



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

DEC 20 2010

Re: K102761
Trade/Device Name: Reusable SteriScan Integrator Test Pack for Steam
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: II
Product Code: JOJ
Dated: September 20, 2010
Received: September 23, 2010

Dear Mr. Bala:

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

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

Page 2- Mr. Bala

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

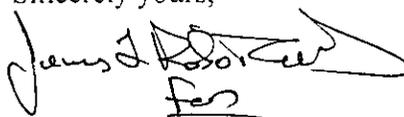
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to

<http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K102761

Indications for Use

DEC 20 2010

510(k) Number (if known):

Device Name: Reusable SteriScan Integrator Test Pack for Steam Sterilization.

Indications For Use:

Dana reusable challenge test pack is designed to challenge steam sterilization process in healthcare facilities. It is intended to be used for routine monitoring of pre-vacuum steam sterilization cycles. It is validated to be used in 4 minute 270°F pre-vacuum steam sterilization cycles with SteriScan Integrators.

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

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1

Elizabeth F. Clavisi-Williams

(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K102761



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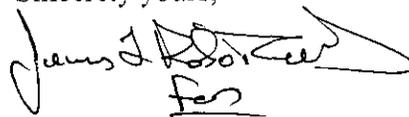
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Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General hospital,
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Page 1 of 1

Elizabeth F. Clavette-Williams

(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K102761



U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center 6 WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

September 24, 2010

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

510k Number: K102761

Received: 9/23/2010

Product: DANA REUSABLE TEST PACK FOR ST

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

Please remember that all correspondence concerning your submission **MUST** be sent to the Document Mail Center (DMC) 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

510k NOTIFICATION

DANA REUSABLE INTEGRATOR
TEST PACK FOR STEAM STERILIZATION

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1. Medical Device User Fee Cover Sheet (Form FDA 3601)
2. CDRH Premarket Review Submission Cover sheet
3. 510(k) Cover letter -----Pages 1 & 2
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5. 510(k) Statement -----Page 4
6. Declaration of Conformity, Devise Description -----Pages 5 -13
Test Results , Proposed Labeling
7. Truthful and Accuracy Statement -----Page 14

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION MEDICAL DEVICE USER FEE COVER SHEET		PAYMENT IDENTIFICATION NUMBER: (b)(4) Write the Payment Identification number on your check.
A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/cover sheet.html		
1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code) DANA PRODUCTS INC 7 Corey Dr. South Barrington IL 60010 US 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: http://www.fda.gov/oc/mdufma) 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: SBD100036		
5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA? <input checked="" type="checkbox"/> YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.) <input type="checkbox"/> NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)		
6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.		
<input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates <input type="checkbox"/> 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		
8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (b)(4)		11-Sep-2010

Form FDA 3601 (01/2007)

"Close Window" [Print Cover sheet](#)

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			Form Approval OMB No. 0910-0120 Expiration Date: August 31, 2010. See OMB Statement on page 5.	
CDRH PREMARKET REVIEW SUBMISSION COVER SHEET				
Date of Submission 9-14-2010	User Fee Payment ID Number (b)(4)	FDA Submission Document Number (if known)		
SECTION A TYPE OF SUBMISSION				
PMA <input type="checkbox"/> Original Submission <input type="checkbox"/> Premarket Report <input type="checkbox"/> Modular Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment <input type="checkbox"/> Licensing Agreement	PMA & HDE Supplement <input type="checkbox"/> Regular (180 day) <input type="checkbox"/> Special <input type="checkbox"/> Panel Track (PMA Only) <input type="checkbox"/> 30-day Supplement <input type="checkbox"/> 30-day Notice <input type="checkbox"/> 135-day Supplement <input type="checkbox"/> Real-time Review <input type="checkbox"/> Amendment to PMA & HDE Supplement <input type="checkbox"/> Other	PDP <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP	510(k) <input checked="" type="checkbox"/> Original Submission: <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated (Complete section I, Page 5) <input type="checkbox"/> Additional Information <input type="checkbox"/> Third Party	Meeting <input type="checkbox"/> Pre-510(K) Meeting <input type="checkbox"/> Pre-IDE Meeting <input type="checkbox"/> Pre-PMA Meeting <input type="checkbox"/> Pre-PDP Meeting <input type="checkbox"/> Day 100 Meeting <input type="checkbox"/> Agreement Meeting <input type="checkbox"/> Determination Meeting <input type="checkbox"/> Other (specify):
IDE <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	Humanitarian Device Exemption (HDE) <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	Class II Exemption Petition <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Evaluation of Automatic Class III Designation (De Novo) <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Other Submission <input type="checkbox"/> 513(g) <input type="checkbox"/> Other (describe submission):
Have you used or cited Standards in your submission? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> 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 (specify below)	<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 (specify below)	<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 (specify below)	<input type="checkbox"/> Report Submission: <input type="checkbox"/> Annual or Periodic <input type="checkbox"/> Post-approval Study <input type="checkbox"/> Adverse Reaction <input type="checkbox"/> Device Defect <input type="checkbox"/> Amendment			
<input type="checkbox"/> Response to FDA correspondence:		<input type="checkbox"/> Change in Ownership <input type="checkbox"/> Change in Correspondent <input type="checkbox"/> Change of Applicant Address			
<input type="checkbox"/> Other Reason (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					
<input type="checkbox"/> 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 (specify):					

