with biological indicators and another chemical indicator.

**This is acceptable.**

**VIII. Biocompatibility**

No biocompatibility data were provided for the subject device. Both the subject device and the chemical emulating indicator intended for use with the subject test pack (K100891) are FDA cleared devices.

(b)(4)



**IX. Software**

N/A

**X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety**

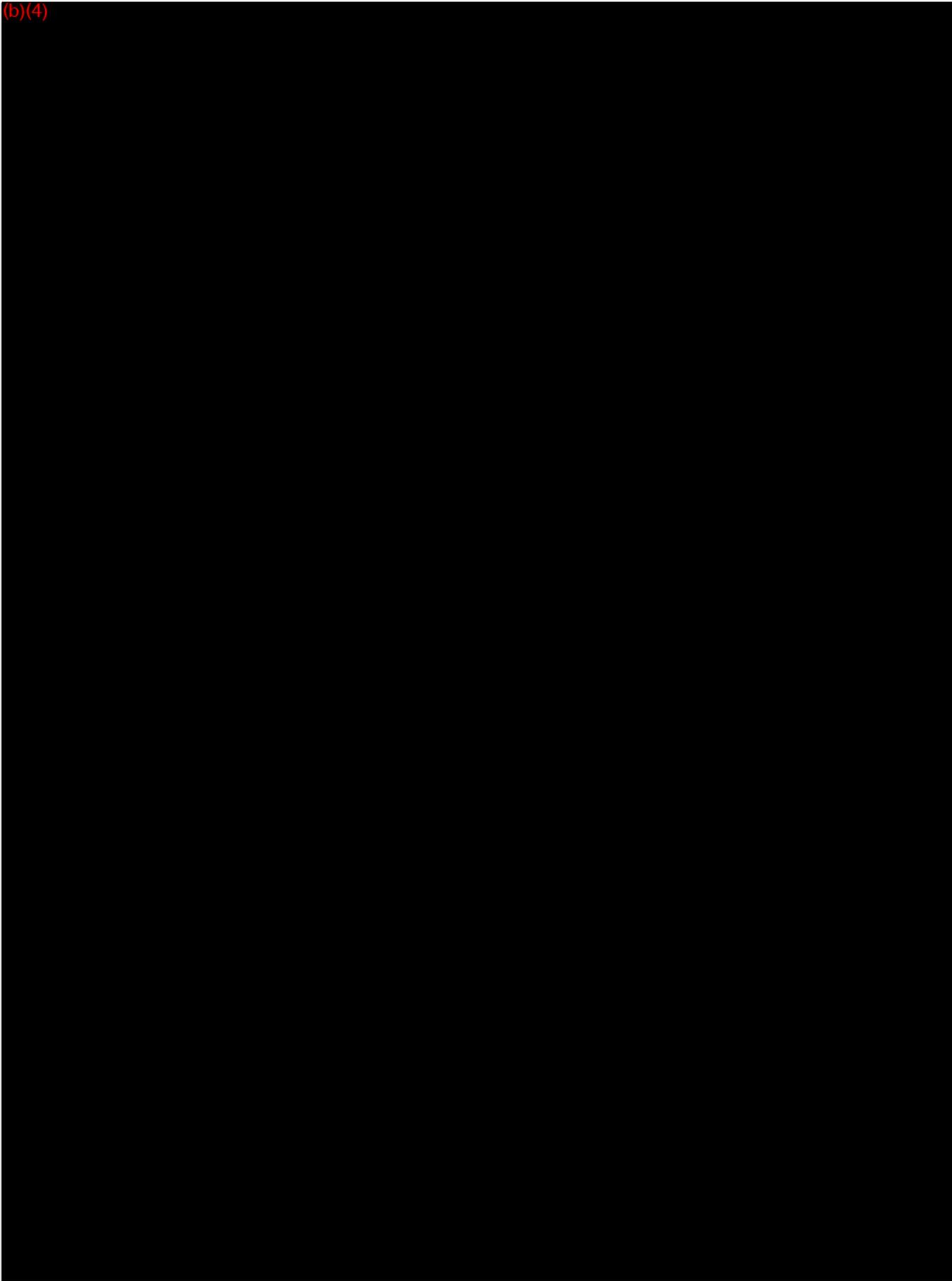
N/A

**XI. Performance Testing – Bench**

The performance of the subject device was tested with the Dana Emulating Indicator and compared to the performance of the naked Dana Emulating indicator and Attest 1296 Rapid Readout test pack (3M). The test parameters and results are summarized below.

- o (b)(4)
- 

(b)(4)



(b)(4)

**XII. Performance Testing – Animal**

N/A

**XIII. Performance Testing – Clinical**

N/A

**XIV. Substantial Equivalence Discussion**

	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?	√		Final Decision: SE

Note: Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

1. Explain how the new indication differs from the predicate device's indication:

The subject device is intended to be used with the Dana Emulating Indicator, not the SteriScan Integrators.

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

The device is intended to increase the time required for a positive signal on a chemical indicator. This can be evaluated with appropriate performance testing.

3. Describe the new technological characteristics:

4. Explain how new characteristics could or could not affect safety or effectiveness:
5. Explain how descriptive characteristics are not precise enough:

(b)(4)

6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:
7. Explain why existing scientific methods can not be used:
8. Explain what performance data is needed: Data to support the claims that their device delivers, "air of clean room quality within minutes." The sponsor will be asked to devices) to support the ability of the device to delivers clean room quality air.
9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

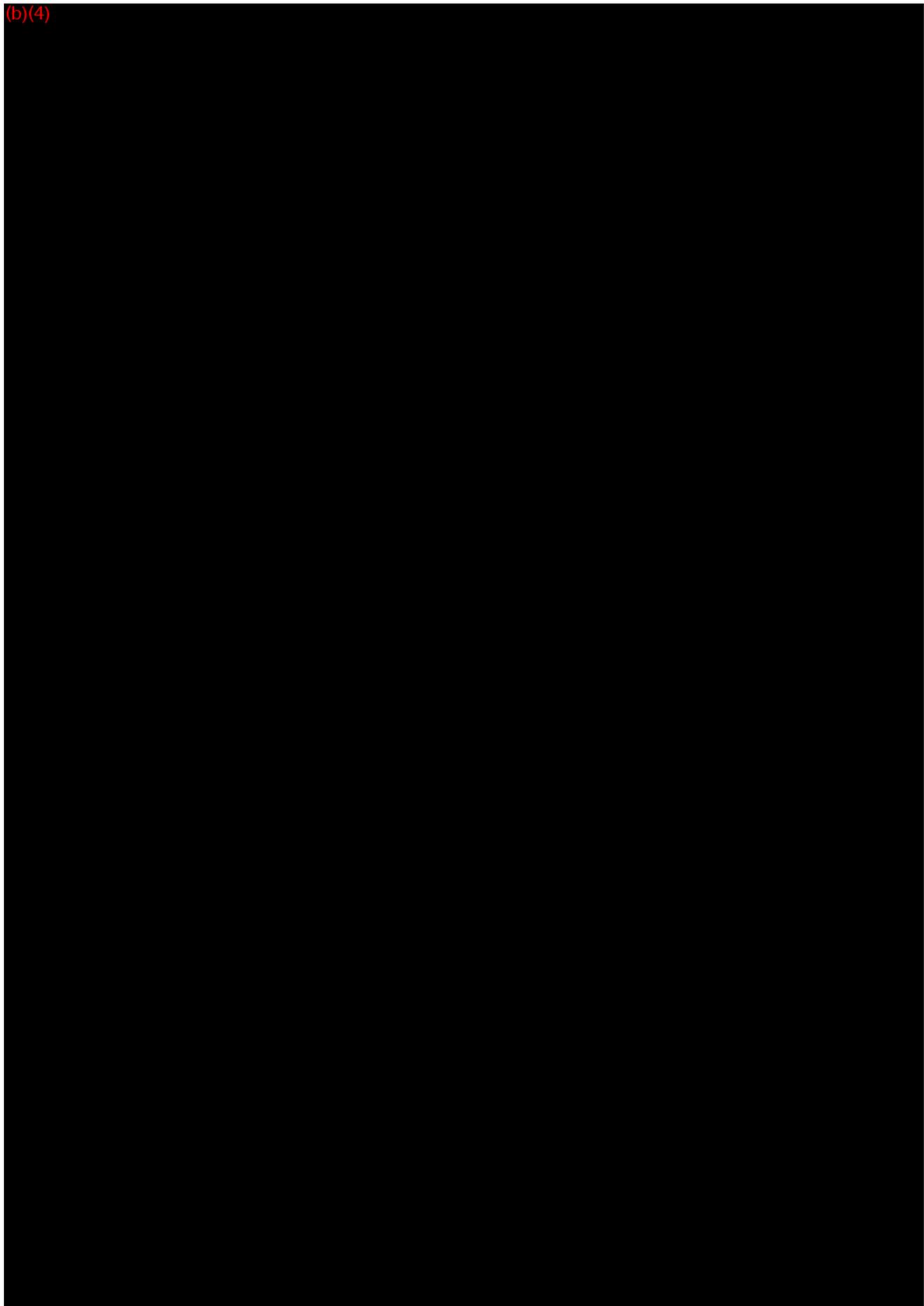
(b)(4)

**XV. Deficiencies**

All deficiencies have been resolved.

