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July 15, 2014

FDA CDRH DMC

JUL 17 2014

Received

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

Reference: Special 510(k) Premarket Notification [21 CFR 807.90(e)]: Stryker S2 Drill

Dear Madam/Sir:

Stryker Instruments (Sponsor), in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act, as amended, hereby submits this Special 510(k) to receive clearance for a modification to the Stryker CORE Sumex Drill (b)(4) (b)(4)

(b)(4)

The (b)(4) of the rotor assembly of the S2 Drill was (b)(4). This modification has not changed the Intended Use, Indications for Use or the fundamental scientific technology of the device, and therefore is eligible for the Special 510(k) process, having the same fundamental technology and intended use as the predicate device(s) identified within the submission.

This information is organized in accordance with the FDA Guidance entitled *The New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications - Final Guidance* dated March 20, 1998. There were no prior submissions for the subject device.

The design and use of this device include:

Question	Yes	No
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over the counter use (21 CFR 807 Subpart C)?		X
Does the device contain components derived from tissue or other biologic source?		X
Is the device provided sterile?		X
Is the device intended for single use?		X
If yes, does this device type require reprocessed validation data?		X
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?		X
Does the submission include clinical information?		X
Is the device implanted?		X

Stryker considers the intent to market this device as confidential commercial information, and requests that FDA treat it as such. Precautions have been taken to protect the confidentiality of the intent to market this device (21 CFR 807.95). Stryker understands that the submission to the government of false information is prohibited by 18 U.S.C. 1001 and 21 U.S.C. 331(q).

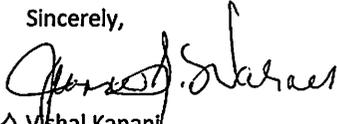
4100 E. Milham Ave.  
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**stryker**<sup>®</sup>

Thank you in advance for your consideration of our application. If there are any questions, please feel free to contact me at (269) 389-4796 or fax (269) 389-5412. In the event that I cannot be reached, please contact Jeanne Warner at (269) 389-5299.

**Note: The eCopy is an exact duplicate of the paper copy.**

Sincerely,

  
for Vishal Kanani

Sr. Regulatory Affairs Representative  
Stryker Instruments  
vishal.kanani@stryker.com  
(269)389-4796

*Contains Nonbinding Recommendations*

## Acceptance Checklist for Special 510(k)s

(should be completed within 15 days of DCC receipt)

*The following information is not intended to serve as a comprehensive review.*

**510(k) Number:** \_\_\_\_\_ **Date Received by DCC:** \_\_\_\_\_

**Lead Reviewer Name:** \_\_\_\_\_ **Branch:** \_\_\_\_\_ **Division:** \_\_\_\_\_ **Office:** \_\_\_\_\_

Note: If an element is left blank on the checklist, it does not mean the checklist is incomplete; it means the reviewer did not assess the element during RTA and that element will be assessed during substantive review.

<b>Special 510(k) Criteria</b>		
The submission should not be reviewed as a Special 510(k) if "No" is selected for any of the 4 criteria below. Complete the Refuse to Accept Checklist for a Traditional 510(k) if submission is converted.		
	Yes	No
<b>1. 510(k) is submitted to modify a legally marketed device (predicate) AND the Special 510(k) submission is submitted by the holder of the 510(k) for the predicate device.</b>	x	
Comments:		
<b>2. Indications for Use of the proposed device are unchanged from the legally marketed device (predicate).</b>	x	
Comments:		
<b>3. Fundamental scientific technology of the proposed device is unchanged from the legally marketed device (predicate).</b>	x	
Comments:		
<b>4. The submission includes only summary-level information (i.e., NO test reports with performance data). Note that if performance data are provided and are conducted under design validation (21 CFR 820.30(g)), for example, to demonstrate continued conformance with a special control or recognized standard, then a Special 510(k) may be appropriate.</b>	x	
Comments:		

**Does the submission meet all 4 criteria above?**

- Yes, submission meets criteria for a Special 510(k). Continue with the remainder of this checklist below.
- No, submission does not meet criteria for a Special 510(k). Discontinue this RTA checklist; convert to a Traditional and apply the Traditional checklist.

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<b><u>Organizational Elements</u></b>		
<i>Failure to include these items along generally should not result in an RTA designation</i>		
	<b>Yes</b>	<b>No</b>
a. Submission contains Table of Contents	<input checked="" type="checkbox"/>	<input type="checkbox"/>
b. Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)	<input checked="" type="checkbox"/>	<input type="checkbox"/>
c. All pages of the submission are numbered <i>All pages should be numbered in such a manner that information can be referenced by page number. This may be done either by consecutively numbering the entire submission, or numbering the pages within a section (e.g., 12-1, 12-2...).</i>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
d. Type of 510(k) is identified– traditional, abbreviated, or special <i>If type of 510(k) is not designated, review as a traditional</i>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Comments:		

<b><u>Elements of a Complete Submission (RTA Items)</u></b> <b><u>(21 CFR 807.87 unless otherwise indicated)</u></b>				
Submission should be designated RTA if not addressed				
<b>Check “Yes” if item is present, “N/A” if it is not needed and “No” if it is not included but needed.</b>				
	<ul style="list-style-type: none"> <li>Any “No” answer will result in a “Refuse to Accept” decision.</li> <li>Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.</li> </ul>	<b>Yes</b>	<b>N/A</b>	<b>No</b>
<b>A.</b>	<b>Administrative</b>			
1.	All content used to support the submission is written in English (including translations of test reports, literature articles, etc.)	<input checked="" type="checkbox"/>		<input type="checkbox"/>
	Comments:			
2.	Submission identifies the following (such as in CDRH Premarket Review Submission Cover Sheet ( <a href="#">Form 3514</a> ) or in 510(k) cover letter):	<input checked="" type="checkbox"/>		<input type="checkbox"/>
	a. Device trade name or proprietary name	<input checked="" type="checkbox"/>		<input type="checkbox"/>
	b. Device common name	<input checked="" type="checkbox"/>		<input type="checkbox"/>
	c. Device class and panel or Classification regulation or	<input checked="" type="checkbox"/>		<input type="checkbox"/>

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Submission should be designated RTA if not addressed					
<b>Check “Yes” if item is present, “N/A” if it is not needed and “No” if it is not included but needed.</b>					
		<ul style="list-style-type: none"> <li>Any “No” answer will result in a “Refuse to Accept” decision.</li> <li>Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.</li> </ul>	<b>Yes</b>	<b>N/A</b>	<b>No</b>
		Statement that device has not been classified with rationale for that conclusion			
		Comments:			
	3.	Submission contains Indications for Use Statement with Rx and/or OTC designated (see also and 801.109) <i>Submitter should use format appropriate for the reviewing Center/Office (CDRH/ODE, CDRH/OIVD, CBER/OBRR, CBER/OCTGT). If not provided in correct format, request the correct format during substantive review.</i>	<input checked="" type="checkbox"/>		<input type="checkbox"/>
		Comments: See Section 4, Indications for Use statement			
	4.	Submission contains 510(k) Summary or 510(k) Statement <i>Either a) or b) must be answered “Yes” to be considered complete. Identify any missing element(s) as Comments.</i>	<input checked="" type="checkbox"/>		<input type="checkbox"/>
	a.	Summary contains all elements per 21 CFR 807.92 <i>See also <a href="#">510(k) Summary Checklist</a></i>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	b.	Statement contains all elements per 21 CFR 807.93	<input type="checkbox"/>		<input checked="" type="checkbox"/>
		Comments: See Section 5, 510(k) Summary, 5-1, 5-2, 5-3			
	5.	Submission contains Truthful and Accuracy Statement per 21 CFR 807.87(k) <i>See recommended <a href="#">format</a>. Select “Yes” if statement is present, and includes the text in the recommended format, and is signed by a responsible person of the firm (not consultant).</i>	<input checked="" type="checkbox"/>		<input type="checkbox"/>
		Comments: See Section 6, Truthful and Accuracy Statement			
	6.	Submission contains Class III Summary and Certification <i>See recommended <a href="#">content</a> Form should be signed by a responsible person of the firm, not a</i>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>

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Submission should be designated RTA if not addressed					
<b>Check “Yes” if item is present, “N/A” if it is not needed and “No” if it is not included but needed.</b>					
			Yes	N/A	No
		<ul style="list-style-type: none"> <li>Any “No” answer will result in a “Refuse to Accept” decision.</li> <li>Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.</li> </ul>			
		<i>consultant. Select “N/A” only if submission is not a Class III 510(k).</i>			
		Comments: See Section 7, Class III Summary and Certification			
	7.	<p>If submission references use of a national or international standard as part of demonstration of substantial equivalence, submission contains Standards Data Report for 510(k)s (<a href="#">FDA Form 3654</a>) or includes detailed information about how and the extent to which the standard has been followed.</p> <p><i>There should be a completed form for each referenced national or international standard.</i></p> <p><i>Select “N/A” only if submission does not reference any standards.</i></p>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		Comments: See Section 10, Declaration of Conformity and Summary Reports			
	8.	<p>The submission identifies prior submissions for the same device which FDA provided feedback related to the data or information needed to support substantial equivalence (e.g., submission numbers for Pre-Submission, IDE, prior not substantially equivalent (NSE) determination, prior 510(k) that was deleted or withdrawn) or states that there were no prior submissions for the subject device.</p> <p><i>This information may be included in the Cover Letter (i.e., as a statement that there were no prior submissions for the device or a listing of the number(s) of the prior submissions). Alternatively, a list of submission numbers may be found in Section F (prior related submissions section) of the CDRH Coversheet form (Form 3514) to address this criterion. Please be advised that if this section of the form is left blank, it should not be considered a statement that there were no prior submissions.</i></p>	<input checked="" type="checkbox"/>		<input type="checkbox"/>
	a.	<p>If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence outlined in prior communications are addressed.</p>	<input checked="" type="checkbox"/>		<input type="checkbox"/>