SECTION E								ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS							
Product codes of devices to which substantial equivalence is claimed								Summary of, or statement concerning, safety and effectiveness information							
1	JOJ	2		3		4		<input type="checkbox"/> 510 (k) summary attached		<input checked="" type="checkbox"/> 510 (k) statement					
5		6		7		8									
Information on devices to which substantial equivalence is claimed (if known)															
	<i>510(k) Number</i>			<i>Trade or Proprietary or Model Name</i>				<i>Manufacturer</i>							
1	K952408	1		Attest 1296 Rapid Readout test pack	1			3M							
2	k926364	2		Attest 1292 Rapid Readout BI	2			3M							
3	k012195	3		SteriScan Integrator	3			Dana Products, Inc.							
4	k092944	4		Dana Reusable Test Pack	4			Dana Products, Inc.							
5		5			5										
6		6			6										
SECTION F												PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS			
Common or usual name or classification name															
Challenge Test Pack for steam sterilization.															
	<i>Trade or Proprietary or Model Name for This Device</i>								<i>Model Number</i>						
1	Dana Reusable Test pack for Steam Sterilization.							1							
2								2							
3								3							
4								4							
5								5							
FDA document numbers of all prior related submissions (regardless of outcome)															
1	2	3	4	5	6	7	8	9	10	11	12				
Data Included in Submission															
<input checked="" type="checkbox"/> Laboratory Testing <input type="checkbox"/> Animal Trials <input type="checkbox"/> Human Trials															
SECTION G												PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS			
Product Code		C.F.R. Section (if applicable)						Device Class							
JOJ		880.2800						<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
<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.					
1	Standards No. ST8	Standards Organization ANSI AAMI	Standards Title Hospital Steam Sterilizers	Version 2001	Date 01/01/2001
2	Standards No. ST 79	Standards Organization ANSI AAMI	Standards Title Comprehensive Guide to steam sterilization and sterility assurance in health care facilities	Version 2006	Date 01/01/2006
3	Standards No.	Standards Organization	Standards Title	Version	Date
4	Standards No.	Standards Organization	Standards Title	Version	Date
5	Standards No.	Standards Organization	Standards Title	Version	Date
6	Standards No.	Standards Organization	Standards Title	Version	Date
7	Standards No.	Standards Organization	Standards Title	Version	Date
Please include any additional standards to be cited on a separate page.					
<p>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:</p> <p style="text-align: center;">Department of Health and Human Services Food and Drug Administration Office of the Chief Information Officer (HFA-710) 5600 Fishers Lane Rockville, Maryland 20857</p> <p><i>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.</i></p>					

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

KC02761

September 20, 2010

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

FDA CDRH DMC

SEP 23 2010

Dear Sir or Madam:

Received

K14

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

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

Device Name: Reusable Integrator Test Pack for
Steam Sterilization

Device Classification Name: Indicator, Physical/Chemical Sterilization Process

Product Code: JOJ

Regulation Number: 880.2800

Review Panel: General Hospital

Device Class: 2

Propriety Name: Dana Reusable Test Pack

Establishment Registration Number: 3007412809

Owner Operator Number: 9054259

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

Predicate Device 510 k: 3M -1296 Test pack- k 952408 & 1292 Rapid Readout BI k926364
SteriScan Integrator – k 012195, Reusable Biological and Integrator
Test Pack for Steam Sterilization K092944

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

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

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

Sincerely,



Harry Bala
President

Indications for Use

510(k) Number (if known):

Device Name: Reusable SteriScan Integrator Test Pack for Steam Sterilization.

Indications For Use:

Dana reusable challenge test pack is designed to challenge steam sterilization process in healthcare facilities. It is intended to be used for routine monitoring of pre-vacuum steam sterilization cycles. It is validated to be used in 4 minute 270°F pre-vacuum steam sterilization cycles with SteriScan Integrators.

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

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

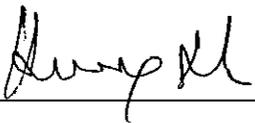
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1

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: 9/22/10

510k Number: _____

Declaration of conformity: The Dana Reusable Test Pack, when used with SteriScan Integrators conforms to the Standard set test pack using 16 surgical towels in section 10.7.2.1 of ANSI/AAMI ST79: 2006. Dana 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. 3 M's1296 test pack was validated against the 16 towel packs. Comparative testing was done with Dana test pack with SteriScan Integrators, 3M 1296 test packs, and with SteriScan Integrators 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 approved for use with 3M's Rapid Readout BIs along with or without SteriScan Integrators. In the submission we also had provided all the test results to qualify the test pack to be used only with SteriScan. In this submission I am resubmitting the data to validate the test pack for use only with SteriScan Integrators.

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

510k Numbers and other relevant data:

Steam Sterilizer used: Our brand new AMSCO CENTURY

Chamber size: 20"x20"x38"

Cycle: Prevac at 270°F (132°C)

510k : K030789

BI: 3M's 1292 Attest Rapid Readout BI

510K: K 926364

1296 Attest Rapid Readout Test Pack

Uses 3M's 1292 Attest Rapid Readout BI

510K: K 952408

3M 290 Auto Reader

For Incubating 1292 BIs

510K: K004009

SteriScan Integrator 510 K: K012195

1296 test packs and (1292 BIs in the test pack) used in this study:

Organism: *Geobacillus Stearothermophilus* ATCC 7953

Lot: 2010-04 DA

Population (mean/strip): 4.7x1, 000,000

Test D-Value (121°C): 1.5 Min.

Survival Time: 7.01 Min.

Kill Time: 16.01 Min.

Z-Value: 10.7°C

Lot: 2010-05 DA

Population (mean/strip): 4.0x1, 000,000

Test D-Value (121°C): 1.6 Min.

Survival Time: 7.36 Min.

Kill Time: 16.96 Min.

Z-Value: 11.0°C

Lot: 2010-05 DB

Population (mean/strip): 3.2 x1, 000,000

Test D-Value (121°C): 1.6 Min.

Survival Time: 7.21 Min.

Kill Time: 16.81 Min.