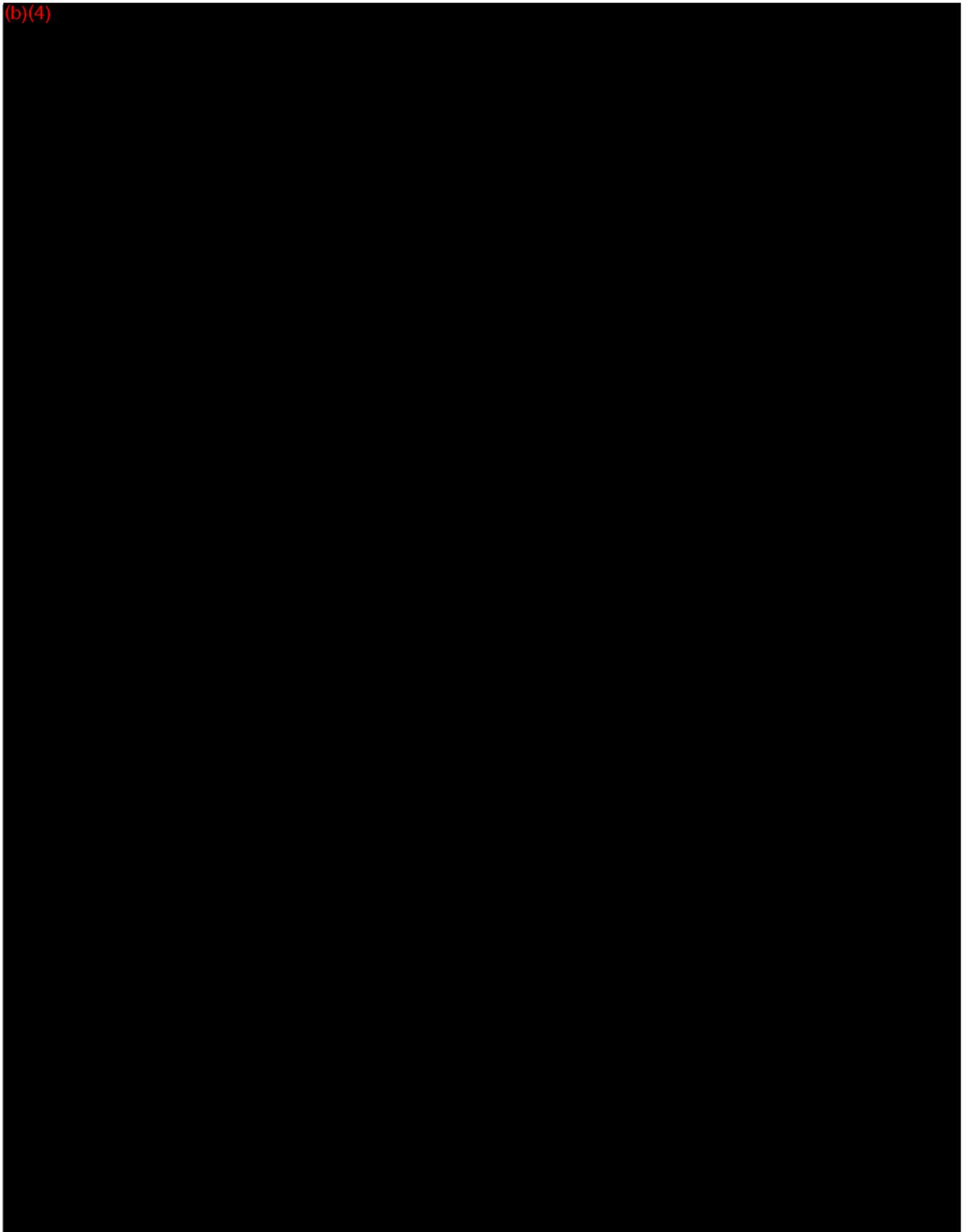
(b)(4)

(b)(4)



(b)(4)

(b)(4)



**XVI. Contact History**

3/21/11 – A request for additional information was e-mailed and faxed to the sponsor.  
3/28/11 – Clarification of Deficiencies.  
3/30/11 – Clarification of Deficiencies.

**XVII. Recommendation:**

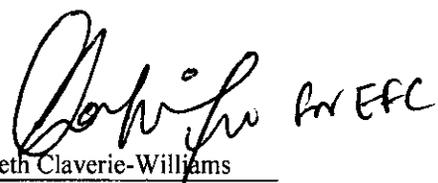
SE

Regulation Number: §880.2800  
Regulation Name: Chemical Sterilization Indicator.  
Regulatory Class: Class II  
Product Code: JOJ



Steven Elliott  
Reviewer

April 26, 2011  
Date



Elizabeth Claverie-Williams  
Branch Chief

4/29/2011  
Date



COVER SHEET MEMORANDUM

From: Reviewer Name

Steven Elliott

Subject: 510(k) Number

K110253

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/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0\\_5631/Screening%20Checklist%20%202%2007.doc](http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%20%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 <a href="http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf">http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf</a> )			
Is this a combination product? (Please specify category _____, see <a href="http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC">http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC</a> )			
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, <a href="http://www.fda.gov/cdrh/ode/guidance/1216.html">http://www.fda.gov/cdrh/ode/guidance/1216.html</a> )			
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.)			

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

880.2800

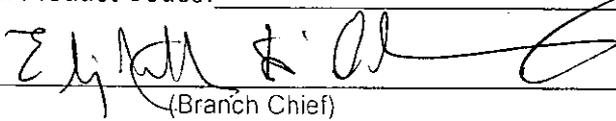
II

JOJ

(\*If unclassified, see 510(k) Staff)

Additional Product Codes:

Review:



(Branch Chief)

INCB

(Branch Code)

3/21/11

(Date)

Final Review:

(Division Director)

(Date)





**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**MEMORANDUM**

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

**Premarket Notification [510(k)] Review  
 Traditional  
 K110253**

*Edy* *8-11*  
 3-21-11

Date: March 21, 2011  
 To: The Record  
 From: Steven Elliott, M.S., Scientific Reviewer Office: ODE  
 Division: DAGID  
 Through: Elizabeth Claverie-Williams, M.S.; Branch Chief, INCB  
 Device Name: Reusable Integrator Test Pack for Dana Emulating Indicator  
 510(k) Holder: Dana Products, Inc.  
 Address: 7 Corey Drive, South Barrington, Illinois 60010, United States  
 Contact: Harry Bala.  
 Phone: (847) 455 2881  
 Fax: (847) 455 2886  
 Email: [bala@voyager.net](mailto:bala@voyager.net)

**I. Purpose and Submission Summary**

The 510(k) holder, Dana Products, Inc. would like to introduce the "Reusable Integrator Test Pack for Dana Emulating Indicator" into interstate commerce. The sponsor has submitted a pre-market notification (PMN) [510(K)] for the device.

The sponsor claims that the "Reusable Integrator Test Pack for Dana Emulating Indicator" is a class II Chemical indicator test pack under 21CFR § 880.2800. Product Code JOJ.

**II. Administrative Requirements**

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription or <b>OTC</b> )	√		
Truthful and Accuracy Statement – signed by Harry Bala	√		
510(k) Summary or <b>510(k) Statement</b>	√		
Standards Data Report Form – Form 3654		√	

**STANDARDS REFERENCED:**

- ANSI/AAMI ST8: 2008: Hospital Steam Sterilizers.
- ANSI/AAMI ST79: 2006: Comprehensive Guide to Steam Sterilization and Sterility in Health Care Facilities.

The sponsor has provided their 510(k) Statement:

	YES	NO	N/A
<b>Required Elements for 510(k) Summary (21 CFR 807.92)</b>			
Clearly labeled "510(k) Summary"			√
Submitter's name, address, phone #, a contact person			√
Date the summary was prepared			√
The name of the device/trade name/common name/classification name			√

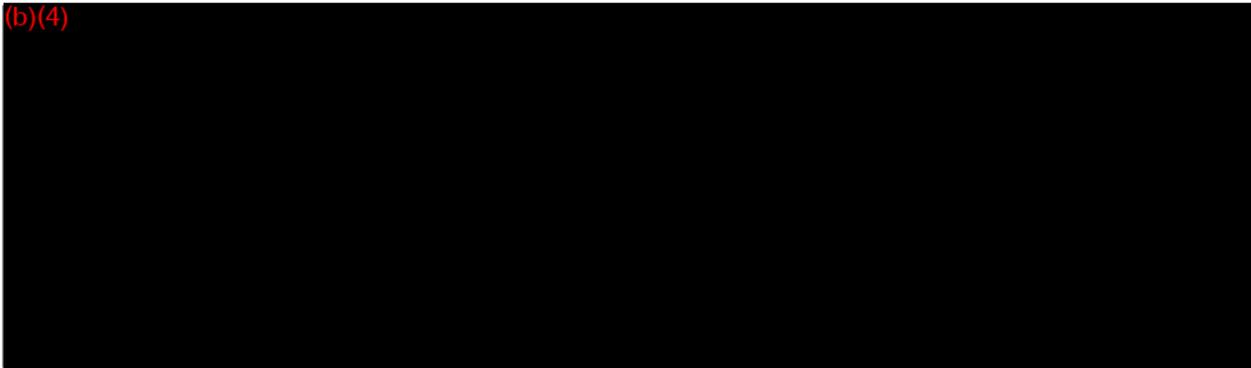
		YES	NO	N/A
An identification of the legally marketed Predicate				√
Description of the subject device				√
Statement of intended use(identical to indications for use)				√
Technological characteristics	if same, a summary of comparison of technological characters			
	If different, a summary of how do they compare to the Predicate			√
Performance Data	Brief discussion of non-clinical data submitted, referenced, or relied on			
	Brief discussion of clinical data submitted, referenced, or relied on, including: <ul style="list-style-type: none"> <li>▪ Description upon whom the device was tested,</li> <li>▪ Data obtained from the tests and especially:</li> <li>▪ Adverse events and complications</li> <li>▪ Other information for SE determination</li> </ul>			√
	Conclusion that data demonstrate SE			√
<b>Required Elements for 510(k) Statement (21 CFR 807.93)</b>				
Signed verbatim statement		√		

### 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 sponsor indicated that the subject device is a reusable test pack that was previously cleared for use with 3M's 1292 Rapid Readout Biological Indicators (K092944). The sponsor is seeking clearance of the device for use with the Dana Emulating Indicator (K100891).

(b)(4)



This is not acceptable.