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Submission should be designated RTA if not addressed							
<b>Check “Yes” if item is present, “N/A” if it is not needed and “No” if it is not included but needed.</b>							
<ul style="list-style-type: none"> <li>Any “No” answer will result in a “Refuse to Accept” decision.</li> <li>Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.</li> </ul>				Yes	N/A	No	
			<p><i>To address this criterion, the submission may include a separate section with the prior submission number(s), a copy of the FDA feedback (e.g., letter, meeting minutes), and a statement of how or where in the submission this prior feedback was addressed. Note that the adequacy of how the feedback was addressed should be assessed during the substantive review. For additional information regarding the Pre-Submission process, please refer to the Draft Guidance “<a href="http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm310375.htm">Medical Devices: The Pre-Submission Program and Meetings with FDA Staff.</a>” (<a href="http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm310375.htm">http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm310375.htm</a>). Once finalized, this guidance will represent the Agency’s current thinking on this topic. Select “N/A” if the submitter states there were no prior submissions in criterion above.</i></p>				
		Comments: See Section 3, Cover Letter					
<b>B.</b>	<b>Device Description</b>						
9.	a.	<p>If there are requirements regarding the device description, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes device description information to establish that the submitter has followed the device-specific requirement.</p> <p><i>Select “N/A” if there are no applicable requirements in a device-specific regulation. Select “No” if the submission does not include a rationale for any omitted information. Note that the adequacy of how such requirements have been addressed should be assessed during the substantive review.</i></p>			<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
	b.	<p>If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes device description information to establish that the</p>			<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>

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<b><u>Elements of a Complete Submission (RTA Items)</u></b> <b><u>(21 CFR 807.87 unless otherwise indicated)</u></b>						
Submission should be designated RTA if not addressed						
<b>Check “Yes” if item is present, “N/A” if it is not needed and “No” if it is not included but needed.</b>						
			<ul style="list-style-type: none"> <li>Any “No” answer will result in a “Refuse to Accept” decision.</li> <li>Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.</li> </ul>	<b>Yes</b>	<b>N/A</b>	<b>No</b>
			<p>submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.</p> <p><i>Select “N/A” if there is no applicable device-specific guidance. Select “No” if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance, etc., have been addressed should be assessed during the substantive review.</i></p>			
		Comments:				
	10.	Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling), including:				
		a.	A description of the principle of operation and mechanism of action for achieving the intended effect.	<input checked="" type="checkbox"/>		<input type="checkbox"/>
		b.	A description of proposed conditions of use such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.	<input checked="" type="checkbox"/>		<input type="checkbox"/>
		c.	A list and description of each device for which clearance is requested. <i>Select “N/A” if there is only one device or model. “Device” may refer to models, part numbers, or various sizes, etc.</i>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		Comments: See Section 11, Device Description				
	11.	A description of all device modification(s) including rationale for each modification.			<input checked="" type="checkbox"/>	<input type="checkbox"/>
		Comments: See Section 11, Device Description, 11-1 - 11-8				

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<b><u>Elements of a Complete Submission (RTA Items)</u></b> <b><u>(21 CFR 807.87 unless otherwise indicated)</u></b>					
Submission should be designated RTA if not addressed					
<b>Check “Yes” if item is present, “N/A” if it is not needed and “No” if it is not included but needed.</b>					
			Yes	N/A	No
		<ul style="list-style-type: none"> <li>Any “No” answer will result in a “Refuse to Accept” decision.</li> <li>Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.</li> </ul>			
	12.	<p>Submission contains representative engineering drawing(s), schematics, illustrations and/or figures of the device that are clear, legible, labeled, and include dimensions.</p> <p><i>In lieu of drawings, schematics, etc. of each device to be marketed, “representative” drawings, etc. may be provided, where “representative” is intended to mean that the drawings, etc. provided capture the differences in design, size, and other important characteristics of the various models, sizes, or versions of the device(s) to be marketed.</i></p> <p><i>Select “N/A” if the sponsor provided a rationale for why the submission does not contain engineering drawings, schematics, etc. (e.g., device is a reagent and figures are not pertinent to describe the device).</i></p>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		Comments: See Attachments 11.1 and Attachments 11.2			
	13.	<p>If device is intended to be marketed with multiple components, accessories, and/or as part of a system,</p> <p><i>Select “N/A” if the device is not intended to be marketed with multiple components, accessories, and/or as part of a system.</i></p>		<input type="checkbox"/>	
	a.	<p>Submission includes a list of all components and accessories to be marketed with the subject device.</p>	<input checked="" type="checkbox"/>		<input type="checkbox"/>
	b.	<p>Submission includes a description (as detailed in item #12.a. and b. and 14 above) of each component or accessory.</p> <p><i>Select “N/A” if the component(s)/accessory(ies) has been previously cleared, or is exempt, and the proposed indications for use are consistent with the cleared indications.</i></p>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	c.	<p>A 510(k) number is provided for each component or accessory that received a prior 510(k) clearance.</p> <p><i>Select “N/A” if the submission states that the component(s)/accessory(ies) does not have a prior 510(k) clearance or the components/accessory(ies) is 510(k) exempt.</i></p>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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<b><u>Elements of a Complete Submission (RTA Items)</u></b> <b><u>(21 CFR 807.87 unless otherwise indicated)</u></b>				
Submission should be designated RTA if not addressed				
<b>Check “Yes” if item is present, “N/A” if it is not needed and “No” if it is not included but needed.</b>				
	<ul style="list-style-type: none"> <li>Any “No” answer will result in a “Refuse to Accept” decision.</li> <li>Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.</li> </ul>	<b>Yes</b>	<b>N/A</b>	<b>No</b>
	Comments: See Section 11, Device Description, 11-1 - 11-7			
<b>C.</b>	<b>Substantial Equivalence Discussion</b>			
14.	Submitter has identified a predicate(s) device		<input checked="" type="checkbox"/>	<input type="checkbox"/>
	a.	Predicate’s 510(k) number, trade name, and model number (if applicable) provided. For predicates that are preamendments devices, information is provided to document preamendments status. <i>Information regarding <a href="http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ComplianceActivities/ucm072746.htm">documenting preamendment status</a> is available online</i> ( <a href="http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ComplianceActivities/ucm072746.htm">http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ComplianceActivities/ucm072746.htm</a> ).	<input checked="" type="checkbox"/>	<input type="checkbox"/>
	b.	The identified predicate(s) is consistent throughout the submission (i.e., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing).	<input checked="" type="checkbox"/>	<input type="checkbox"/>
	Comments: See Section 12, Substantial Equivalence Discussion			
15.	Submission includes a comparison of the following for the predicate(s) and subject device			
	a.	Indications for use	<input checked="" type="checkbox"/>	<input type="checkbox"/>
	b.	Technology, including features, materials, and principles of operation	<input checked="" type="checkbox"/>	<input type="checkbox"/>
	Comments: See Section 12, Substantial Equivalence Discussion 12-2 - 12-5			
16.	Submission includes an analysis of why any differences between the subject device and predicate(s) do not render the device NSE (e.g., do not constitute a new intended use, and any differences in technological characteristics are accompanied by information that demonstrates the		<input checked="" type="checkbox"/>	<input type="checkbox"/>

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Submission should be designated RTA if not addressed					
<b>Check “Yes” if item is present, “N/A” if it is not needed and “No” if it is not included but needed.</b>					
			Yes	N/A	No
	<ul style="list-style-type: none"> <li>Any “No” answer will result in a “Refuse to Accept” decision.</li> <li>Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.</li> </ul>				
	<p>device is as safe and effective as the predicate and do not raise different questions of safety and effectiveness than the predicate) affect safety or effectiveness, or raise different questions of safety and effectiveness) (see section 513(i)(1)(A) of the FD&amp;C Act)</p> <p><i>If there is no difference between the subject and predicate(s with respect to the indications or technology), this should be explicitly stated, in which case “N/A” should be selected. Select “No” only if the submission does not include an analysis of differences as described above or a statement that there are no differences. Note that the adequacy of the analysis should be assessed during the substantive review; only the presence of such an analysis is required for acceptance.</i></p>				
	Comments: See Section 12, Substantial Equivalence Discussion				
<b>D.</b>	<b>Design Control Activities</b>				
	17.	Design Control Activities Summary includes all of the following:			
	a.	Identification of Risk Analysis methods(s) used to assess the impact of the modification on the device and its components AND the results of the analysis	<input checked="" type="checkbox"/>		<input type="checkbox"/>
	b.	Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria.	<input checked="" type="checkbox"/>		<input type="checkbox"/>
	c.	Declaration of conformity with design controls, including: <i>All 3 must be present to answer “Yes.”</i>	<input checked="" type="checkbox"/>		<input type="checkbox"/>
		i.	Statement that all verification and validation activities were performed by designated individuals and results demonstrate that predetermined acceptance criteria were met.		
		ii.	Statement that manufacturing facility is in conformance with design control		

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	<ul style="list-style-type: none"> <li>Any "No" answer will result in a "Refuse to Accept" decision.</li> <li>Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.</li> </ul>	<b>Yes</b>	<b>N/A</b>	<b>No</b>
				procedure requirements as specified in 21 CFR 820.30
		iii.		Statement is signed by the individual responsible for these activities
Comments: See Section 9, Design Control and Summary Description				
<b>E.</b>	<b>Proposed Labeling (see also 21 CFR part 801)</b>			
	18.	Submission includes proposed package labels, and labeling (e.g., instructions for use, package insert, operator's manual) that include a description of the device, its intended use, and the directions for use		<input checked="" type="checkbox"/> <input type="checkbox"/>
		a.	All changes in proposed labeling resulting from device modification(s) are highlighted or prominently identified.	<input checked="" type="checkbox"/> <input type="checkbox"/>
Comments: See Section 13, Labeling and Intended Use				
	19.	Statement that the intended use of the modified device, as described in the labeling, has not changed as a result of the modification(s).		<input checked="" type="checkbox"/> <input type="checkbox"/>
Comments: See Section 13, Labeling and Intended Use, 13-1 Instructions for Use, 13-2 Care Instructions				

**Decision:** Accept \_\_\_ Refuse to Accept \_\_\_

**If Accept, notify applicant; if Refuse to Accept, notify applicant in writing and include a copy of this checklist.**

**Reviewer Signature:** \_\_\_\_\_ **Date:** \_\_\_\_\_

**Supervisory Signature:** \_\_\_\_\_ **Date:** \_\_\_\_\_

Acceptance Checklist for Special 510(k)



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 www.stryker.com

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Device Description .....	11 – 1
Substantial Equivalence Discussion .....	12 – 1
Proposed Labeling .....	13 – 1

**Section 1**  
**Medical Device User Fee Cover Sheet (FORM FDA 3601)**

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION <b>MEDICAL DEVICE USER FEE COVER SHEET</b>	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)

STRYKER INSTRUMENTS  
1901 Romence Road Pkwy  
Kalamazoo  
MI 49002  
US

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)

\*\*\*\*\*2424

2. CONTACT NAME

Vishal Kanani

2.1 E-MAIL ADDRESS

vishal.kanani@stryker.com

2.2 TELEPHONE NUMBER (include Area code)

269-323-7700

2.3 FACSIMILE (FAX) NUMBER (Include Area code)

269-389-5412

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/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm>

Select an application type:

Premarket notification(510(k)); except for third party

513(g) Request for Information

Biologics License Application (BLA)

Premarket Approval Application (PMA)

Modular PMA

Product Development Protocol (PDP)

Premarket Report (PMR)

30-Day Notice

3.1 Select a center

CDRH

CBER

3.2 Select one of the types below

Original Application

Supplement Types:

Efficacy (BLA)

Panel Track (PMA, PMR, PDP)

Real-Time (PMA, PMR, PDP)

180-day (PMA, PMR, PDP)

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

YES, I meet the small business criteria and have submitted the required qualifying documents to FDA

NO, I am not a small business

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

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?