Z-Value: 10.0°C

Lot: 2011-01 DI

Population (mean/strip): 4.4x1, 000,000

Test D-Value (121°C): 1.8

Survival Time: 8.36 Min.

Kill Time: 19.16 Min.

Z-Value: 12°C

Performance Testing:

Predicate device: SteriScan Integrators, 3M's 1296 Test Pack

Object: To show that SteriScan Integrators in Dana Test Pack is more resistant than the ones outside the test pack and also 1296 Test Packs in 270°F prevac cycles.

Test Parameters:

1. All tests were conducted in our AMSCO CENTURY Steam Sterilizer at 270°F prevac cycle. The Steam sterilizer and the cycles are cleared for healthcare use.
2. Dana Test pack containing SteriScan Integrators is compared with 3M's 1296 Test Pack and also to SteriScan Integrators on an open tray.
3. Dana Test pack, 1296 test packs and SteriScan on an open tray are placed side by side on the bottom shelf directly on top of the drain along with 1296 test packs. This is the coldest part of the Sterilizer.
4. All comparative testing was done with just the two test packs along with SteriScan on an open tray but otherwise empty Sterilizer. This is the worst Sterilizer load condition (per ANSI/AAMI ST-8).
5. Exposure times are 20 seconds, 1, 2, and 4 minutes.
6. At least 3 lots of SteriScan are used in testing.
7. After exposure the 1292 BIs were removed from 1296 test packs and incubated in 3M's 290 Auto Reader. Positive or negative fluorescent reading was taken after 3 hours. Final visual color change reading is taken after 48 hours.
8. The distance traveled by the migrating dye for SteriScan was measured and tabulated.

Statement of Purpose/ Objective of Studies

Study : The object of the study is to show that SteriScan Integrators in Dana Test packs are more resistant than the ones outside the test packs. In all cases, acceptance criterion is that SteriScan integrators in the test pack should be more resistant than the ones outside. Also Dana test Pack should be more resistant than 1296 test packs.

STUDY :

**Performance of SteriScan Integrator in Dana Test Pack
in 4 min. 270°F Prevac cycles.**

Exposure times: 20 sec, 1 min., 2 min., and 4 min.

Sterilizer: AMSCO CENTURY

Integrator Placement: The pellet of SteriScan to the bottom of the test pack.

Placement of Test Packs: Both Dana Test pack and 1296 Test Packs directly above the drain along with SteriScan Integrators from the same lot on an open tray.

Sterilizer Load: Just the test packs and Integrators otherwise empty chamber. (Per ST 8)

Object: To show that SteriScan Indicator in the test pack is significantly more resistant than the ones placed outside and also 1296 test packs.

Performance of SteriScan Integrator

Acceptance Criterion: SteriScan Integrator in Dana test pack should be more resistant than the integrator placed outside and also 1296 test packs.

3 lots of SteriScan migrating front integrators were tested in Dana Test Packs along with SteriScan integrators placed in the open tray on the bottom shelf. The migrating steam sensitive dye has to travel 45 mm to reach the accept window and 63 mm to completely cover the accept window. The distance in mm traveled by the migrating dye are tabulated in the following table:

**Distance Traveled in Millimeters
Exposure Time 20 Seconds**

Inside Test Pack

Outside Test Pack

Lot 118	Lot 019	Lot 039	Lot 118	Lot 019	Lot 039
22	26	24	48	50	49
26	23	27	45	49	50
21	25	28	47	48	48
24	22	26	42	46	48
23	21	24	48	43	44
24	25	22	46	45	48
26	22	24	49	49	46
23	27	22	46	50	49
25	21	27	48	49	48
21	26	24	49	46	50

Distance Traveled in Millimeters
Exposure Time 1 Minute

Inside Test Pack

Outside Test Pack

Lot 118	Lot 019	Lot 039		Lot 118	Lot 019	Lot 039
47	42	48		63	63	63
48	45	47		63	63	63
49	46	50		63	63	63
49	45	48		63	63	63
46	49	50		63	63	63
45	47	49		63	63	63
42	41	45		63	63	63
45	42	49		63	63	63
48	50	46		63	63	63
44	42	46		63	63	63

Distance Traveled in Millimeters
Exposure Time 2 & 4 Minutes

Inside Test Pack

All 10 integrators from each of three lots (total 30) –118, 019, 039

Distance traveled by the migrating dye – 63 mm. (covered the accept window completely)

Distance Traveled in Millimeters
Exposure Time 2 & 4 Minutes

Outside Test Pack

All 10 integrators from each of three lots (total 30) –118, 019, 039

Distance traveled by the migrating dye – 63 mm. (covered the accept window completely)

Conclusion: SteriScan placed on an open tray reached the accept mark in 20 seconds whereas it took the ones in the test pack 1 minute to do the same. This study shows SteriScan in the test pack is more resistant than the ones outside. The test pack adds significant resistance to the performance of the integrator.

Number of Positives Per Auto Reader by 3M (after 3 hrs.)