**IV. Indications for Use**

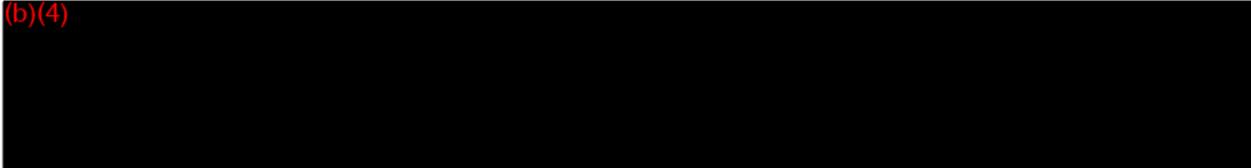
Device Name: Reusable Integrator Test Pack for Dana Emulating Indicator.

The sponsor states that the indication for use for the device is as follows:

Dana Reusable Test Pack is designed to challenge steam sterilization process in healthcare facilities. It is intended to be used for routine monitoring of prevacuum steam sterilization cycles. It is validated to be used in 4 minute 270°F prevacuum steam sterilization cycles with Dana Emulating Indicators.

The sponsor has indicated Over the Counter Use.

(b)(4)



**V. Predicate Device Comparison**

The sponsor has identified the following predicate devices:

K952408 Attest 1296 Rapid Readout test pack (3M)

K926364 Attest 1292 Rapid Readout BI (3M)

K092944 Dana Reusable Test Pack (Dana Product, Inc.)

K102761 Reusable Test Pack for steam sterilization for SteriScan Indicators

(b)(4)



**VI. Labeling**

The sponsor provided a product insert that was stated to be included with the subject device. This insert contains instructions for the use of the device.

This insert indicates the use life of the device: 100 cycles

Step by step directions for use.

Cleaning: Use alcohol – wipe the outside and rinse the inside of the device with alcohol.

(b)(4)



(b)(4)



**VII. Sterilization/Shelf Life/Reuse:**

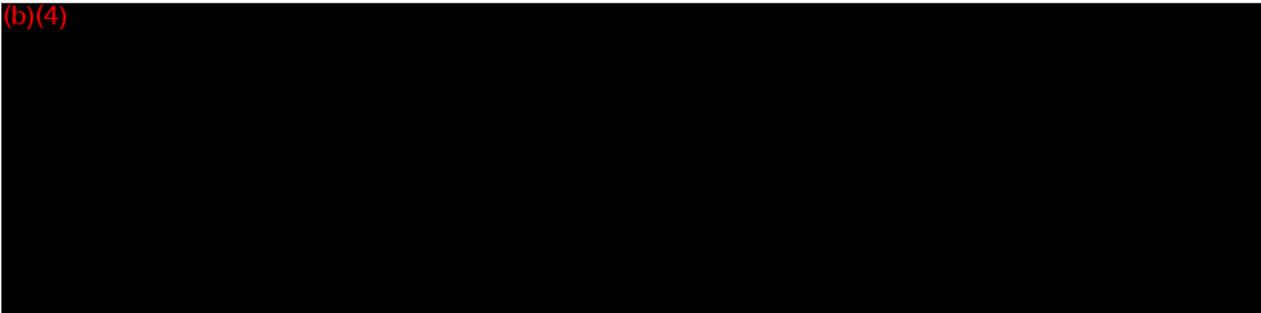
The sponsor has indicated that the subject device is a non-sterile, reusable device. The use-life of the device is for 100 cycles. The device has been previously cleared for use with the claimed cycle with biological indicators and another chemical indicator.

**This is acceptable.**

**VIII. Biocompatibility**

No biocompatibility data were provided for the subject device. Both the subject device and the chemical emulating indicator intended for use with the subject test pack (K100891) are FDA cleared devices.

(b)(4)



**IX. Software**

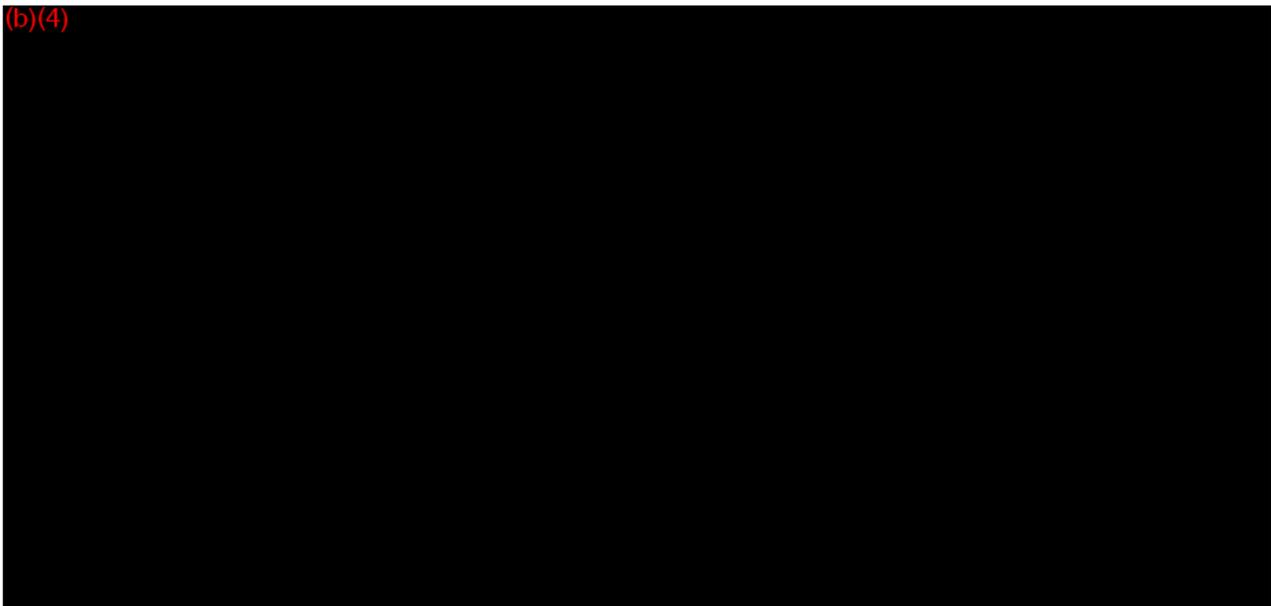
N/A

**X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety**

N/A

**XI. Performance Testing – Bench**

(b)(4)



(b)(4)



**XII. Performance Testing – Animal**

N/A

**XIII. Performance Testing – Clinical**

N/A

**XIV. Substantial Equivalence Discussion**

	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?			Final Decision: TH

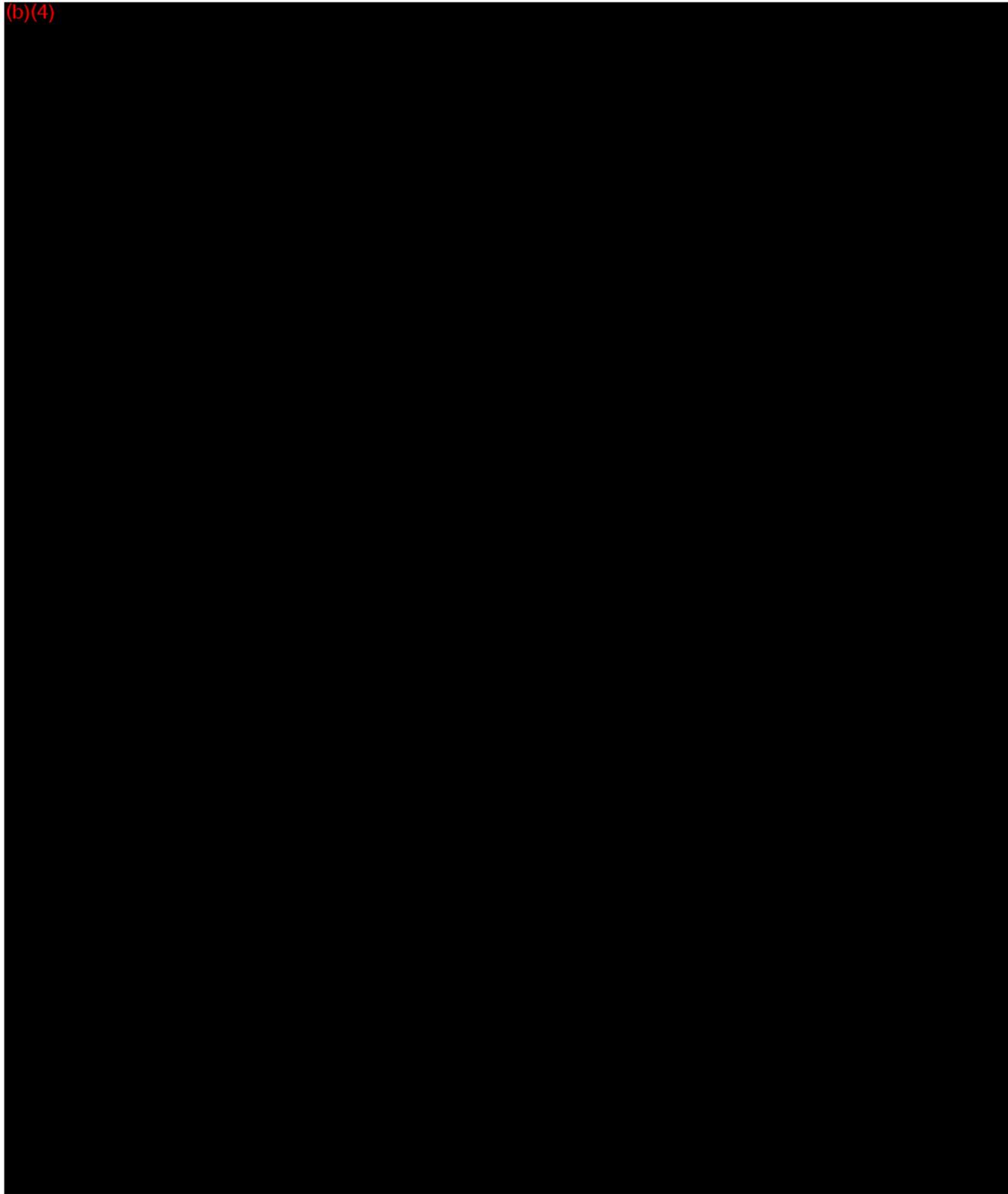
Note: Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

1. Explain how the new indication differs from the predicate device's indication:
2. Explain why there is or is not a new effect or safety or effectiveness issue:
3. Describe the new technological characteristics:
4. Explain how new characteristics could or could not affect safety or effectiveness:
5. Explain how descriptive characteristics are not precise enough:
6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:
7. Explain why existing scientific methods can not be used:
8. Explain what performance data is needed: [REDACTED] (b)(4); [REDACTED]  
[REDACTED] r.
9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

**XV. Deficiencies**

(b)(4)

(b)(4)



**XVI. Contact History**

3/21/11 – A request for additional information was e-mailed and faxed to the sponsor.