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.)

NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This

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

submission will not be processed, see <http://www.fda.gov/cdm/ndufma> for additional information)

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

- This application is the first PMA submitted by a qualified small business, including any affiliates
- This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only
- The sole purpose of the application is to support conditions of use for a pediatric population
- 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).)

YES                       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, 8455 Colesville Road, COLE-14-14253 Silver Spring, MD 20993-0002  
[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) (b)(4)

17-Jun-2014

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

**Section 2**  
**CDRH Premarket Review Submission Cover Sheet**  
**(FORM FDA 3514)**

FOOD AND DRUG ADMINISTRATION

OMB No. 0910-0120

Expiration Date: December 31, 2013

See PRA Statement on page 5.

**CDRH PREMARKET REVIEW SUBMISSION COVER SHEET**

Date of Submission 07/15/2014	User Fee Payment ID Number (b)(4) (b)	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 type="checkbox"/> Traditional <input checked="" type="checkbox"/> Special <input type="checkbox"/> Abbreviated (Complete section I, Page 5) <input type="checkbox"/> Additional Information <input type="checkbox"/> Third Party	<b>Request for Feedback</b> <input type="checkbox"/> Pre-Submission <input type="checkbox"/> Informational Meeting <input type="checkbox"/> Submission Issue Meeting <input type="checkbox"/> Day 100 Meeting <input type="checkbox"/> Agreement Meeting <input type="checkbox"/> Determination Meeting <input type="checkbox"/> Study Risk Determination <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 Stryker Corporation	Establishment Registration Number (if known) 1811755		
Division Name (if applicable) Stryker Instruments	Phone Number (including area code) 269-389-4796		
Street Address 4100 E. Milham Avenue	FAX Number (including area code) 269-389-5412		
City Kalamazoo	State / Province MI	ZIP/Postal Code 49001	Country USA
Contact Name Vishal Kanani			
Contact Title Sr. Regulatory Affairs Representative		Contact E-mail Address vishal.kanani@stryker.com	

**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** Records processed under **REASON FOR APPLICATION - PMA, PDP, OR IDE** CDRH on 02-01-2016

<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 type="checkbox"/> New Device	<input type="checkbox"/> Additional or Expanded Indications	<input type="checkbox"/> Change in Technology
-------------------------------------	---	---

Other Reason (*specify*):

Modification to the dimension of the rotor of the Stryker CORE Sumex Drill (b)(4)

**SECTION E** Records processed under the additional information on 510(k) submissions CDRH on 02-01-2016

Product codes of devices to which substantial equivalence is claimed				Summary of, or statement concerning, safety and effectiveness information	
1	ERL	2		3	
5		6		7	
				4	
				8	

510 (k) summary attached  
 510 (k) statement

Information on devices to which substantial equivalence is claimed (if known)

	510(k) Number	Trade or Proprietary or Model Name	Manufacturer
1	K112593	Stryker Consolidated Operating Room Equipment (CORE) System	Stryker Corporation
2			
3			
4			
5			
6			

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

Common or usual name or classification name  
 Ear, nose, and throat electric or pneumatic surgical drill.

	Trade or Proprietary or Model Name for This Device	Model Number
1	Stryker S2 Drill	1 5450-400-000
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 ERL	C.F.R. Section (if applicable) 874.4250	Device Class <input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified
Classification Panel Ear Nose & Throat		

Indications (from labeling)  
 The Stryker S2 Drill (handpiece) is intended for use with the Stryker Consolidated Operating Room Equipment (CORE™) System. When used with a variety of attachments and cutting accessories, the drill is intended for use in cutting, drilling, reaming, decorticating and smoothing of bone, bone cement and teeth in a variety of surgical procedures including but not limited to Neuro, Spine, ENT (Ear, Nose, and Throat), Dental and Endoscopic applications. It is also usable in the placement or cutting of screws, metal, wires, pins, and other fixation devices.

**Note:** Submission of the information entered in Section H does not affect the need to submit device establishment registration.

FD-304 (Rev. 11/10/07)

**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 1811755	<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler	
Company / Institution Name Stryker Corporation		Establishment Registration Number 1811755		
Division Name (if applicable) Stryker Instruments		Phone Number (including area code) 269-389-4796		
Street Address 4100 E. Milham Avenue		FAX Number (including area code) 269-389-5412		
City Kalamazoo		State / Province MI	ZIP Code 49001	Country USA
Contact Name Vishal Kanani		Contact Title Sr. Regulatory Affairs Representative		Contact E-mail Address vishal.kanani@stryker.com

<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** Records processed under FOIA **UTILIZATION OF STANDARDS** used by CDRH on 02-01-2016

**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	60601-1	AAMI ANSI	AAMI / ANSI ES60601-1:2005/(R) 2012 and C1:2009/(R) 2012 and, a2:2010/(R) 2012 (consolidated text) medical electrical equipment -- part 1: general requirements for basic and essential performance (IEC 60601-1:2005, mod).	2010	5-78
2	60601-1-2	AAMI	AAMI / ANSI / IEC 60601-1-2:2007/(R) 2012, medical electrical equipment - part 1-2: general requirements for basic safety and essential performance - collateral standard: electromagnetic compatibility - requirements and tests (edition 3).	2007	5-54
3	10993-1	AAMI / ANSI / ISO	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	2009/ AC: 2010	2-156
4	ISTA 3A	ISTA	Packaged-Products for Parcel Delivery System Shipment 70kg (150 lbs.) or Less (General Simulation Performance Test Procedure)	2008	Not Recognized
5	ST81	AAMI/ANSI	AAMI/ANSI ST81:2004/(R)2010, Sterilization of medical devices- Information to be provided by the manufacturer for the processing of resterilizable medical devices	2004(R)2010	14-295
6	17665-1	AAMI / ANSI / ISO	Sterilization of health care products Moist heat, Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices-Supersedes BS EN 554:1994	2006	14-261
7	14971	ISO	Medical devices - Applications of risk management to medical devices	2012	Not Recognized

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

This section applies only to requirements of the Paperwork Reduction Act of 1995.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF ADDRESS BELOW.\***

The burden time for this collection of information is estimated to average 0.5 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services  
 Food and Drug Administration  
 Office of Chief Information Officer  
 Paperwork Reduction Act (PRA) Staff  
 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.*

## **Section 3 Cover Letter**

4100 E. Milham Ave.  
 Kalamazoo, MI 49001  
 t: 269 323 7700 f: 269 389 5412  
 www.stryker.com



July 15, 2014

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

Reference: Special 510(k) Premarket Notification [21 CFR 807.90(e)]: Stryker S2 Drill

Dear Madam/Sir:

Stryker Instruments (Sponsor), in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act, as amended, hereby submits this Special 510(k) to receive clearance for a modification to the Stryker CORE Sumex Drill (b)(4) Stryker CORE Sumex Drill was cleared as an accessory to the Stryker CORE System in 2012 (K112593). (b)(4)

(b)(4)

The (b)(4) rotor assembly of the S2 Drill was (b)(4) This modification has not changed the Intended Use, Indications for Use or the fundamental scientific technology of the device, and therefore is eligible for the Special 510(k) process, having the same fundamental technology and intended use as the predicate device(s) identified within the submission.

This information is organized in accordance with the FDA Guidance entitled *The New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications - Final Guidance* dated March 20, 1998. There were no prior submissions for the subject device.

The design and use of this device include:

Question	Yes	No
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over the counter use (21 CFR 807 Subpart C)?		X
Does the device contain components derived from tissue or other biologic source?		X
Is the device provided sterile?		X
Is the device intended for single use?		X
If yes, does this device type require reprocessed validation data?		X
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?		X
Does the submission include clinical information?		X
Is the device implanted?		X

Stryker considers the intent to market this device as confidential commercial information, and requests that FDA treat it as such. Precautions have been taken to protect the confidentiality of the intent to market this device (21 CFR 807.95). Stryker understands that the submission to the government of false information is prohibited by 18 U.S.C. 1001 and 21 U.S.C. 331(q).



Thank you in advance for your consideration of our application. If there are any questions, please feel free to contact me at (269) 389-4796 or fax (269) 389-5412. In the event that I cannot be reached, please contact Jeanne Warner at (269) 389-5299.

**Note: The eCopy is an exact duplicate of the paper copy.**

Sincerely,

for

Vishal Kanani  
Sr. Regulatory Affairs Representative  
Stryker Instruments  
vishal.kanani@stryker.com  
(269)389-4796



## **Section 4**

# **Indications for Use Statement**

## Indications for Use

510(k) Number (if known)

Device Name  
Stryker S2 Drill

### Indications for Use (Describe)

The Stryker S2 Drill is intended for use with the Stryker Consolidated Operating Room Equipment (CORE) System. When used with a variety of attachments and cutting accessories, the drill is intended for use in cutting, drilling, reaming, decorticating, shaping, and smoothing of bone, bone cement and teeth in a variety of surgical procedures, including but not limited to dental, ENT (ear, nose, and throat), neuro, spine, and endoscopic applications. It is also usable in the placement or cutting of screws, metal, wires, pins, and other fixation devices.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

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

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

### FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services  
Food and Drug Administration  
Office of Chief Information Officer  
Paperwork Reduction Act (PRA) Staff  
[PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov)

*“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 number.”*

## **Section 5 510(k) Summary**

**510(k) Summary**

**510(k) Owner:** Stryker Instruments  
 4100 E. Milham Avenue  
 Kalamazoo, MI 49001  
 (p) 269-323-7700  
 (f) 269-389-5412

**Contact Person:** Vishal Kanani  
 Sr. Regulatory Affairs Representative

**Registration Number:** 1811755

**Date Summary Prepared:** July 07, 2014

**Trade Name(s):** Stryker S2 Drill

**Common Name:** Ear, nose, and throat electric or pneumatic surgical drill.

**Classification Data:**

	Product Code	Device	Regulation Number	Class	Review Panel
Primary Code	ERL	Drill, Surgical, ENT (Electric or Pneumatic) Including Handpiece	21 CFR 874.4250	II	Ear, Nose and Throat
Secondary Codes	HBE	Drills, burs, trephines, and accessories (simple, powered)	21 CFR 872.4120	II	Neurology
	DZJ	Driver, wire, and bone drill, manual	21 CFR 872.4120	II	Dental

**Predicate Device:**

510(k) number	Product code	Trade name	Manufacturer
K112593	ERL	Stryker® Consolidated Operating Room Equipment (CORE) System	Stryker Instruments

**Indications for**

**Use:**

The Stryker S2 Drill is intended for use with the Stryker Consolidated Operating Room Equipment (CORE) System. When used with a variety of attachments and cutting accessories, the drill is intended for use in cutting, drilling, reaming, decorticating, shaping, and smoothing of bone, bone cement and teeth in a variety of surgical procedures, including but not limited to dental, ENT (ear, nose, and throat), neuro, spine, and endoscopic applications. It is also usable in the placement or cutting of screws, metal, wires, pins, and other fixation devices.