Lot No.	Time	3M 1296	Time	3M 1296
2010-04-DA	20Sec.	0/10	1 Min.	0/10
2010-05-DA	20Sec.	0/10	1 Min.	0/10
2010-05-DB	20Sec.	0/10	1 Min.	0/10
2011-01-DI	20Sec.	0/10	1 Min.	0/10

Lot No.	Time	3M 1296	Time	3M 1296	Time	3M 1296
2010-04-DA	2 Min.	0/10	3 Min.	0/10	4 Min.	0/10
2010-05-DA	2 Min.	0/10	3 Min.	0/10	4 Min.	0/10
2010-05-DB	2 Min.	0/10	3 Min.	0/10	4 Min.	0/10
2011-01-DI	2 Min.	0/10	3 Min.	0/10	4 Min.	0/10

SUMMARY

Time	3M 1296	Time	3M 1296
20 sec.	0/40	1 Min.	0/40
3 Min.	0/40	4 Min.	0/40

Number of Positives by Color Change after 48 hours of incubation in the Auto Reader

Lot No.	Time	3M 1296	Time	3M 1296
2010-04-DA	20Sec.	0/10	1 Min.	0/10
2010-05-DA	20Sec.	0/10	1 Min.	0/10
2010-05-DB	20Sec.	0/10	1 Min.	0/10
2011-01-DI	20Sec.	0/10	1 Min.	0/10

Lot No.	Time	3M 1296	Time	3M 1296	Time	3M 1296
2010-04-DA	2 Min.	0/10	3 Min.	0/10	4 Min.	0/10
2010-05-DA	2 Min.	0/10	3 Min.	0/10	4 Min.	0/10
2010-05-DB	2 Min.	0/10	3 Min.	0/10	4 Min.	0/10
2011-01-DI	2 Min.	0/10	3 Min.	0/10	4 Min.	0/10

SUMMARY

Time	3M 1296	Time	3M 1296
20 sec.	0/40	1 Min.	0/40
3 Min.	0/40	4 Min.	0/40

Conclusion: It took 1 minute for SteriScan in the Dana Test Pack to reach the accept mark. The 1292 BIs from 1296 test packs did not show any growth for all exposures. The results show that Dana Test pack is more resistant than 3M's 1296 test pack.

LABELING:

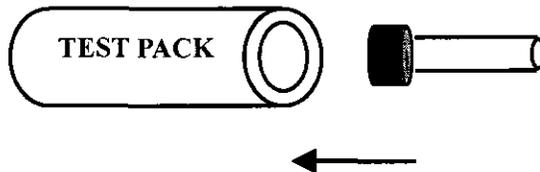
The following is the draft of the labeling that will be applied on each test pack.

Dana Reusable Test Pack

For 270° F 4minute Pre-Vacuum Cycles

For use with 3M Attest 1292 BI

or with SteriScan Integrator or both



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

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

Serial Number:
Lot Number:
Exp.:

LABELING:

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

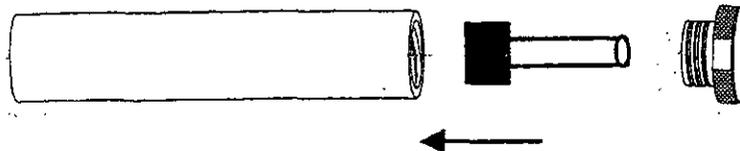
Dana Reusable Test Pack

Product Description:

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

Direction for Use:

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



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

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

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

Dana Test Pack

Serial Number:

Date of initial use:

Discard test pack after 100 uses

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

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

Cleaning:

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

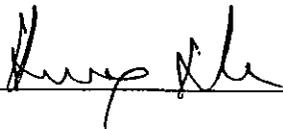
Precautions:

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

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

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

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

Signature: 

Harry Bala

Date 9/22/11

510k Number: K092944



COVER SHEET MEMORANDUM

From: Reviewer Name Kapi Panguluv, Ph.D
 Subject: 510(k) Number K102761
 To: The Record

Please list CTS decision code SE

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

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	Attach IFU	<input checked="" type="checkbox"/>	<input type="checkbox"/>
510(k) Summary / <u>510(k) Statement</u>	Attach Summary	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Truthful and Accurate Statement.	Must be present for a Final Decision	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Is the device Class III?		<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, does firm include Class III Summary?	Must be present for a Final Decision	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)		<input checked="" type="checkbox"/>	<input type="checkbox"/>
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC)		<input type="checkbox"/>	<input type="checkbox"/>
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Is this device intended for pediatric use only?		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Is this a prescription device? (If both prescription & OTC, check both boxes.)		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Is clinical data necessary to support the review of this 510(k)?		<input type="checkbox"/>	<input checked="" type="checkbox"/>
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.)		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Does this device include an Animal Tissue Source?		<input type="checkbox"/>	<input checked="" type="checkbox"/>
All Pediatric Patients' age <= 21		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Neonate/Newborn (Birth to 28 days)		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Infant (29 days - < 2 years old)		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Child (2 years - < 12 years old)		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Adolescent (12 years - < 18 years old)		<input type="checkbox"/>	<input checked="" type="checkbox"/>
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.)		<input type="checkbox"/>	<input checked="" type="checkbox"/>

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

Regulation Number	Class*	Product Code
21 CFR 880.2800	II	J0J
(*If unclassified, see 510(k) Staff)		

Additional Product Codes: _____

Review: Elizabeth F. (Laurie) Williams I NCB 12/20/2010
(Branch Chief) (Branch Code) (Date)

Final Review: James A. [Signature] 12/20/2010
(Division Director) (Date)
Deputy Division Director



DEPARTMENT OF HEALTH AND HUMAN SERVICES MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
WO66, 10903 New Hampshire Ave
Silver Spring, MD 20993

**Premarket Notification [510(k)] Review
Traditional
K102761**

*Elizabeth F. Lawrence Williams
12-20-10*

Date: December 9, 2010

To: The Record

From: Kapil Panguluri, Ph.D.

Office: ODE

Division: DAGID

510(k) Holder: Dana Products, Inc., 7 Corey Drive, South Barrington, IL 60010.

Device Name: Dana Reusable Test Pack

Contact: Harry Bala, President, Dana Products, Inc.