**XVII. Recommendation:**

Recommend that K110253 be placed on HOLD pending receipt of response from the sponsor to our request for additional information.

Regulation Number: §880.2800  
Regulation Name: Chemical Sterilization Indicator.  
Regulatory Class: Class II  
Product Code: JOJ



Steven Elliott  
Reviewer

March 21, 2011

Date



Elizabeth Claverie-Williams  
Branch Chief

3/21/11

Date

**K110253**

Date: March 21, 2011  
To: The Record Office: ODE  
From: Steven Elliott, M.S., Scientific Reviewer Division: DAGID  
Through: Elizabeth Claverie-Williams, M.S.; Branch Chief, INCB  
Device Name: Reusable Integrator Test Pack for Dana Emulating Indicator  
510(k) Holder: Dana Products, Inc.  
Address: 7 Corey Drive, South Barrington, Illinois 60010, United States  
Contact: Harry Bala.  
Phone: (847) 455 2881  
Fax: (847) 455 2886  
Email: [bala@voyager.net](mailto:bala@voyager.net)

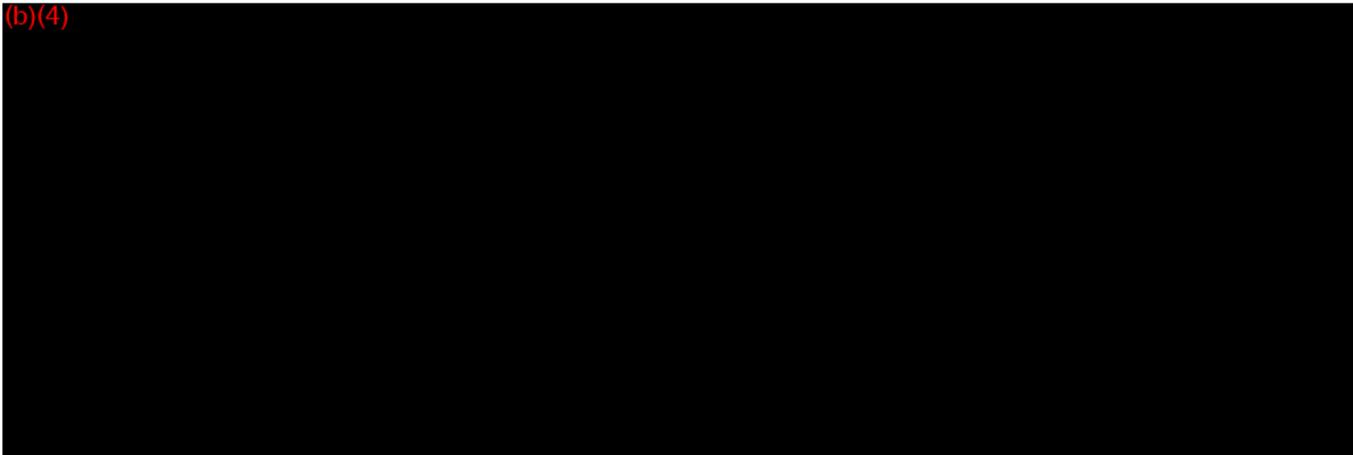
---

We have completed our review of the above referenced 510(k). We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you have provided. To complete the review of this submission, please provide a response to the following questions and/or recommendations.

(b)(4)



(b)(4)



Please provide this information within 30 days. Your document has been placed on hold pending receipt of the above additional information. The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to the Document Mail Center (DMC) at the following address:

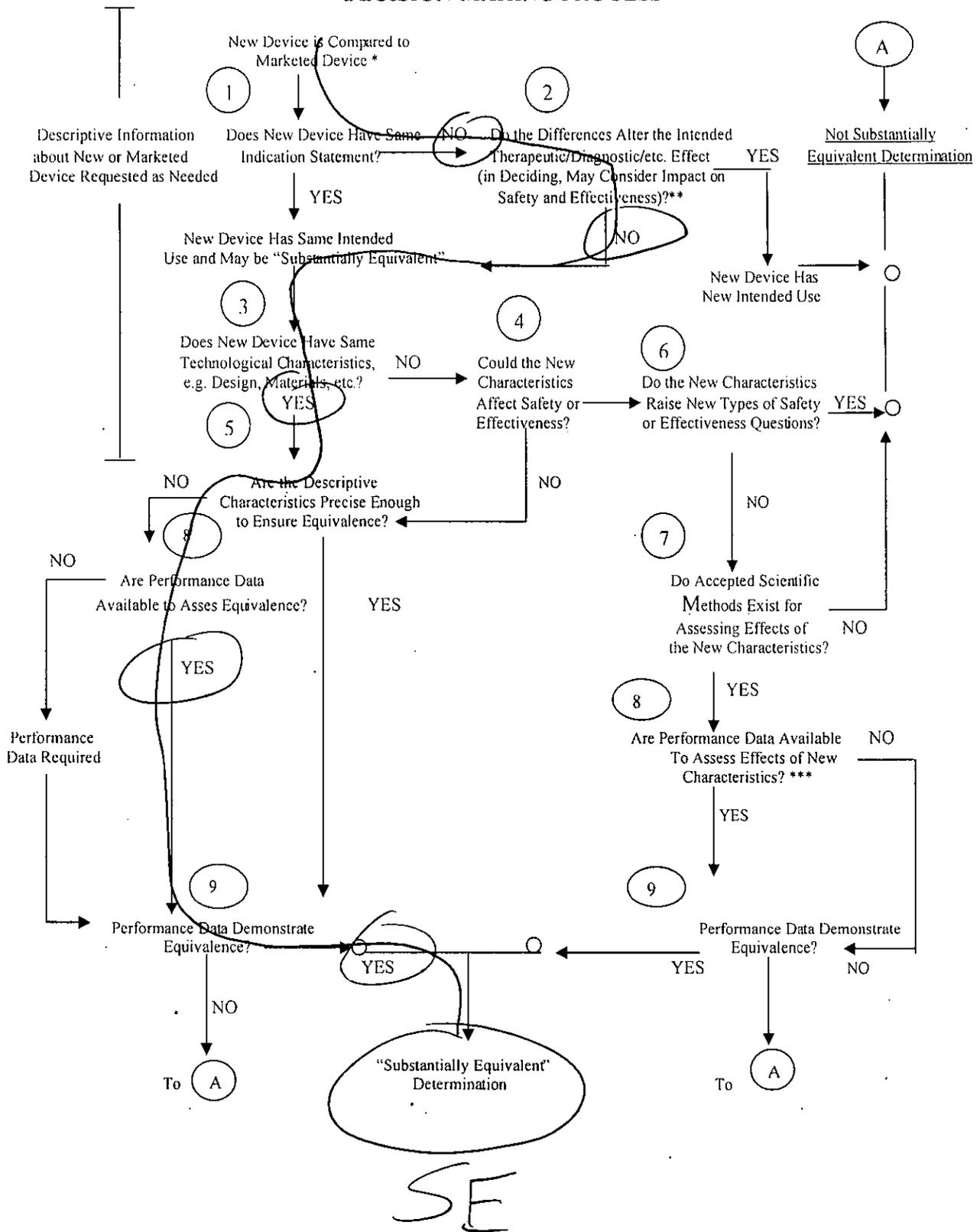
U.S. Food and Drug Administration  
Center for Devices and Radiological Health  
10903 New Hampshire Avenue  
Document Mail Center - WO66-0609  
Silver Spring, MD 20993-0002

Correspondence sent to any address other than the above address will not be considered as part of your official 510(k) submission. Therefore, please forward the original copies of all correspondence to the DMC so that we may proceed with the review of your submission. To expedite the processing of your review, you may forward an electronic response to the deficiencies directly to me (Steven Elliott at [steven.elliott@fda.hhs.gov](mailto:steven.elliott@fda.hhs.gov)). We request that you provide detailed item-by-item responses to the attached request for additional information. The suggested format is to restate the question and/ or comment, state your response to the Agency's request/recommendation and reference the location of appropriate supporting documentation in file.

If you have any questions concerning the content of this letter, please contact me by fax at (301) 847-8109, phone at (301)796-5285 or by e-mail at [steven.elliott@fda.hhs.gov](mailto:steven.elliott@fda.hhs.gov).

Steven Elliott, B.S. M.S.  
Biochemistry/Physiology Reviewer  
Infection Control Devices Branch  
Division of Anesthesiology, General Hospital, Infection Control, and Dental Devices  
Office of Device Evaluation/Center for Devices and Radiological Health

## 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.

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

K110253/S1

April 4, 2011

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

APR 5 2011

~~Receipt~~

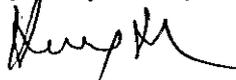
Dear Sir or Madam:

**510(k) Number: K 110253 Reusable Test Pack for use with Dana Emulating Indicator -  
Your request for additional information dated March 21, 2011**

Following is the additional information you requested in your letter dated March 21, 2011. I have made every effort to produce all of the information you have requested.

Thanking you,

Very Truly Yours,

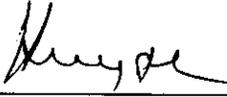


Harry Bala  
President

K310 - 20

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.