**Device**

**Description:**

The Stryker S2 Drill is an electric powered (40V DC) motor. When connected to the CORE console, it directly rotates cutting accessories up to speeds of 75,000 RPM.

**Performance Data**

**(Non Clinical**

**Tests):**

Following verification tests were performed which demonstrate that the design outputs of the modified device meet the design input requirements:

- Verification of the improved rotor driveshaft
- Simulated use tests
- Temperature testing of different torque-speed setting

Results of these tests demonstrate that the functionality, integrity, and safety and effectiveness of the Stryker S2 Drill is sufficient for their intended use and support a determination of substantial equivalence.

**Clinical Tests:**

No clinical testing was deemed necessary for this 510(k).

**Conclusion/**

**Substantial**

**Equivalence**

**(SE) Rationale:**

The Stryker S2 Drill is substantially equivalent in intended use, technological characteristics, safety, and effectiveness to the previously cleared Stryker CORE Sumex Drill. The products have the same fundamental scientific technology, basic design, functional characteristics and applications.

The modifications introduced raise no new issues of safety and effectiveness. Therefore, the Stryker S2 Drill is substantially equivalent to the existing predicate device.



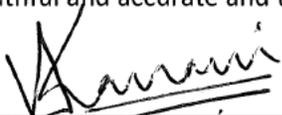
<b>Summary of Substantial Equivalence Table</b>		
<b>Description</b>	<b>Stryker CORE Sumex Drill (Predicate)</b>	<b>Stryker S2 Drill (Subject)</b>
<b>Intended Use</b>	The Stryker Consolidated Operating Room Equipment (CORE) System is intended for use in cutting, drilling, reaming, decorticating, shaping, and smoothing of bone, bone cement and teeth in a variety of surgical procedures, including but not limited to, dental, ENT (ear, nose, and throat), neuro, spine, and endoscopic applications. It is also usable in the placement or cutting of screws, metal, wires, pins, and other fixation devices.	The S2 Drill is intended for use with the Stryker Consolidated Operating Room Equipment (CORE) System. When used with a variety of attachments and cutting accessories, the drill is intended for use in cutting, drilling, reaming, decorticating, shaping and smoothing of bone, bone cement and teeth in a variety of surgical procedures, including but not limited to ENT, neuro, spine and Endoscopic applications. It is also usable in the placement or cutting of screws, metal, wires, pins, and other fixation devices.
<b>Housing Material</b>	Stainless Steel	Stainless Steel and Aluminum
<b>Motor Diameter</b>	20mm	17mm
<b>Length of the drill</b>	105mm	123.5mm
<b>Weight of the drill</b>	399g	313g
<b>Power source</b>	40V DC Electric Motor connected via cable to CORE console	40V DC Electric Motor connected via cable to CORE console
<b>Speed</b>	0-75,000 rpm	0-75,000 rpm
<b>Attachment retention method by drill</b>	Mechanical lock activated by rotation of attachment onto drill	Mechanical lock activated by rotation of attachment onto drill
<b>Mode of activation</b>	Footswitch and Handswitch	Footswitch

## **Section 6**

# **Truthful and Accuracy Statement**

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

I certify that, in my capacity as Sr. Regulatory Affairs Representative of Stryker Instruments, 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)

Printed Name: Vishal Kanani

Date: July 07, 2014

\_\_\_\_\_  
Premarket Notification [510(k) Number]

**Section 7**  
**Class III Summary and Certification (FORM FDA 3674)**



### **Class III Summary and Certification**

The device that is the subject of this submission is classified as Class II; therefore, this section does not apply. FORM FDA 3674 follows.





**DEPARTMENT OF HEALTH AND HUMAN SERVICES**  
Food and Drug Administration

**Certification of Compliance**

**Under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))**

(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

**SPONSOR / APPLICANT / SUBMITTER INFORMATION**

1. Name of Sponsor/Applicant/Submitter  Stryker Instruments		2. Date of the Application/Submission Which This Certification Accompanies  07/15/2014	
3. Address		4. Telephone and Fax Numbers (Include country code if applicable and area code)	
Address 1 (Street address, P.O. box, company name c/o) 4100 E. Milham Ave.		(Tel): 269-389-4796	
Address 2 (Apartment, suite, unit, building, floor, etc.)		(Fax): 269389-5412	
City Kalamazoo	State/Province/Region MI		
Country USA	ZIP or Postal Code 49001		

**PRODUCT INFORMATION**

5. **For Drugs/Biologics:** Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s).  
**For Devices:** Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s)

Common name: Ear, nose, and throat electric or pneumatic drill, Class II

Trade name: Stryker S2 drill, 5450-400-000

Continuation Page for #5

**APPLICATION / SUBMISSION INFORMATION**

6. Type of Application/Submission Which This Certification Accompanies

- IND    NDA    ANDA    BLA    PMA    HDE    510(k)    PDP    Other

7. Include IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/ Other Number  
(If number previously assigned)

If BLA was selected in item 6, provide Supplement Number

8. Serial Number Assigned to Application/Submission Which This Certification Accompanies

**CERTIFICATION STATEMENT / INFORMATION**

9. Check only one of the following boxes (See instructions for additional information and explanation)

- A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act do not apply because the application/submission which this certification accompanies does not reference any clinical trial.
- B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act do not apply to any clinical trial referenced in the application/submission which this certification accompanies.
- C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.

Certification Statement / Information section continued on page 2

**CERTIFICATION STATEMENT / INFORMATION (Continued)**

10. If you checked box C, in number 9, provide the National Clinical Trial (NCT) Number(s) for any "applicable clinical trial(s)," under 42 U.S.C. § 282(j)(1)(a)(i), section 402(j)(1)(a)(i) of the Public Health Service Act, referenced in the application/ submission which this Certification accompanies. (Add continuation page as necessary.)

NCT Number(s): \_\_\_\_\_

Continuation Page for #10

The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act.

**Warning:** A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.

11. Name and Title of the Person who Signs Number 15

Name Vishal J. Kanani	Title Sr. Regulatory Affairs Representative
--------------------------	--

12. Address

Address 1 (Street address, P.O. box, company name c/o) 4100 E. Milham Ave.	
Address 2 (Apartment, suite, unit, building, floor, etc.)	
City Kalamazoo	State/Province/Region MI
Country USA	ZIP or Postal Code 49001

13. Telephone and Fax Numbers

(Include country code if applicable and area code)

(Tel): 269-389-4796

(Fax): 269-389-5412

14. Date of Certification

07/07/2014

15. Signature of Sponsor/Applicant/Submitter or an Authorized Representative (Sign)

Sign



This section applies only to requirements of the Paperwork Reduction Act of 1995.

**\*\*\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\*\*\***

The burden time for this collection of information is estimated to average 15 minutes and 45 minutes (depending on the type of application/ submission) per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden to:

Department of Health and Human Services  
Food and Drug Administration  
Office of Chief Information Officer  
Paperwork Reduction Act (PRA) Staff  
PRAStaff@fda.hhs.gov

*"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 number."*

## **Section 8**

# **Financial Certification and Disclosure Statement**



## Financial Certification and Disclosure Statement

This submission does not contain any clinical studies; therefore, this section does not apply.

## **Section 9**

# **Design Control Summary & Declarations**

## Summary of Design Control

A Risk Management File in compliance with ISO 14971:2012 – *Application of Risk Management to Medical Devices* was completed for the subject device(s). (b)(4)

(b)(4)

(b)(4)