Phone: (847) 455-2881

Fax: (847) 455-2886

Email: bala@voyager.net

I. Purpose and Submission Summary:

The 510(k) holder would like to introduce Reusable SteriScan Integrator Test Pack for Steam Sterilization into interstate commerce. The firm states that the subject Reusable SteriScan Integrator Test Pack for Steam Sterilization is designed to challenge steam sterilization process in healthcare facilities for routine monitoring of pre-vacuum steam sterilization cycles (4 minutes at 270°F). The subject device submission was reviewed and it is recommended that the subject device be found substantially equivalent to its predicate device.

II. Administrative Requirements

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription or OTC)	X		
Truthful and Accuracy Statement	X		
510(k) Summary or <u>510(k) Statement</u>	X		
Standards Form	X		

Conclusion: Administrative information is adequate.

III. Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)?		X	

	Yes	No	N/A
Does the device design use software?		X	
Is the device sterile?		X	
Is the device reusable (not reprocessed single use)?	X		
Are "cleaning" instructions included for the end user?			

The subject test pack was validated for use with 3M's 1292 Rapid Readout Biological Indicators (K092944) along with or without SteriScan Integrators (K012195). The subject Dana Reusable Test Pack was previously cleared (K092944) for use with 3M's Rapid Readout BIs along with or without SteriScan Integrators. In this submission the firm intends to use the subject test pack with 3M Attest 1292 Bi or with SteriScan Integrators or both. The firm states that the subject test pack when used with SteriScan integrators conforms to ANSI/AAMI ST79:2006 (Standard set test pack using 16 surgical towels (section 10.7.2.1 of the standard). Comparative testing was performed with the subject Dana test pack with SteriScan integrators, 3M 1296 Test packs and with SteriScan integrators on an open tray placed directly over the drain but otherwise empty sterilizer (worst case sterilizer load condition per section 5.5.2.2 of ANSI/AAMI ST-8). The subject test packs with SteriScan integrators were shown to be more resistant than 3M's 1296 test packs, and with SteriScan integrators on an open tray placed directly over the drain.

The subject reusable test pack consists of (b)(4)

(b)(4)

(b)(4)

The test

pack design is essentially same as that was cleared in the 510(k) K092944.

Conclusion: Device Description information is adequate.

IV. Indications for Use

"Dana reusable challenge test pack is designed to challenge steam sterilization process in healthcare facilities. It is intended to be used for routine monitoring of pre-vacuum steam sterilization cycles. It is validated to be used in 4 minute 270⁰F pre-vacuum steam sterilization cycles with SteriScan Integrators".

Conclusion: Indications for Use statement is deemed acceptable..

V. Predicate Device Comparison

The firm identified the following predicate devices:
 K926364 – 3M 1292 Attest Rapid Readout BI
 K952408 – 1296 Attest Rapid Readout Test Pack
 K012195 – SteriScan Integrator
 K092944 – Dana reusable test pack for steam sterilization

VI. Labeling

The firm provided the proposed labeling for the subject device including the draft directions for use, cleaning the test pack, and precautions. Within the Labeling the firm states that the subject Dana reusable test pack is designed to challenge steam sterilization process in

healthcare facilities and for routine monitoring of pre-vacuum steam sterilization cycles (270F for 4 minutes) with 3M 1292 Rapid Readout Biological indicators along with or without SteriScan Integrators. The subject pack can be used 100 times without the test pack losing its effectiveness.

Conclusion: *The draft labeling provided is acceptable.*

VII. Sterilization/Shelf Life/Reuse

Sterilization: The device is non-sterile.

Reuse: The device is single use.

Shelf- life: No Shelf life claims were made.

VIII. Biocompatibility

Biocompatibility testing is not applicable for this device.

IX. Software

Software information is not applicable for this device.

Version:		
Level of Concern:		
	Yes	No
Software description:		
Device Hazard Analysis:		
Software Requirements Specifications:		
Architecture Design Chart:		
Design Specifications:		
Traceability Analysis/Matrix:		
Development:		
Verification & Validation Testing:		
Revision level history:		
Unresolved anomalies:		

X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

This information is not applicable for this device type.

XI. Performance Testing – Bench

The firm performed the following evaluations:

- o Performance of SteriScan Integrator in Dana Test Pack (270⁰F for 4 minutes pre-vacuum cycles)

- Performance of SteriScan Integrator and the distance travelled both inside and outside the test pack (for comparative purposes to show that the subject Dana test pack is more resistant than the integrator placed outside and also the predicate 3M 1296 test pack).

The objective of this test is to show that the SteriScan Integrators in Dana Test Packs are more resistant than the one outside the test pack. The acceptance criterion is that the SteriScan integrators within the Test pack should be more resistant than the one outside and that the subject test pack should be more resistant than the predicate 3M 1296 test packs. This performance testing was conducted at 270F for 4 minutes in Prevac cycles. The firm used different exposure times all of which fall within the maximum exposure period for the intended sterilization cycle (exposure times 20 seconds, 1 minute, 2 minute and 4 minute). The SteriScan integrator was placed in the bottom of the test pack and both the subject Dana Test Pack and the predicate 3M 1296 Test Packs were placed directly above the drain (worst case placement) along with SteriScan Integrators (without test pack) from the same lot on an open tray. The sterilization load consists of an empty sterilization chamber which is considered to be worst case as per ST8 standard. The objective intent of this test is to show that the SteriScan indicators in the test pack is significantly more resistant than the ones placed outside and also to the predicate 3M 1296 test packs.

Three lots of SteriScan integrators were tested in the subject Dana Test Packs along with SteriScan integrators placed in the open tray on the bottom shelf. The migrating steam sensitive dye has to travel 45mm to reach the accept window and 63mm to completely cover the accept window. The distance in mm traveled by the migrating dye is tabulated as shown in the table below.