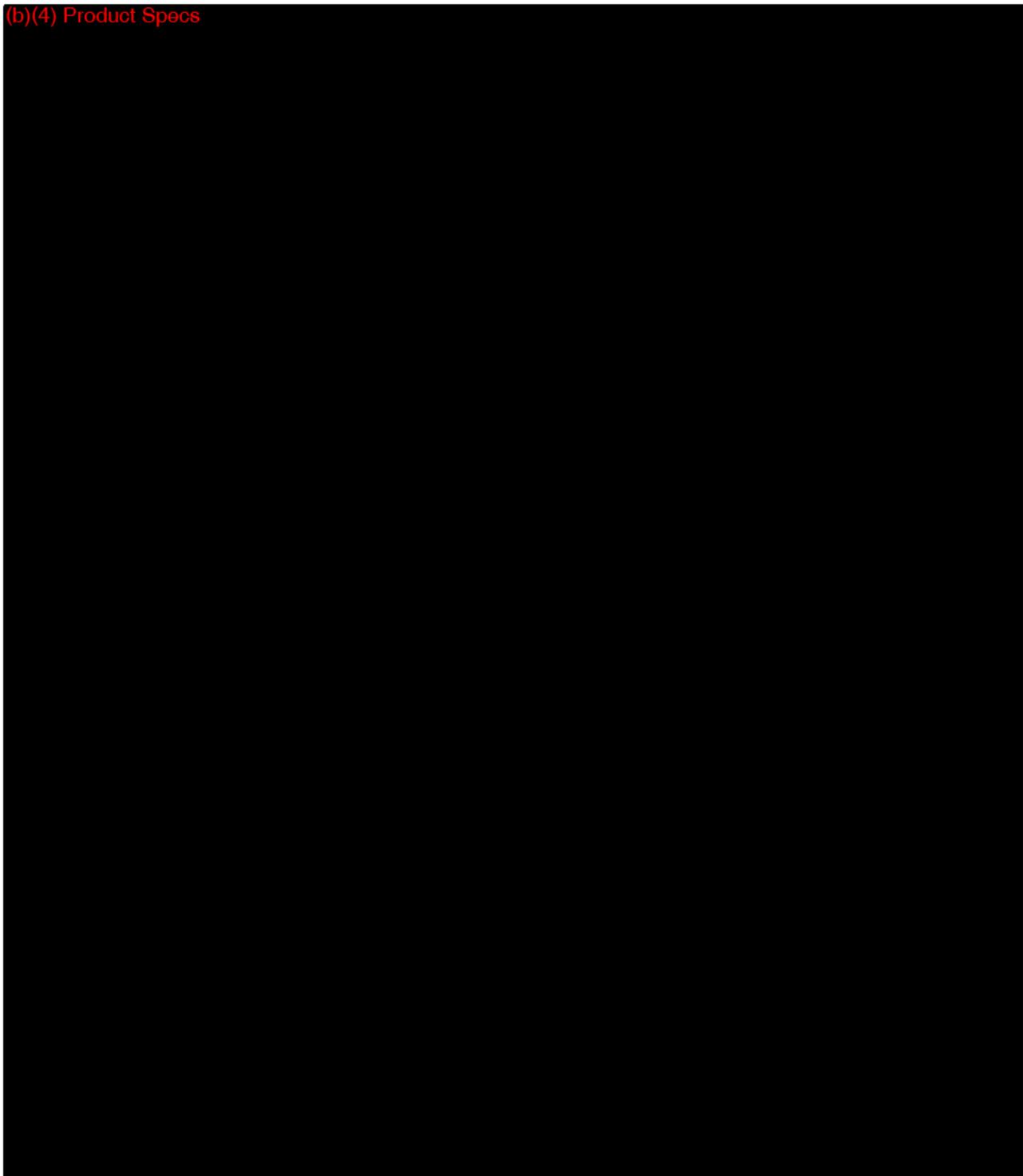
Signature: 