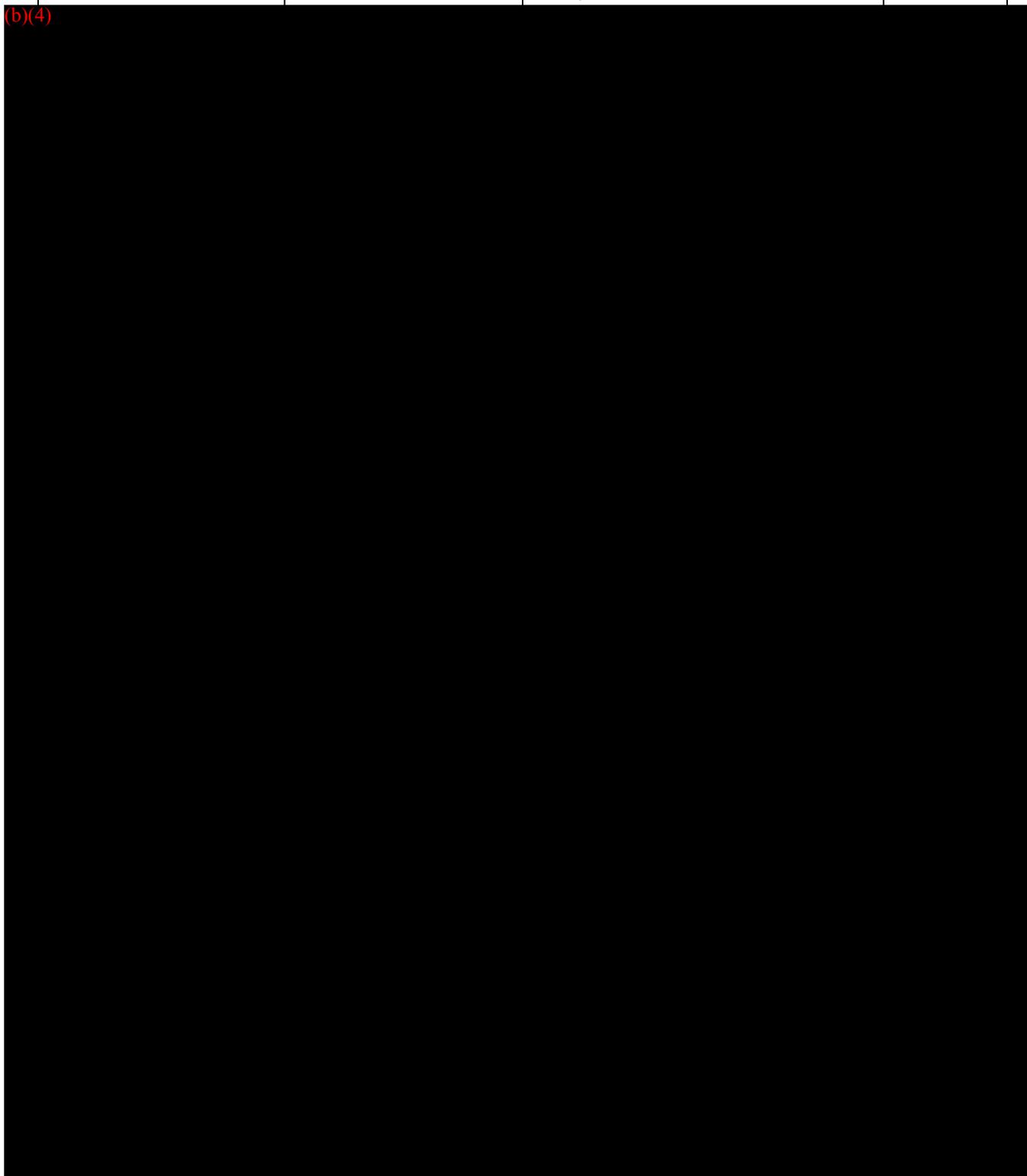
(b)(4) The testing listed below verifies the effectiveness of this device modification.

The following table describes the tests performed, relevant standards, acceptance criteria and conclusion.

### Summary of Verification Tests

Test Performed	Method of Test used	Acceptance Criteria	Conclusion
----------------	---------------------	---------------------	------------

(b)(4)



**Design Control Declarations**

**Verification  
Activities**

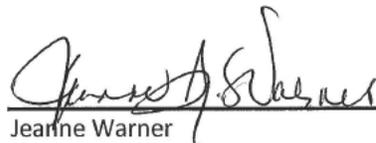
To the best of my knowledge, the verification activities, as required by the risk analysis, for the modification were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met.

  
\_\_\_\_\_  
Jon Ahola  
Director, R&D  
Stryker Instruments

3-July-2014  
[Date]

**Manufacturing  
Facility**

The manufacturing facility, Stryker Instruments, is in conformance with the design control requirements as specified in 21 CFR 820.30, and the records are available for review.

  
\_\_\_\_\_  
Jeanne Warner  
Manager, Regulatory Affairs  
Stryker Instruments

15 July-2014  
[Date]

**Section 10**  
**Declaration of Conformity and Summary Reports**

4100 E. Milham Ave.  
Kalamazoo, MI 49001  
t: 269 323 7700 f: 269 389 5412  
www.stryker.com



Below is a list of standards to which Stryker claims conformance to, completely or in part, for this submission. Attached are the corresponding Standards Data Report for 510(k) Forms (Form FDA 3654) and Summary Report tables.

Table 10.1 List of Standards

Standard Number	Standard Organization	Standards Title	Standard Version/Date	FDA Recognition No.
60601-1	AAMI ANSI	AAMI / ANSI ES60601-1:2005/(R) 2012 and C1:2009/(R) 2012 and, a2:2010/(R) 2012 (consolidated text) medical electrical equipment - part 1: general requirements for basic and essential performance (IEC 60601-1:2005, mod).	2010	5-78
60601-1-2	AAMI	AAMI / ANSI / IEC 60601-1-2:2007/(R) 2012, medical electrical equipment - part 1-2: general requirements for basic safety and essential performance - collateral standard: electromagnetic compatibility - requirements and tests (edition 3).	2007	5-54
10993-1	AAMI / ANSI / ISO	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	2009/ AC: 2010	2-156
ISTA 3A	ISTA	Packaged-Products for Parcel Delivery System Shipment 70kg (150 lbs.) or Less (General Simulation Performance Test Procedure)	2008	Not Recognized
ST81	AAMI / ANSI	AAMI/ANSI ST81:2004/(R)2010, Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices	2004/(R)2010	14-295
17665-1	AAMI / ANSI / ISO	Sterilization of health care products Moist heat, Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices- Supersedes BS EN 554:1994	2006	14-261
14971	ISO	Medical devices - Applications of risk management to medical devices	2012	Not Recognized

Department of Health and Human Services Food and Drug Administration <b>STANDARDS DATA REPORT FOR 510(k)s</b> (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 <input type="checkbox"/> Traditional <input checked="" type="checkbox"/> Special <input type="checkbox"/> Abbreviated				
STANDARD TITLE <sup>1</sup> AAMI ANSI ES60601-1:2005/(R)2012 and C1:2009/(R)2012 Medical Electrical Equipment -- Part 1: General Requirements For Basic Safety and Essential Performance (IEC 60601-1:2005, mod)				
<b>Please answer the following questions</b>		Yes    No		
Is this standard recognized by FDA <sup>2</sup> ? .....		<input checked="" type="checkbox"/> <input type="checkbox"/>		
FDA Recognition number <sup>3</sup> .....		#    5-78		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? .....		<input checked="" type="checkbox"/> <input type="checkbox"/>		
Is a summary report <sup>4</sup> 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) <sup>5</sup> ? .....		<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 <sup>6</sup> that is associated with this standard?.....		<input type="checkbox"/> <input checked="" type="checkbox"/>		
If yes, was the guidance document followed in preparation of this 510k? .....		<input type="checkbox"/> <input type="checkbox"/>		
Title of guidance: _____				
<table border="0" style="width: 100%;"> <tr> <td style="width: 50%; vertical-align: top;"> <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], <a href="http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm">http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm</a>  <sup>3</sup> <a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm">http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm</a>  <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                             </td> <td style="width: 50%; vertical-align: top;">                             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 <a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm">http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm</a>  <sup>6</sup> The online search for CDRH Guidance Documents can be found at <a href="http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm">http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm</a> </td> </tr> </table>			<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], <a href="http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm">http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm</a> <sup>3</sup> <a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm">http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm</a> <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 <a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm">http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm</a> <sup>6</sup> The online search for CDRH Guidance Documents can be found at <a href="http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm">http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm</a>
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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE See attached Summary Report Table		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *  		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *  		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *  		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *  		
DESCRIPTION		
JUSTIFICATION		
<p>* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.</p> <p>* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.</p>		
<p>This section applies only to requirements of the Paperwork Reduction Act of 1995.</p> <p><b>*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.*</b></p> <p>The burden time for this collection of information is estimated to average 1 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:</p> <div style="display: flex; justify-content: space-between;"> <div style="width: 60%;"> <p>Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff <a href="mailto:PRStaff@fda.hhs.gov">PRStaff@fda.hhs.gov</a></p> </div> <div style="width: 35%; text-align: right;"> <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> </div> </div>		

## Summary Report for FORM 3654

Standard Title: AAMI / ANSI ES60601-1:2005/(R) 2012 and C1:2009/(R) 2012 and, a2:2010/(R) 2012 (consolidated text) medical electrical equipment -- part 1: general requirements for basic safety and essential performance (IEC 60601-1:2005, mod).

NOTE: A determination of "Yes" to conformance without a listed deviation or option selected indicates a conformance to all subsections under that section.

NOTE: A "yes" to conformance with a listed deviation will have an added entry in Table 2 for any subsections or clauses that deviate or require an option designation.

Informative Sections will be marked "Informative" for conformance since these sections do not require conformance.

### Name and Address of Test Laboratory:

(b)(4)

A large black rectangular redaction box covering the name and address of the test laboratory.

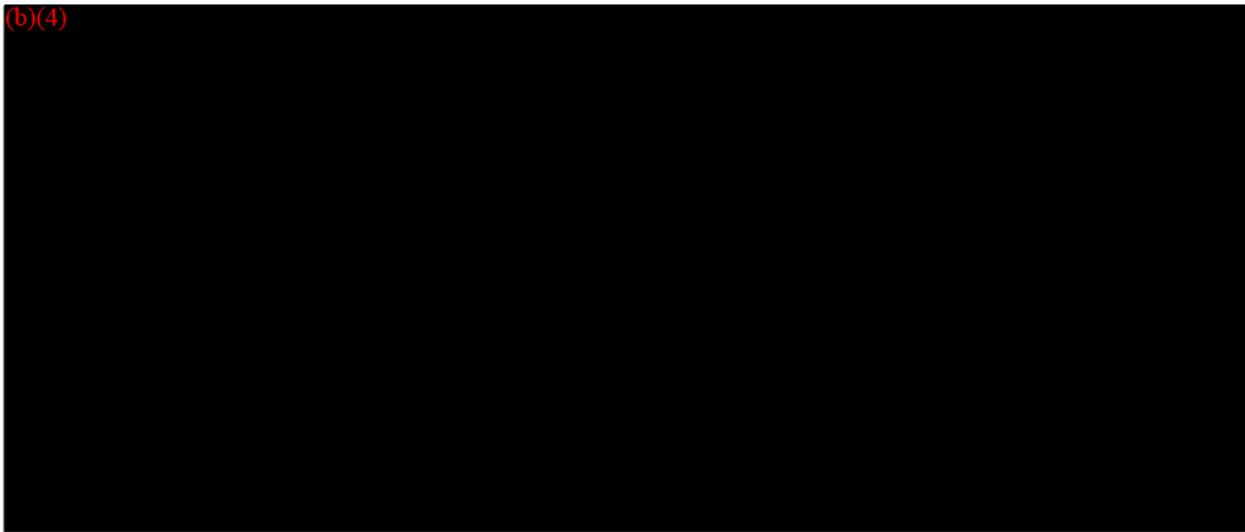
Table 1: Conformance of Sections

Section Number	Section Title	Conformance (Yes or No or Informative)	Type of Deviation or Option Selected (see Justification table for additional details)
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(b)(4)

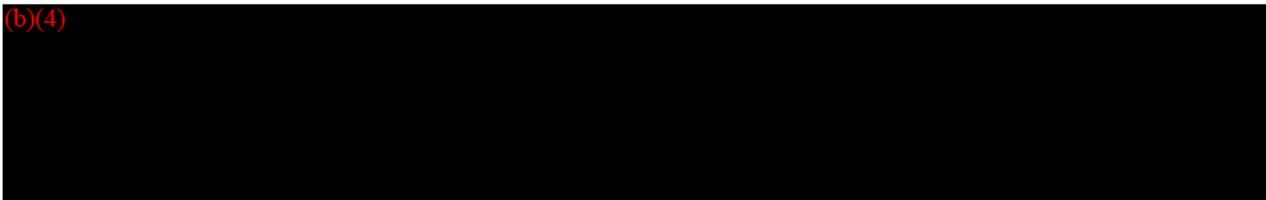
A large black rectangular redaction box covering the entire content of Table 1, including all data rows.