Table: Distance Traveled (mm) by the migrating steam sensitive dye when the steam sterilant exposure time is 20 seconds

Inside Test Pack			Outside Test Pack		
LOT # 118	LOT #019	LOT # 039	LOT # 118	LOT #019	LOT # 039
22	26	24	48	50	49
26	23	27	45	49	50
21	25	28	47	48	48
24	22	26	42	46	48
23	21	24	48	43	44
24	25	22	46	45	48
26	22	24	49	49	46
23	27	22	46	50	49
25	21	27	48	49	48
21	26	24	49	46	50

Table: Distance Traveled (mm) by the migrating steam sensitive dye when the steam sterilant exposure time is 1 minute

Inside Test Pack			Outside Test Pack		
LOT # 118	LOT #019	LOT # 039	LOT # 118	LOT #019	LOT # 039
47	42	48	63	63	63

10

48	45	47	63	63	63
49	46	50	63	63	63
49	45	48	63	63	63
46	49	50	63	63	63
45	47	49	63	63	63
42	41	45	63	63	63
45	42	49	63	63	63
48	50	46	63	63	63
44	42	46	63	63	63

Table: Distance Traveled (mm) by the migrating steam sensitive dye when the steam sterilant exposure time is 2 and 4 minutes

Inside Test Pack			Outside Test Pack		
LOT # 118	LOT #019	LOT # 039	LOT # 118	LOT #019	LOT # 039
63	63	63	63	63	63
63	63	63	63	63	63
63	63	63	63	63	63
63	63	63	63	63	63
63	63	63	63	63	63
63	63	63	63	63	63
63	63	63	63	63	63
63	63	63	63	63	63
63	63	63	63	63	63
63	63	63	63	63	63

Based on the above performance of the SteriScan integrators within the subject test pack the firm states that the SteriScan placed on an open tray reached the accept mark in 20 seconds whereas it took the ones in the test pack one minute to do the same. The firm concludes that SteriScan in the test pack is more resistant than the ones outside and that the test pack adds significant resistance to the performance of the integrator.

The firm also provided performance data from the tests conducted using the predicate 3M 1296 test pack after exposure to the sterilant for 20 sec and 3 minutes. Subsequently enumeration of the positives was detected through color change in the medium when incubated using the 3M Auto Reader after 3 hours and 48 hours. Of the 40 samples tested there was zero growth for the exposure periods 20 seconds and 3 minutes. The firm states that it took one minute for SteriScan in the Dana Test Pack to reach the accept window while the 1292 BI from the predicate 1296 test packs did not show any growth for all exposures (20 seconds and 3 minutes). The firm concludes that the results from the testing shows that Dana test pack is more resistant than the predicate 3M 1296 Test Pack.

Conclusion: *The performance data as provided in the submission shows that the SteriScan integrators within the subject Test pack are more resistant compared to SteriScan integrators outside the test pack. The subject test pack containing a BI was previously cleared by the Agency under the 510(k) submission K092944 and the purpose of the present submission is to incorporate SteriScan integrator (cleared under the 510(k) K012195) within the test pack and to show that the integrator within the test pack is more resistant compared to the integrator outside*

the test pack. The firm also provided comparative testing using the predicate 3M 1296 test pack to show that the subject Dana test packs are more resistant than the predicate. Although the testing provided is deemed adequate however the firm should not claim any relative superiority over the predicate in the device labeling. The labeling for this device was reviewed and the firm does not claim any comparative claims to that of the predicate test pack. The performance provided is adequate.

XII. Performance Testing – Animal: This information is not applicable for this device type.

XIII. Performance Testing – Clinical: This information is not applicable for this device type.

XIV. Substantial Equivalence Discussion:

	Yes	No	
1. Same Indication Statement?	X		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?	X		If YES = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 6
5. Descriptive Characteristics Precise Enough?		X	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?	X		If NO = Request Data
9. Data Demonstrate Equivalence?	X		Final Decision: SE

Note: See

http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPreMarketNotification510kProgram/0_4148/FLOWCHART%20DECISION%20TREE%20.DOC for Flowchart to assist in decision-making process. 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: *The subject device test pack contains a chemical integrator that should show greater resistance than the naked chemical integrator when exposed to sterilant. Hence descriptive characteristics are not enough and performance of the device is evaluated.*

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:
9. Explain how the performance data demonstrates that the device is or is not substantially equivalent: *The SteriScan integrators within the subject test pack took one minute to reach the detection window while the SteriScan integrators outside the test pack reached the accept mark in 20 seconds. The performance of the test pack shows that it is more resistant than the ones outside and that the test pack adds significant resistance to the performance of the integrator.*

XV. Deficiencies: None

XV. Contact History: See Email communication with the firm.

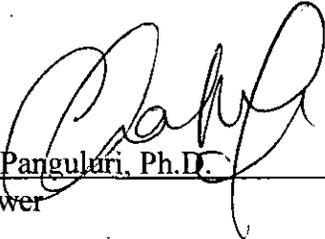
XVI. Recommendation: I recommend that the submission be found substantially equivalent to its predicate device.