Harry Bala

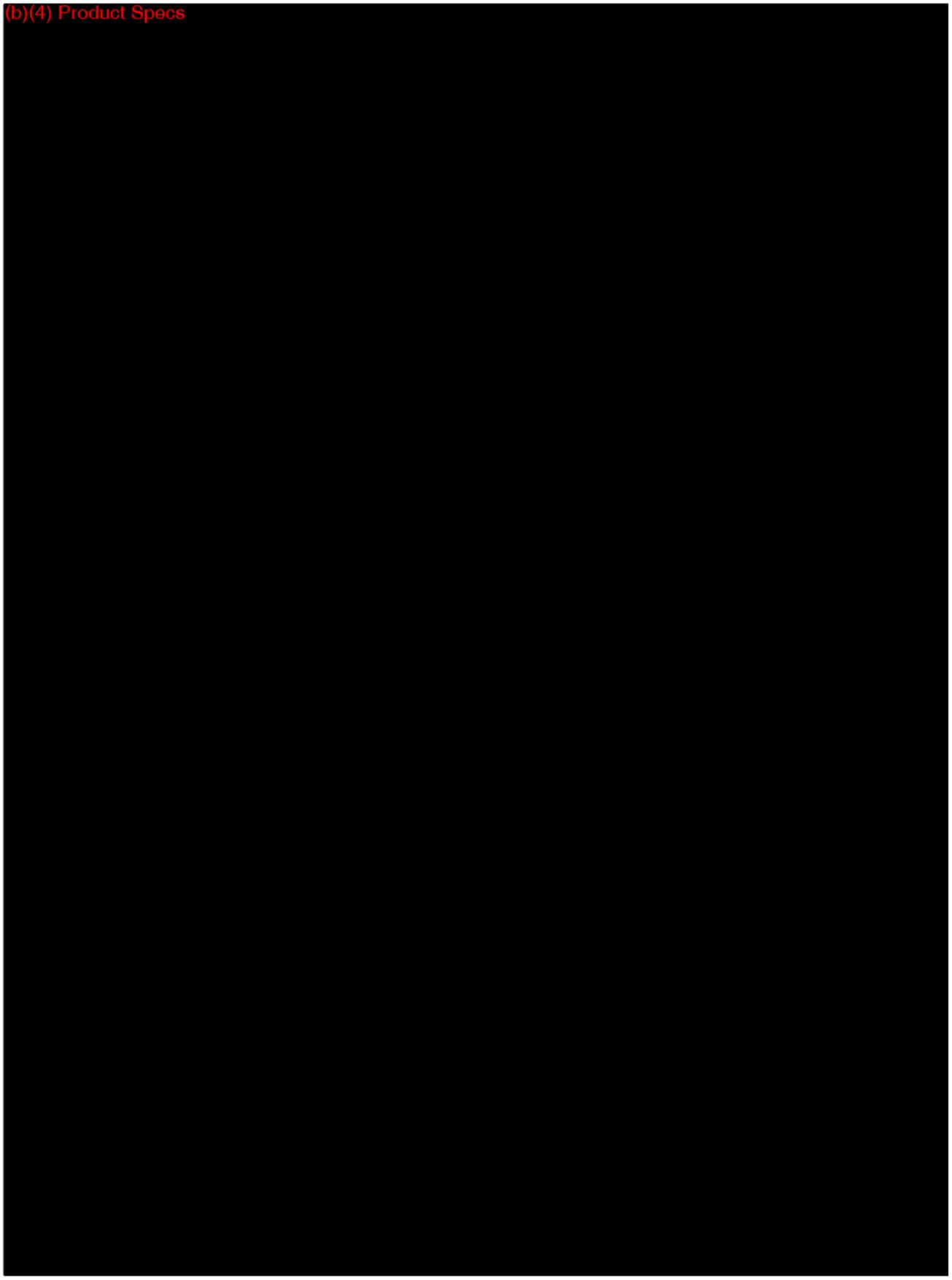
Date 04/04/2011

510k Number: K110253

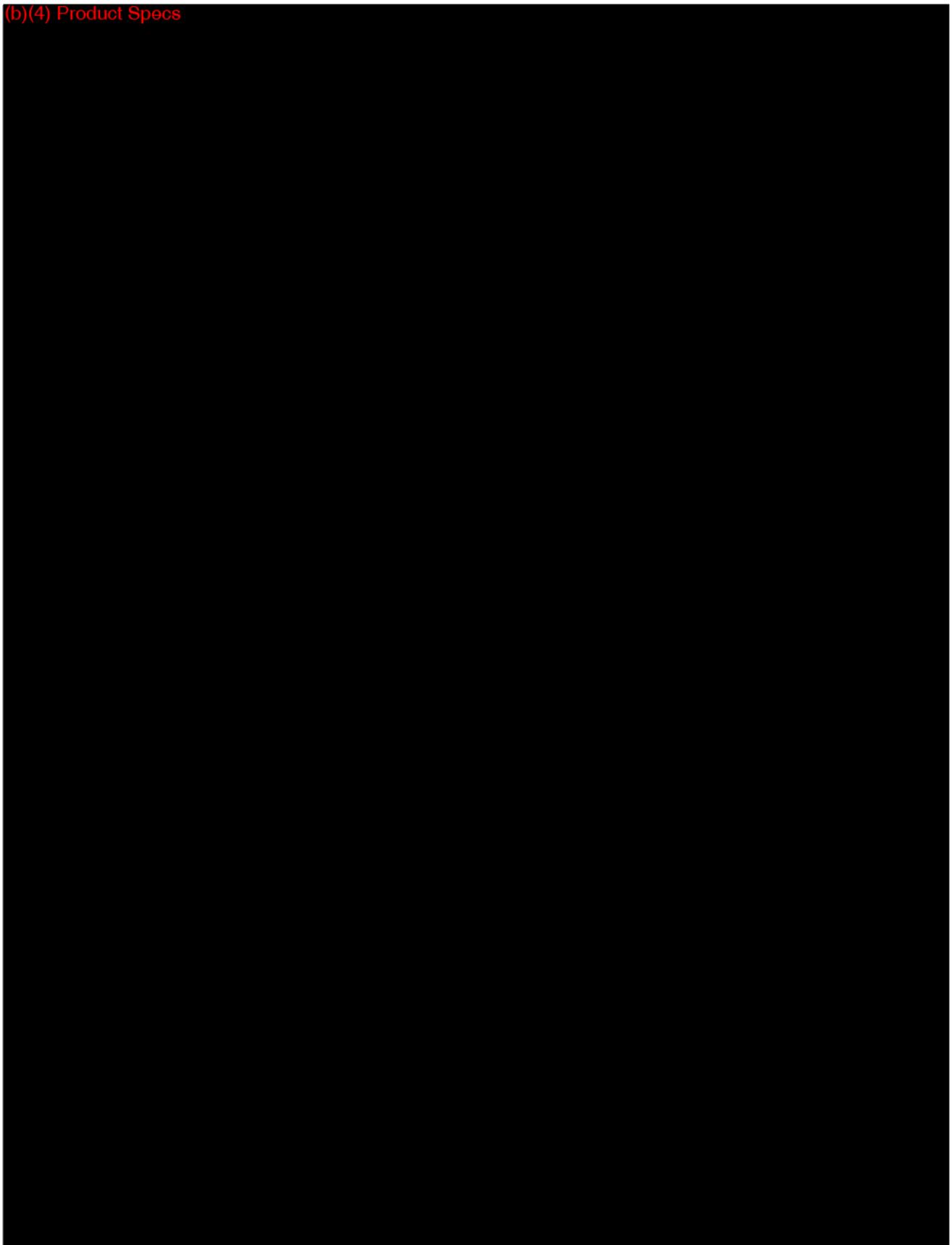
(b)(4) Product Specs



(b)(4) Product Specs



(b)(4) Product Specs



(b)(4) Product Specs

**Substantial Equivalence Comparison:** *Dana Reusable Test Pack for use with the Dana Emulating Indicator that is the subject of this submission and the Dana Reusable Test Pack for use with the SteriScan Integrator cleared under K102761.*

Intended Use:

Predicate: For routine monitoring of steam sterilization cycles using SteriScan Integrators.

Device in this submission: For routine monitoring of steam sterilization cycles using Dana Emulating Indicators.

Indications for use:

Predicate: It is validated to be used in 4 minute 270°F pre-vacuum steam sterilization cycles with SteriScan Integrators.

Device in this submission: It is validated to be used in 4 minute 270°F pre-vacuum 4 minute steam sterilization cycles with Dana Emulating Indicators (K100891).

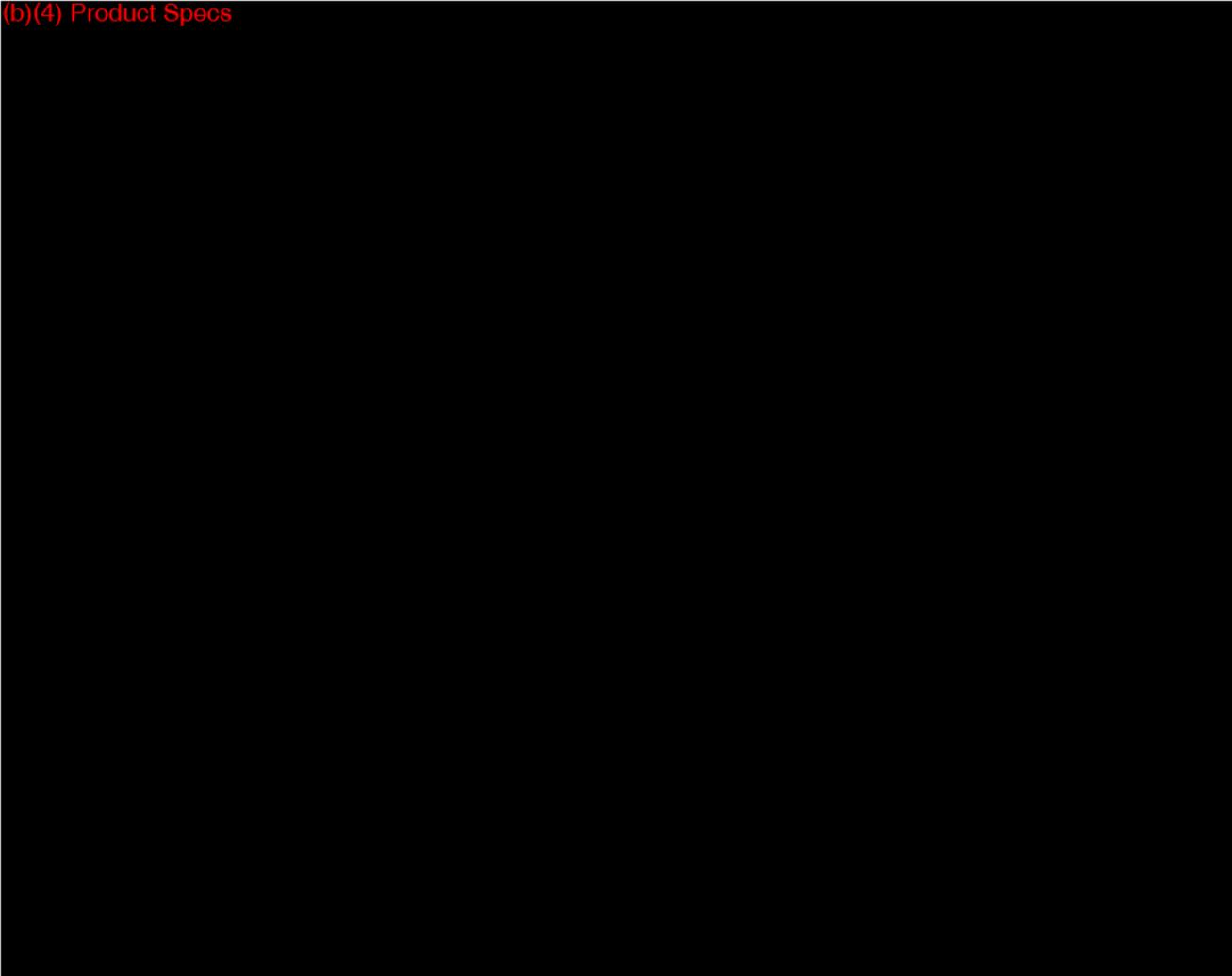
Used in:

Predicate: In health care facilities.

Device in this submission: In health care facilities.

Design and Performance:

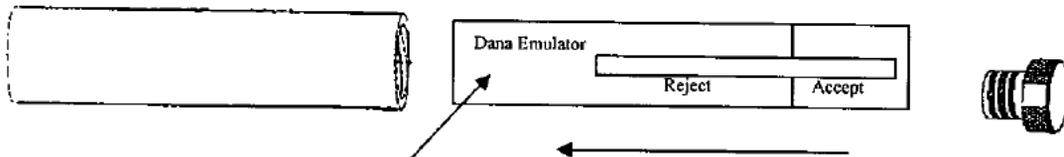
(b)(4) Product Specs



**ITEM – 4:** Labeling and Instructions

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

**Dana Reusable Test Pack**  
**For 270° F 4 minute Pre-Vacuum Cycles**  
**For use with Dana Emulating Indicator**



Insert pellet end first of Dana Emulating Indicator  
Discard after 100 uses

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

Serial Number:  
Lot Number:  
Exp.:

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

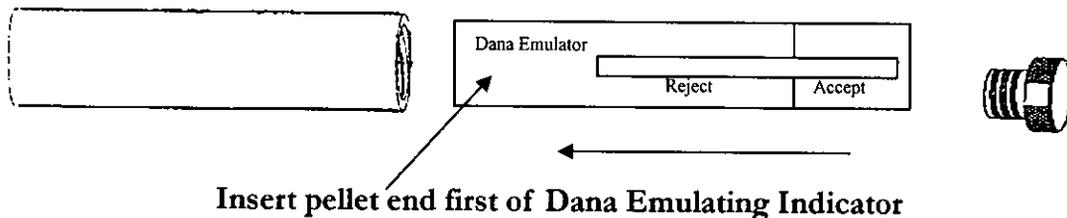
### **Dana Reusable Test Pack**

#### **Product Description:**

Dana Reusable Test Pack is designed to challenge the 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 the Dana Emulating Indicator. The Dana Reusable Test Pack can be used 100 times without losing its effectiveness.

#### **Direction for Use:**

1. Open the screw cap.
2. Insert Dana Emulating Indicator with the pellet end first into the test pack.



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 Dana Emulating Indicator.
11. Follow the instructions provided with the Dana Emulating Indicator by its manufacturer to read and interpret the results.
12. The Dana Emulating Indicators is a single use device. Dispose of the device 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 Reusable 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. The Dana Emulating Indicator is not a replacement for a Biological Indicator.