(b)(4)



**Table 2: Justifications for Deviations or Options selected**

(b)(4)



Department of Health and Human Services Food and Drug Administration <b>STANDARDS DATA REPORT FOR 510(k)s</b> (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 <input type="checkbox"/> Traditional <input checked="" type="checkbox"/> Special <input type="checkbox"/> Abbreviated				
STANDARD TITLE <sup>1</sup> AAMI ANSI IEC 60601-1-2:2007/(R)2012 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance-Collateral standard: Electromagnetic compatibility-Requirements and tests				
<b>Please answer the following questions</b>		Yes    No		
Is this standard recognized by FDA <sup>2</sup> ? .....		<input checked="" type="checkbox"/> <input type="checkbox"/>		
FDA Recognition number <sup>3</sup> .....		# 5-54		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? .....		<input checked="" type="checkbox"/> <input type="checkbox"/>		
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.		<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) <sup>5</sup> ? .....		<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 <sup>6</sup> that is associated with this standard?..... If yes, was the guidance document followed in preparation of this 510k? .....		<input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>		
Title of guidance: _____				
<table style="width: 100%; border: none;"> <tr> <td style="width: 50%; border: none; vertical-align: top;"> <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], <a href="http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm">http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm</a>  <sup>3</sup> <a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm">http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm</a>  <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                             </td> <td style="width: 50%; border: none; vertical-align: top;">                                 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 <a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm">http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm</a>  <sup>6</sup> The online search for CDRH Guidance Documents can be found at <a href="http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm">http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm</a> </td> </tr> </table>			<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], <a href="http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm">http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm</a> <sup>3</sup> <a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm">http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm</a> <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 <a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm">http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm</a> <sup>6</sup> The online search for CDRH Guidance Documents can be found at <a href="http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm">http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm</a>
<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], <a href="http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm">http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm</a> <sup>3</sup> <a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm">http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm</a> <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 <a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm">http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm</a> <sup>6</sup> The online search for CDRH Guidance Documents can be found at <a href="http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm">http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm</a>			

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE <p style="text-align: center;">See attached Summary Report Table</p>		
<b>CONFORMANCE WITH STANDARD SECTIONS*</b>		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED ♦		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED ♦		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED ♦		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED ♦		
DESCRIPTION		
JUSTIFICATION		
<p>* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.</p> <p>♦ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.</p>		
<p>This section applies only to requirements of the Paperwork Reduction Act of 1995.</p> <p><b>*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.*</b></p> <p>The burden time for this collection of information is estimated to average 1 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:</p> <div style="display: flex; justify-content: space-between;"> <div style="width: 60%;"> <p>Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff <a href="mailto:PRASStaff@fda.hhs.gov">PRASStaff@fda.hhs.gov</a></p> </div> <div style="width: 35%; text-align: right;"> <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> </div> </div>		

## Summary Report for FORM 3654

**Standard Title: AAMI / ANSI / IEC 60601-1-2:2007/(R) 2012, medical electrical equipment - part 1-2: general requirements for basic safety and essential performance - collateral standard: electromagnetic compatibility - requirements and tests (edition 3).**

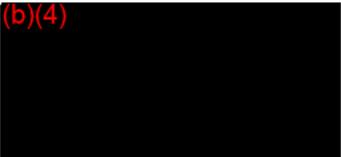
NOTE: A determination of "Yes" to conformance without a listed deviation or option selected indicates a conformance to all subsections under that section.

NOTE: A "yes" to conformance with a listed deviation will have an added entry in Table 2 for any subsections or clauses that deviate or require an option designation.

Informative Sections will be marked "Informative" for conformance since these sections do not require conformance.

### Name and Address of Test Laboratory:

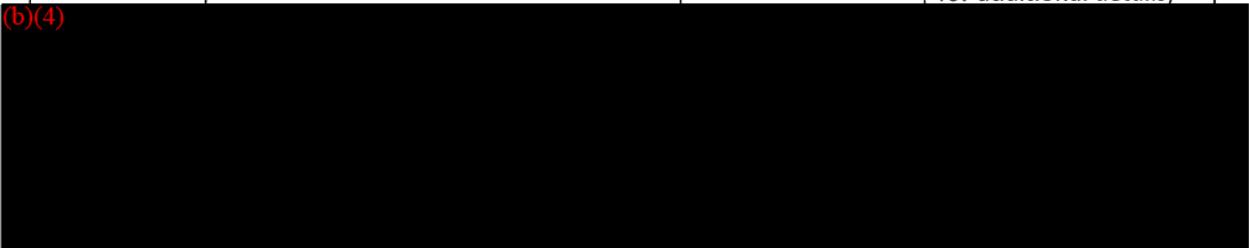
(b)(4)



**Table 1: Conformance of Sections**

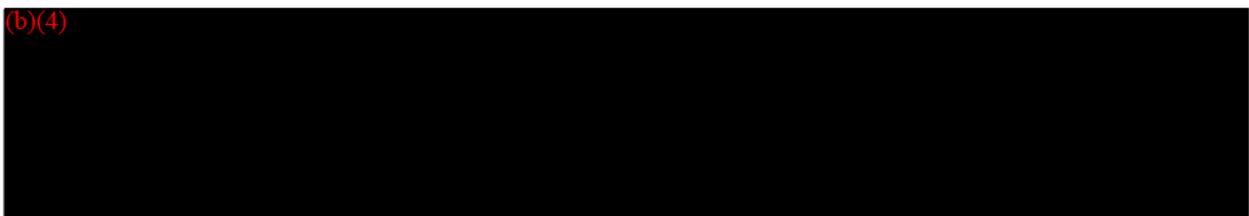
Section Number	Section Title	Conformance (Yes or No or Informative)	Type of Deviation or Option Selected (see Justification table for additional details)
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(b)(4)



**Table 2: Justifications for Deviations or Options selected**

(b)(4)



Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

Department of Health and Human Services Food and Drug Administration <b>STANDARDS DATA REPORT FOR 510(k)s</b> (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 <input type="checkbox"/> Traditional <input checked="" type="checkbox"/> Special <input type="checkbox"/> Abbreviated		
STANDARD TITLE <sup>1</sup> AAMI / ANSI / ISO 10993-1:2009, biological evaluation of medical devices -- part 1: evaluation and testing within a risk management process		
<b>Please answer the following questions</b>		Yes    No
Is this standard recognized by FDA <sup>2</sup> ? .....		<input checked="" type="checkbox"/> <input type="checkbox"/>
FDA Recognition number <sup>3</sup> .....		# 2-156
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 <sup>4</sup> 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 type="checkbox"/> <input checked="" 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) <sup>5</sup> ? .....		<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 <sup>6</sup> 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>G95-1 (1995) Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1</u>		
<small> <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], <a href="http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm">http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm</a>  <sup>3</sup> <a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm">http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm</a>  <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 <a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm">http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm</a>  <sup>6</sup> The online search for CDRH Guidance Documents can be found at <a href="http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm">http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm</a> </small>		

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE AAMI / ANSI / ISO 10993-1:2009, biological evaluation of medical devices -- part 1: evaluation and testing within a risk management process		
<b>CONFORMANCE WITH STANDARD SECTIONS*</b>		
SECTION NUMBER	SECTION TITLE See attached Summary Report Table	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *  		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *  		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *  		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *  		
DESCRIPTION		
JUSTIFICATION		
<p>* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.</p> <p>* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.</p>		
<p>This section applies only to requirements of the Paperwork Reduction Act of 1995.</p> <p><b>*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.*</b></p> <p>The burden time for this collection of information is estimated to average 1 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:</p> <div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <p>Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff <a href="mailto:PRAStaff@fda.hhs.gov">PRAStaff@fda.hhs.gov</a></p> </div> <div style="width: 45%; text-align: right;"> <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> </div> </div>		

## Summary Report for FORM 3654

### Standard Title: ISO 10993-1: Biological evaluation of medical devices-Part 1: Evaluation and testing within a risk management process (2009)

NOTE: A determination of "Yes" to conformance without a listed deviation or option selected indicates a conformance to all subsections under that section.