Regulation Number: 21 CFR 880.2800

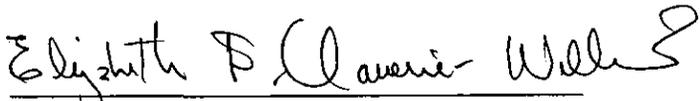
Regulation Name: Indicator, physical/chemical sterilization process

Regulatory Class: Class II

Product Code: JOJ


Kapil Panguluri, Ph.D.
Reviewer

December 15, 2010
Date


Ms. Elizabeth Claverie-Williams, Branch Chief

12/20/10
Date

Panguluri, Ramesh K

From: Harry Bala [bala@voyager.net]
Sent: Tuesday, December 14, 2010 3:03 PM
To: Panguluri, Ramesh K
Subject: K102761
Attachments: CCE00000.jpg; CCE00001.jpg

Dear Dr Panguluri,
I am attaching the scanned standards forms.
I hope they are Ok.
Harry

Department of Health and Human Services Food and Drug Administration STANDARDS DATA REPORT FOR 510(k)s <i>(To be filled in by applicant)</i>				
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 <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated				
STANDARD TITLE ¹ Hospital Steam Sterilizers				
Please answer the following questions		Yes No		
Is this standard recognized by FDA ² ?		<input checked="" type="checkbox"/> <input type="checkbox"/>		
FDA Recognition number ³ # 14-264				
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?		<input type="checkbox"/> <input checked="" type="checkbox"/>		
Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.		<input checked="" type="checkbox"/> <input type="checkbox"/>		
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?		<input checked="" type="checkbox"/> <input type="checkbox"/>		
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).		<input checked="" type="checkbox"/> <input type="checkbox"/>		
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.		<input type="checkbox"/> <input checked="" type="checkbox"/>		
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) ⁵ ?		<input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>		
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.		<input type="checkbox"/> <input checked="" type="checkbox"/>		
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.		<input type="checkbox"/> <input checked="" type="checkbox"/>		
Is there an FDA guidance ⁶ that is associated with this standard? If yes, was the guidance document followed in preparation of this 510k?		<input checked="" type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/>		
Title of guidance: <u>premarket notification submissions for chemical indicators</u>				
<table border="0" style="width: 100%;"> <tr> <td style="width: 50%; vertical-align: top;"> ¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication] ² Authority [21 U.S.C. 360d]. www.fda.gov/cdrh/stdsprog.html ³ http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm ⁴ 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 </td> <td style="width: 50%; vertical-align: top;"> certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device. ⁵ 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 ⁶ The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html </td> </tr> </table>			¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication] ² Authority [21 U.S.C. 360d]. www.fda.gov/cdrh/stdsprog.html ³ http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm ⁴ 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. ⁵ 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 ⁶ The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html
¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication] ² Authority [21 U.S.C. 360d]. www.fda.gov/cdrh/stdsprog.html ³ http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm ⁴ 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. ⁵ 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 ⁶ The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html			

Department of Health and Human Services Food and Drug Administration STANDARDS DATA REPORT FOR 510(k)s <i>(To be filled in by applicant)</i>		
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 <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated		
STANDARD TITLE ¹ 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 ² ?		<input checked="" type="checkbox"/> <input type="checkbox"/>
FDA Recognition number ³		# 14-280
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?		<input type="checkbox"/> <input checked="" type="checkbox"/>
Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?		<input checked="" type="checkbox"/> <input type="checkbox"/>
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?		<input checked="" type="checkbox"/> <input type="checkbox"/>
Does this standard include acceptance criteria?		<input checked="" type="checkbox"/> <input type="checkbox"/>
If no, include the results of testing in the 510(k).		
Does this standard include more than one option or selection of tests?		<input type="checkbox"/> <input checked="" type="checkbox"/>
If yes, report options selected in the summary report table.		
Were there any deviations or adaptations made in the use of the standard?		<input type="checkbox"/> <input checked="" type="checkbox"/>
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵ ?		<input type="checkbox"/> <input type="checkbox"/>
Were deviations or adaptations made beyond what is specified in the FDA SIS?		<input type="checkbox"/> <input checked="" type="checkbox"/>
If yes, report these deviations or adaptations in the summary report table.		
Were there any exclusions from the standard?		<input type="checkbox"/> <input checked="" type="checkbox"/>
If yes, report these exclusions in the summary report table.		
Is there an FDA guidance ⁶ that is associated with this standard?		<input checked="" type="checkbox"/> <input type="checkbox"/>
If yes, was the guidance document followed in preparation of this 510k?		<input checked="" type="checkbox"/> <input type="checkbox"/>
Title of guidance: <u>premarket notification submissions for chemical indicators</u>		
¹ The formatting convention for the title is: [SDO] [numeric Identifier] [title of standard] [date of publication] ² Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html ³ http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm ⁴ 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. ⁵ 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 ⁶ The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

Panguluri, Ramesh K

From: Panguluri, Ramesh K
Sent: Tuesday, December 14, 2010 10:16 AM
To: 'bala@voyager.net'
Cc: Panguluri, Ramesh K
Subject: K102761

Dear Mr. Harry Bala,

This Email is regarding your 510(k) submission K102761 (Dana Reusable Test Pack). I need the following information from you ASAP.

Please provide a completed Standards Data Report Form (FDA form 3654) for each of the national or international standards cited in the submission.

Thanks

Regards

Kapil Panguluri, Ph.D.

Microbiologist

Phone:	(301) 796-6303
Fax:	(301) 847-8109
E-Mail:	Ramesh.Panguluri@fda.hhs.gov
Address:	FDA/CDRH/ODE/DAGID/INCB WO66 Room 2506 10903 New Hampshire Ave. Silver Spring, MD 20993

Thank you for your email. Please be advised that any informal response to FDA questions does not undergo substantive review. This communication is consistent with 21 CFR 10.85 (k) and constitutes an informal communication that represents my best judgment at this time. It does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed. **No final decision of substantial equivalence should be inferred from this informal interaction.**

This e-mail message is intended for the exclusive use of the recipient named above. It may contain information that is protected, privileged, or confidential, and it should not be disseminated, distributed, or copied to persons not authorized to receive such information. If you are not the intended recipient, any dissemination, distribution or copying is strictly prohibited. If you think you have received this e-mail message in error, please e-mail the sender immediately at Ramesh.Panguluri@fda.hhs.gov.