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

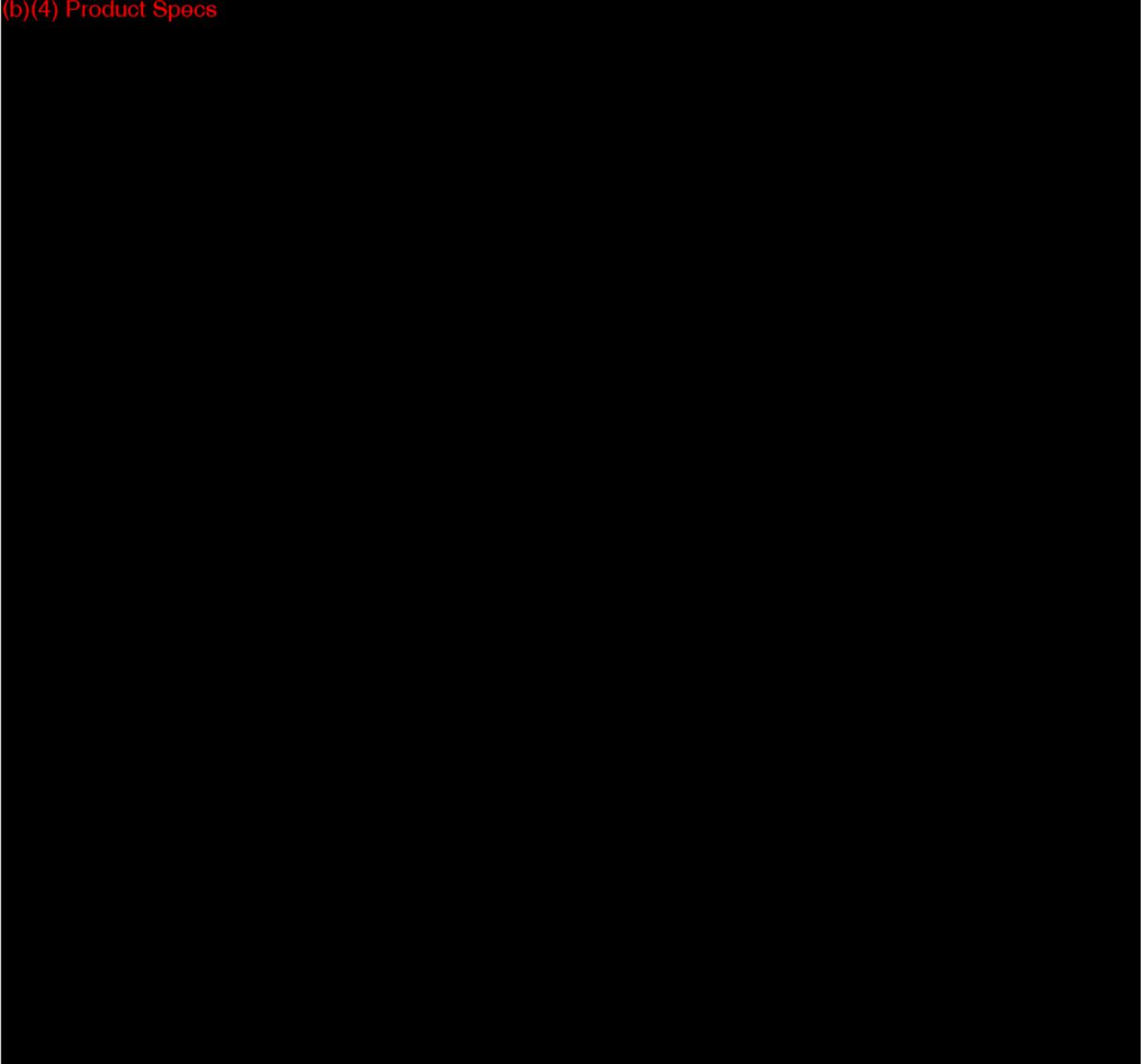
**ITEM 5:**

The Dana Reusable Test Pack that is the subject of this submission is identical in material, manufacturing, construction, dimensions and processing to the Dana Reusable Test Pack validated for use with biological indicators (K092944) and the SteriScan Integrator (K1027611). The Dana Emulating Indicator that is the subject of this submission is identical in material, construction, manufacturing, dimensions and processing to the Dana Emulating Indicator that was approved in K100891.