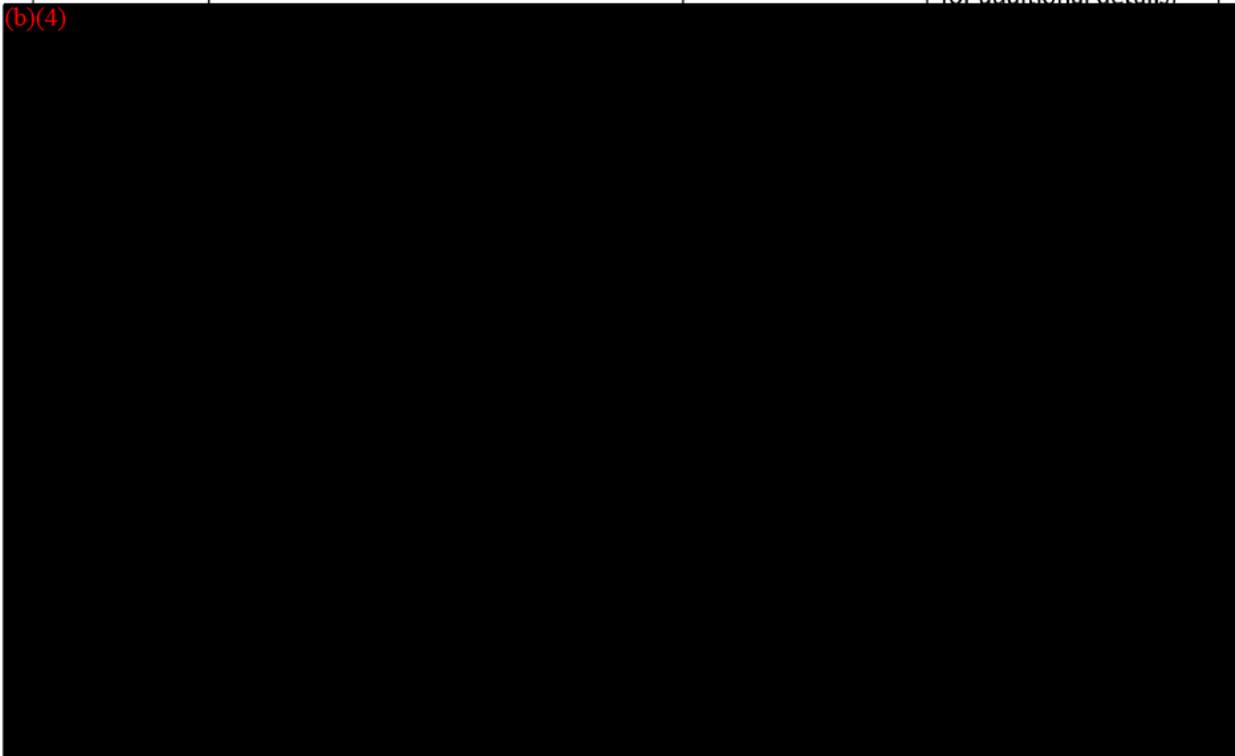
NOTE: A "yes" to conformance with a listed deviation will have an added entry in Table 2 for any subsections or clauses that deviate or require an option designation.

Informative Sections will be marked "Informative" for conformance since these sections do not require conformance.

**Table 1: Conformance of Sections**

Section Number	Section Title	Conformance (Yes or No or Informative)	Type of Deviation or Option Selected (see Justification table for additional details)
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(b)(4)



(b)(4)

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**Table 2: Justifications for Deviations or Options selected**

(b)(4)

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Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

Department of Health and Human Services Food and Drug Administration <b>STANDARDS DATA REPORT FOR 510(k)s</b> (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 <input type="checkbox"/> Traditional <input checked="" type="checkbox"/> Special <input type="checkbox"/> Abbreviated		
STANDARD TITLE <sup>1</sup> ISTA 3A Packaged-Product for Parcel Delivery System Shipment 70Kg (150 lbs) or Less		
<b>Please answer the following questions</b>		Yes      No
Is this standard recognized by FDA <sup>2</sup> ? .....		<input type="checkbox"/> <input checked="" type="checkbox"/>
FDA Recognition number <sup>3</sup> .....		# N/A
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 <sup>4</sup> 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 checked="" type="checkbox"/> <input 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) <sup>5</sup> ? .....		<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 <sup>6</sup> that is associated with this standard?.....		<input type="checkbox"/> <input checked="" type="checkbox"/>
If yes, was the guidance document followed in preparation of this 510k? .....		<input type="checkbox"/> <input type="checkbox"/>
Title of guidance: _____		
<div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <p><sup>1</sup> The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]</p> <p><sup>2</sup> Authority [21 U.S.C. 360d], <a href="http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm">http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm</a></p> <p><sup>3</sup> <a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm">http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm</a></p> <p><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</p> </div> <div style="width: 45%;"> <p>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.</p> <p><sup>5</sup> The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm">http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm</a></p> <p><sup>6</sup> The online search for CDRH Guidance Documents can be found at <a href="http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm">http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm</a></p> </div> </div>		

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE AAMI/ANSI ST81:2004/(R)2010, Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices		
<b>CONFORMANCE WITH STANDARD SECTIONS*</b>		
SECTION NUMBER	SECTION TITLE See attached Summary Report Table	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED ♦		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED ♦		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED ♦		
DESCRIPTION		
JUSTIFICATION		
<p>* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.</p> <p>♦ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.</p>		
<p>This section applies only to requirements of the Paperwork Reduction Act of 1995.</p> <p><b>*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.*</b></p> <p>The burden time for this collection of information is estimated to average 1 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:</p> <div style="display: flex; justify-content: space-between;"> <div style="width: 60%;"> <p>Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff <a href="mailto:PRAStaff@fda.hhs.gov">PRAStaff@fda.hhs.gov</a></p> </div> <div style="width: 35%; text-align: center;"> <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> </div> </div>		

## Summary Report for FORM 3654

**Standard Title: ANSI/AAMI ST81: 2004/(R)2010, Sterilization of medical devices – Information to be provided by the manufacturer for the processing of resterilizable medical devices**

NOTE: A determination of “Yes” to conformance without a listed deviation or option selected indicates a conformance to all subsections under that section.

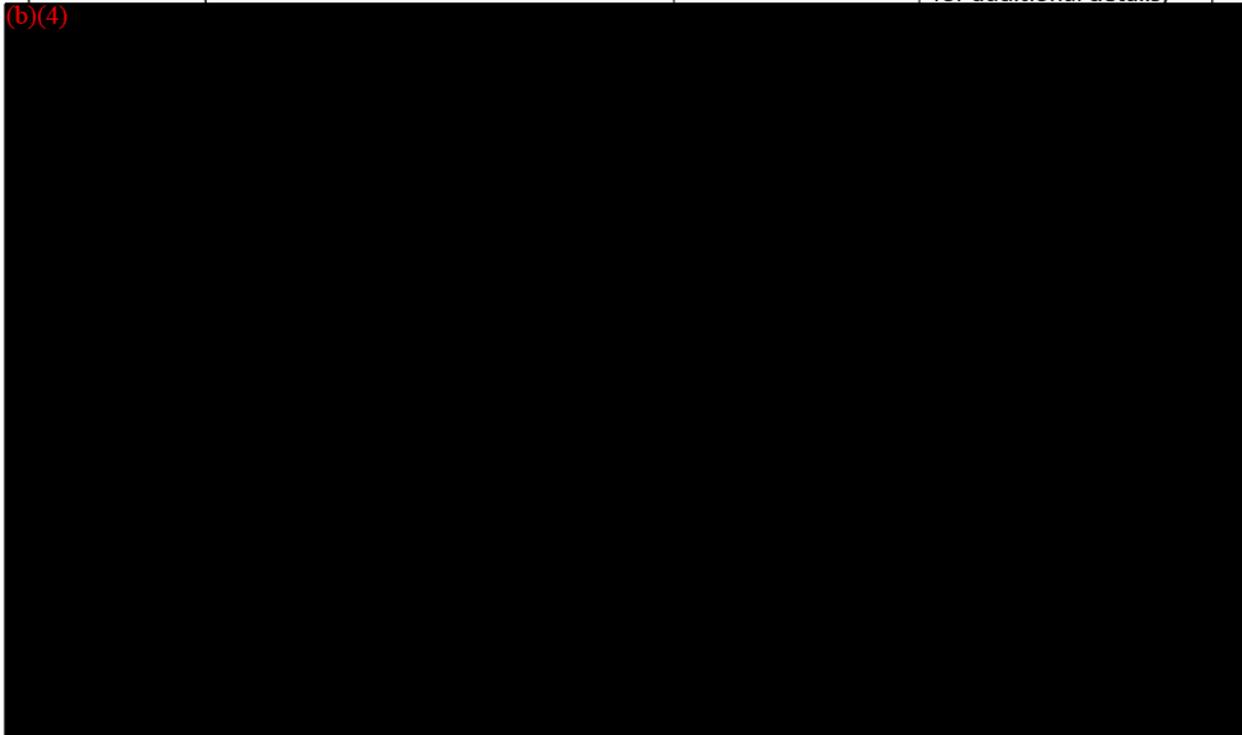
NOTE: A “yes” to conformance with a listed deviation will have an added entry in Table 2 for any subsections or clauses that deviate or require an option designation.

Informative Sections will be marked “Informative” for conformance since these sections do not require conformance.

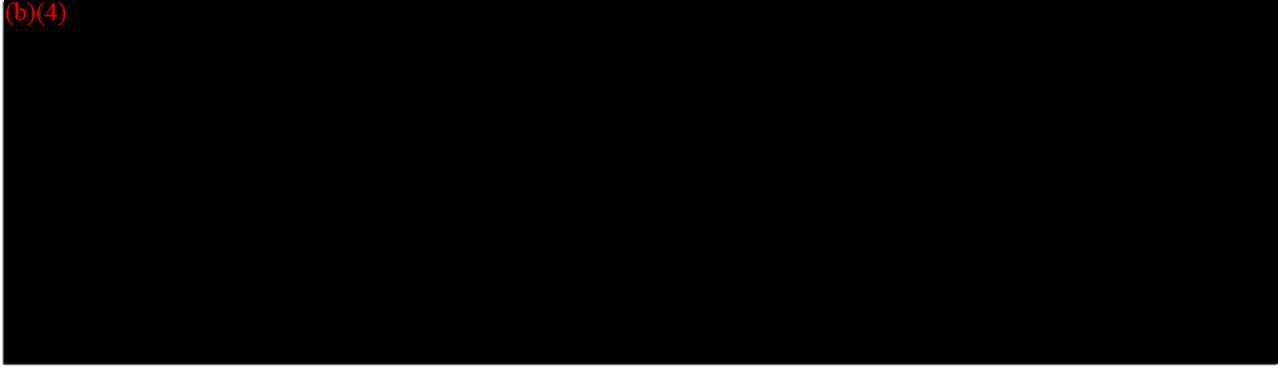
**Table 1: Conformance of Sections**

Section Number	Section Title	Conformance (Yes or No or Informative)	Type of Deviation or Option Selected (see Justification table for additional details)
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(b)(4)



(b)(4)



**Table 2: Justifications for Deviations or Options selected**

(b)(4)