Panguluri, Ramesh K

From: Harry Bala [bala@voyager.net]
Sent: Tuesday, December 14, 2010 3:48 PM
To: Panguluri, Ramesh K
Subject: Re: K102761

Dear Mr. Panguluri,

Just to let you know that I will be on vacation starting Dec 16th through Jan.3rd, 2011. I will be checking my email regularly.

Best Regards

Harry

On 12/14/2010 2:15 PM, Panguluri, Ramesh K wrote:

Thank you very much for your prompt reply Mr. Bala!!

Kapil Panguluri, Ph.D.

Microbiologist

Phone: (301) 796-6303

Fax: (301) 847-8109

E-Mail: Ramesh.Panguluri@fda.hhs.gov

Address: FDA/CDRH/ODE/DAGID/INCB

WO66 Room 2506

10903 New Hampshire Ave.

Silver Spring, MD 20993

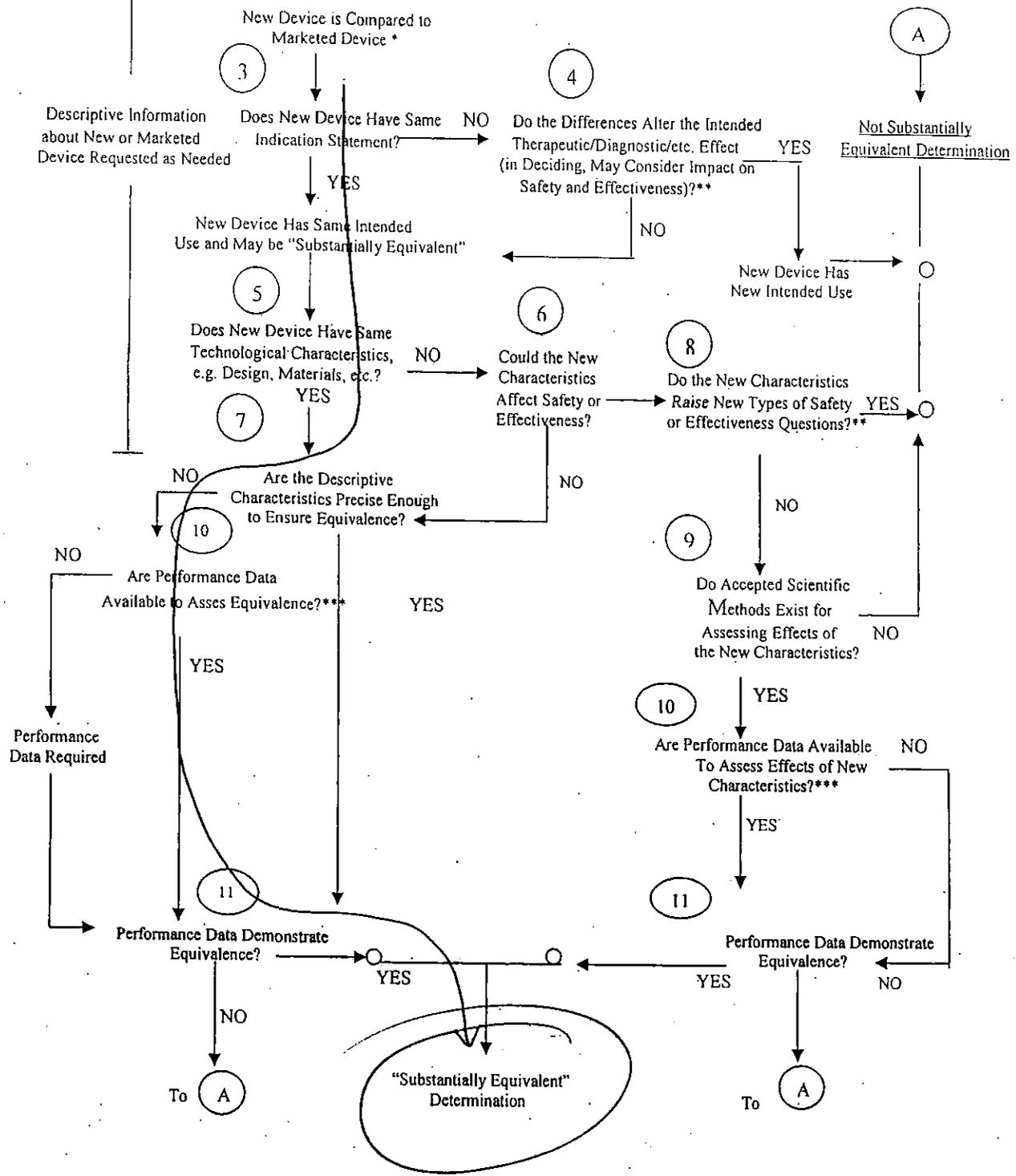
Thank you for your email. Please be advised that any informal response to FDA questions does not undergo *substantive review*. This communication is consistent with 21 CFR 10.85 (k) and constitutes an informal communication that represents my best judgment at this time. It does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed. **No final decision of substantial equivalence should be inferred from this informal interaction.**

This e-mail message is intended for the exclusive use of the recipient named above. It may contain information that is protected, privileged, or confidential, and it should not be disseminated, distributed, or copied to persons not authorized to receive such information. If you are not the intended recipient, any dissemination, distribution or copying is strictly prohibited. If you think you have received this e-mail message in error, please e-mail the sender immediately at Ramesh.Panguluri@fda.hhs.gov.

From: Harry Bala [<mailto:bala@voyager.net>]
Sent: Tuesday, December 14, 2010 3:03 PM
To: Panguluri, Ramesh K
Subject: K102761

Dear Dr Panguluri,
 I am attaching the scanned standards forms.
 I hope they are Ok.
 Harry

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