**ITEM 6:**

**Performance Testing:**

(b)(4) Product Specs

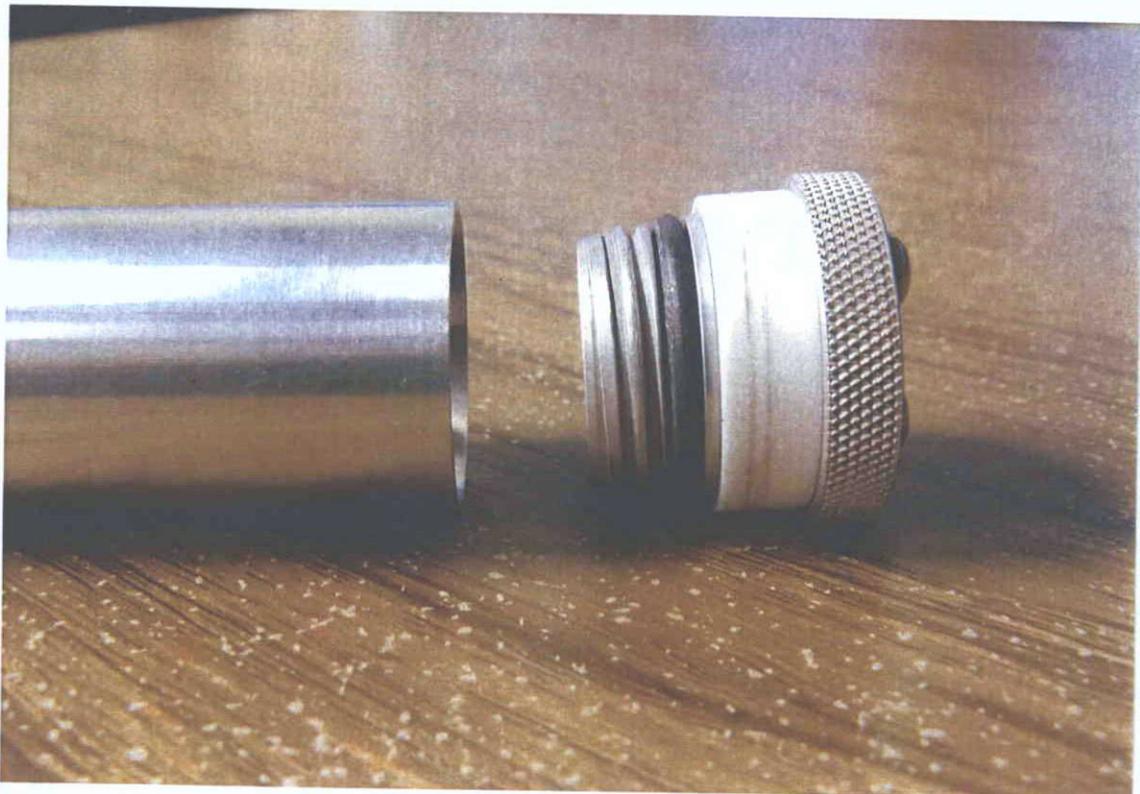


(b)(4) Product Specs

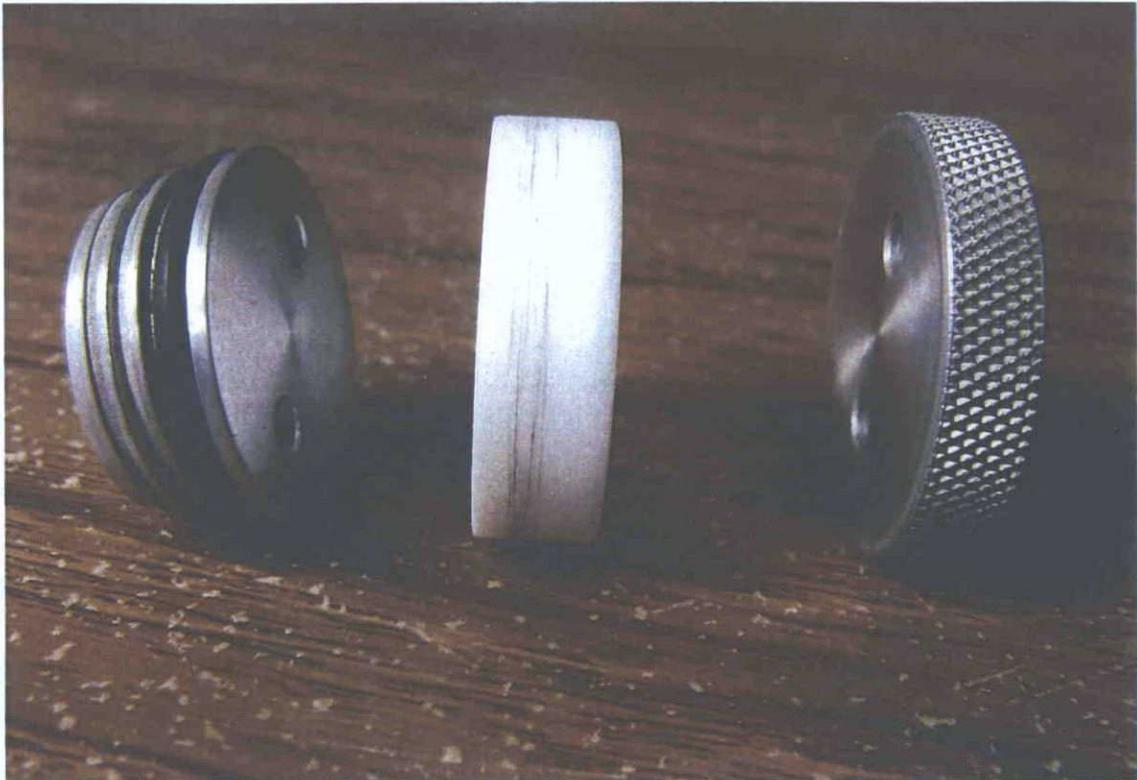




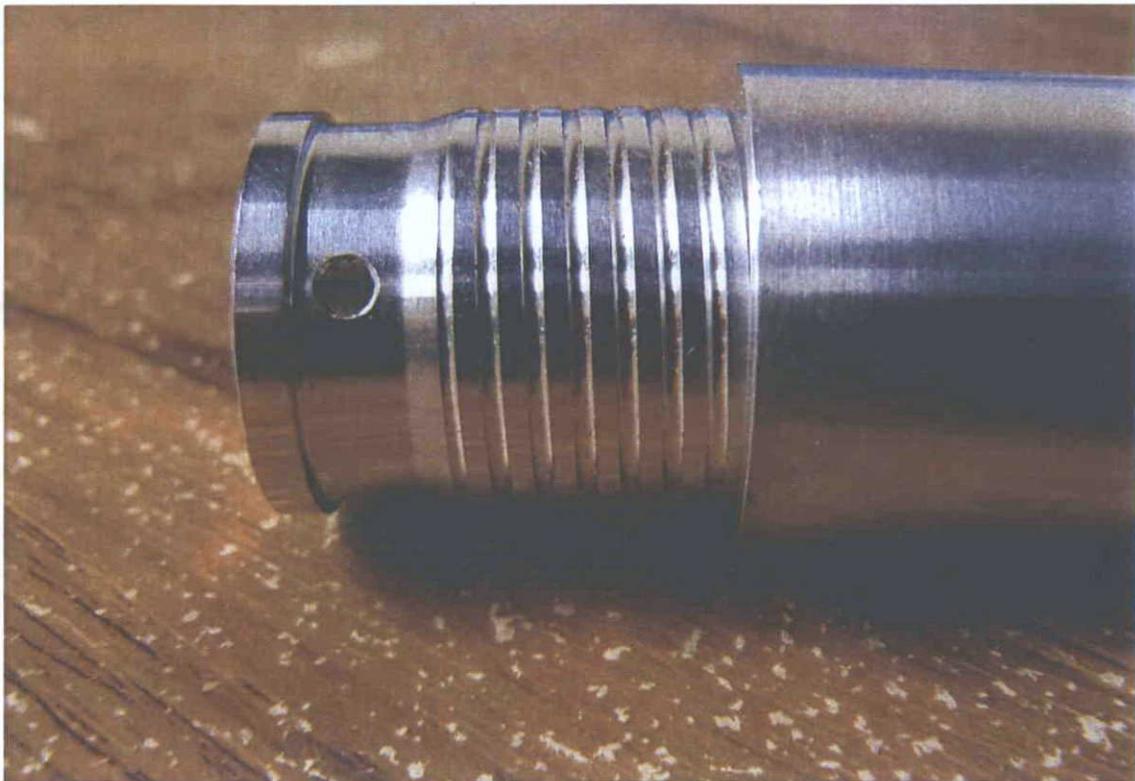
**PHOTO - 1**



**PHOTO 2**



**PHOTO-3**



**PHOTO 4**

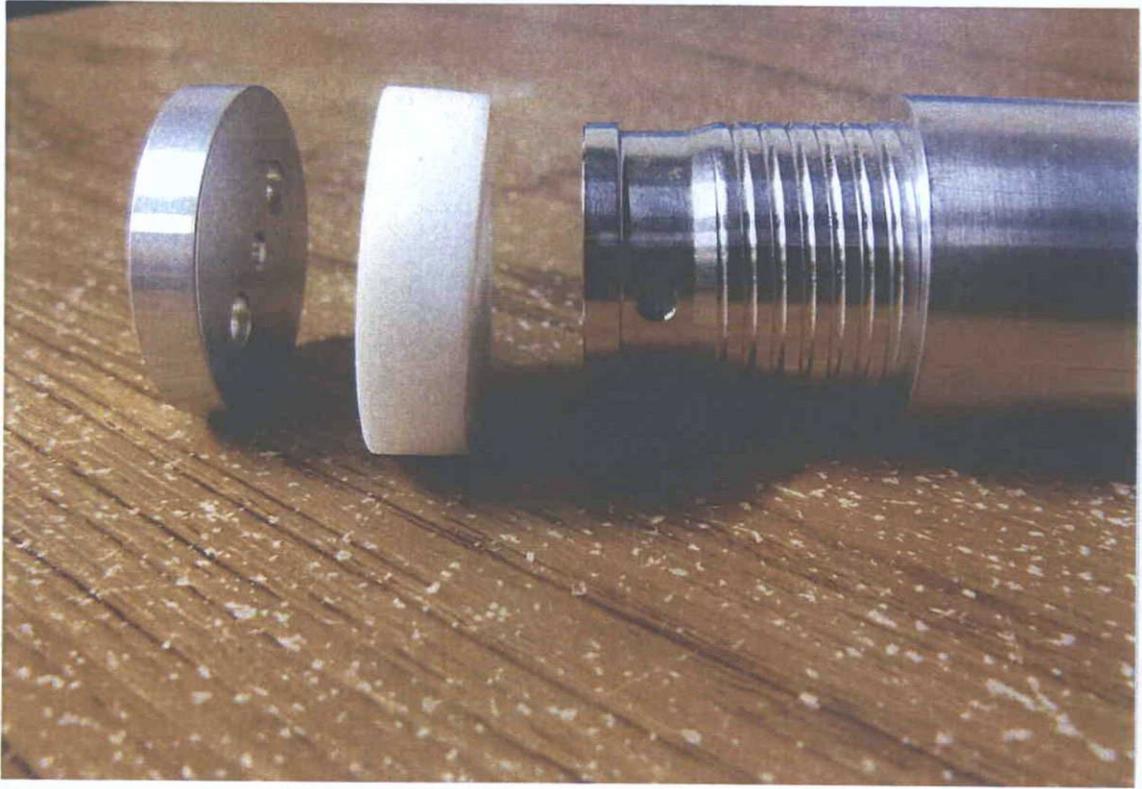


PHOTO-5

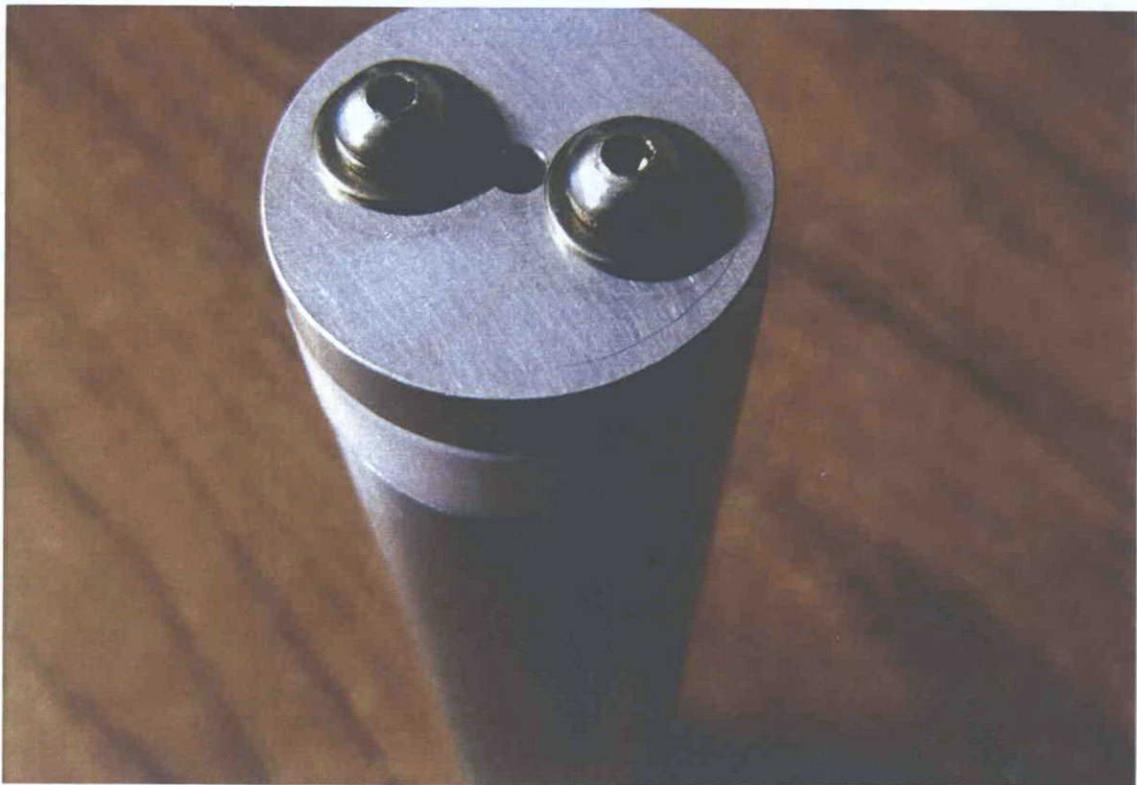


PHOTO 6



**PHOTO 7**

## Indications for Use

510(k) Number (if known): K110253

Device Name: Reusable Integrator Test Pack for Dana Emulating Indicator.

### 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 4 minute steam sterilization cycles with the Dana Emulating Indicator cleared by FDA under K100891.

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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of  1

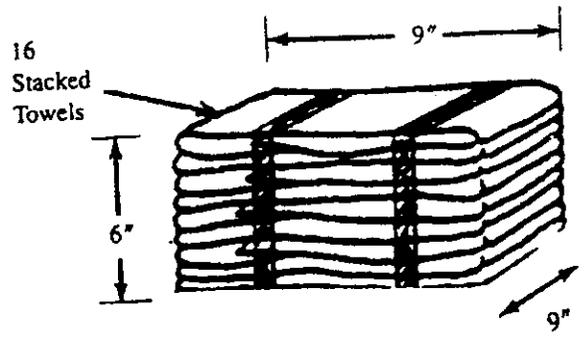
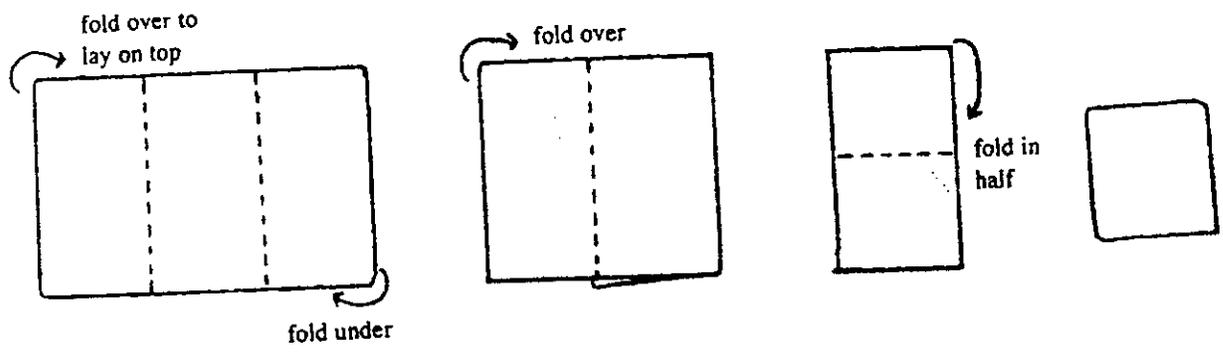


FIGURE 1