Department of Health and Human Services Food and Drug Administration <b>STANDARDS DATA REPORT FOR 510(k)s</b> (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 <input type="checkbox"/> Traditional <input checked="" type="checkbox"/> Special <input type="checkbox"/> Abbreviated		
STANDARD TITLE <sup>1</sup> AAMI ANSI ISO 17665-1:2006 Sterilization of health care products -- Moist heat -- Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices		
<b>Please answer the following questions</b>		Yes    No
Is this standard recognized by FDA <sup>2</sup> ? .....		<input checked="" type="checkbox"/> <input type="checkbox"/>
FDA Recognition number <sup>3</sup> .....		# 14-261
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 <sup>4</sup> 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) <sup>5</sup> ? .....		<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 <sup>6</sup> that is associated with this standard?.....		<input type="checkbox"/> <input checked="" type="checkbox"/>
If yes, was the guidance document followed in preparation of this 510k? .....		<input type="checkbox"/> <input type="checkbox"/>
Title of guidance: _____		
<p><sup>1</sup> The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]</p> <p><sup>2</sup> Authority [21 U.S.C. 360d], <a href="http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm">http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm</a></p> <p><sup>3</sup> <a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm">http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm</a></p> <p><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</p>	<p>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.</p> <p><sup>5</sup> The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm">http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm</a></p> <p><sup>6</sup> The online search for CDRH Guidance Documents can be found at <a href="http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm">http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm</a></p>	

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE AAMI ANSI ISO 17665-1:2006 Sterilization of health care products -- Moist heat -- Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices		
<b>CONFORMANCE WITH STANDARD SECTIONS*</b>		
SECTION NUMBER	SECTION TITLE See attached Summary Report Table	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED ♦		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED ♦		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED ♦		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED ♦		
DESCRIPTION		
JUSTIFICATION		
<p>* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.</p> <p>♦ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.</p>		
<p>This section applies only to requirements of the Paperwork Reduction Act of 1995.</p> <p><b>*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.*</b></p> <p>The burden time for this collection of information is estimated to average 1 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:</p> <div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <p>Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff <a href="mailto:PRASStaff@fda.hhs.gov">PRASStaff@fda.hhs.gov</a></p> </div> <div style="width: 45%; text-align: right;"> <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> </div> </div>		

## Summary Report for FORM 3654

**Standard Title: AAMI / ANSI / ISO 17665-1:2006, sterilization of health care products -- moist heat -- part 1: requirements for the development, validation, and routine control of a sterilization process for medical devices. (2006)**

NOTE: A determination of "Yes" to conformance without a listed deviation or option selected indicates a conformance to all subsections under that section.

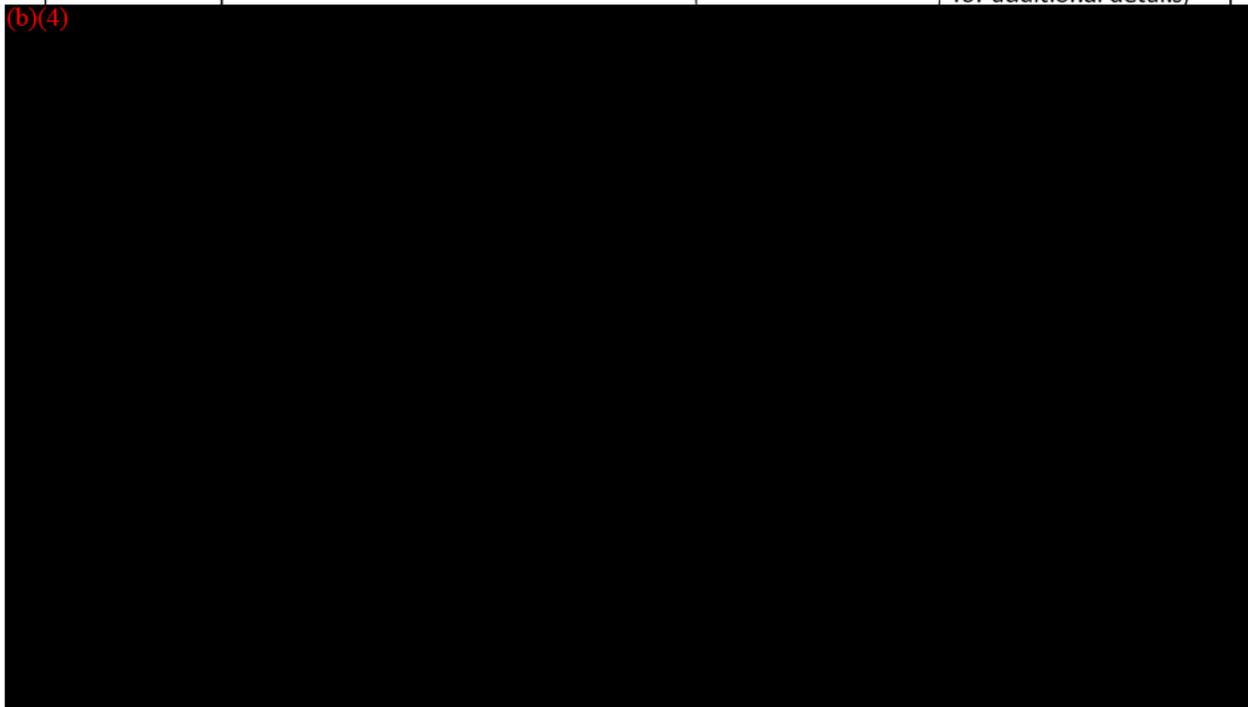
NOTE: A "yes" to conformance with a listed deviation will have an added entry in Table 2 for any subsections or clauses that deviate or require an option designation.

Informative Sections will be marked "Informative" for conformance since these sections do not require conformance.

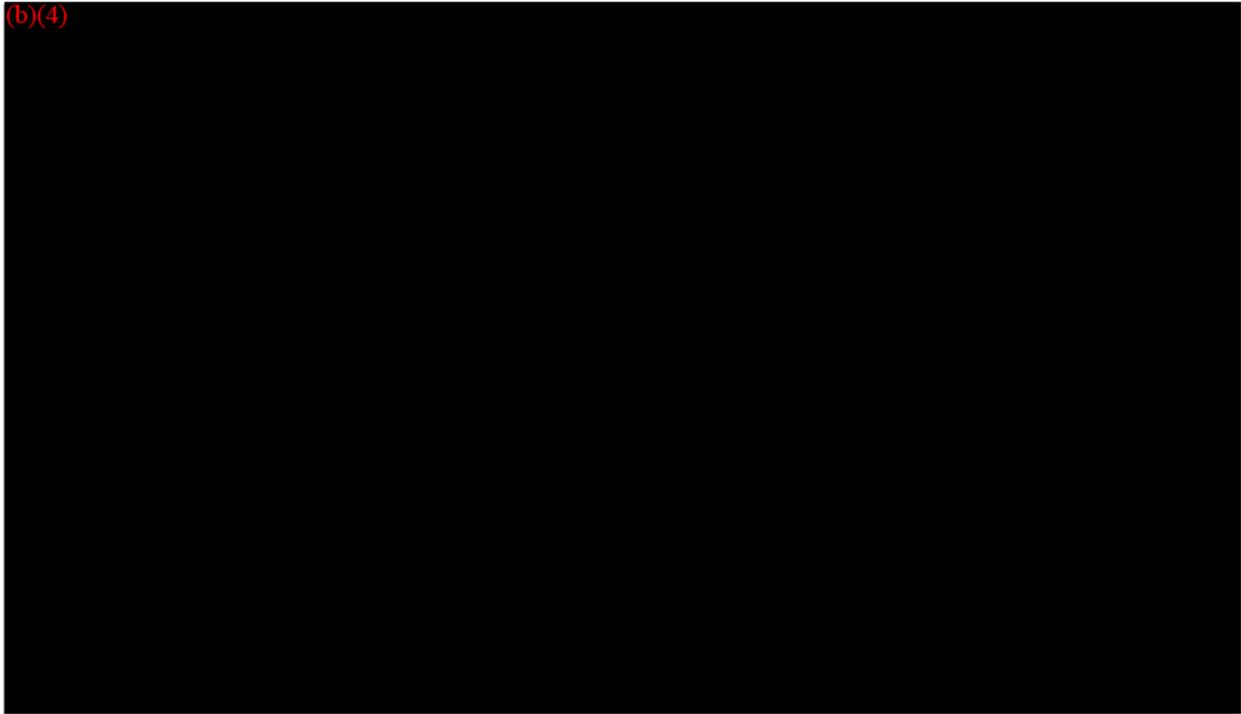
**Table 1: Conformance of Sections**

Section Number	Section Title	Conformance (Yes or No or Informative)	Type of Deviation or Option Selected (see Justification table for additional details)
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(b)(4)

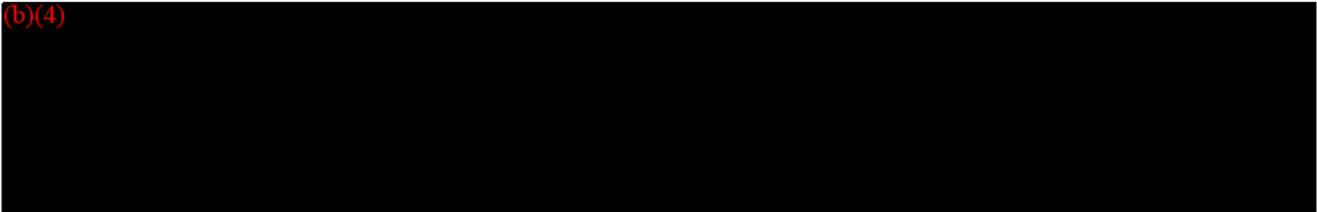


(b)(4)



**Table 2: Justifications for Deviations or Options selected**

(b)(4)



Department of Health and Human Services Food and Drug Administration <b>STANDARDS DATA REPORT FOR 510(k)s</b> (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 <input type="checkbox"/> Traditional <input checked="" type="checkbox"/> Special <input type="checkbox"/> Abbreviated				
STANDARD TITLE <sup>1</sup> EN ISO 14971:2012 Medical devices - Application of risk management to medical devices				
<b>Please answer the following questions</b>		Yes    No		
Is this standard recognized by FDA <sup>2</sup> ? .....		<input type="checkbox"/> <input checked="" type="checkbox"/>		
FDA Recognition number <sup>3</sup> .....		#    N/A		
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 <sup>4</sup> 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 type="checkbox"/> <input checked="" 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) <sup>5</sup> ? .....		<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 <sup>6</sup> that is associated with this standard?..... If yes, was the guidance document followed in preparation of this 510k? .....		<input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>		
Title of guidance: _____				
<table border="0" style="width: 100%;"> <tr> <td style="width: 50%; vertical-align: top;"> <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], <a href="http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm">http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm</a>  <sup>3</sup> <a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm">http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm</a>  <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                             </td> <td style="width: 50%; vertical-align: top;">                             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 <a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm">http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm</a>  <sup>6</sup> The online search for CDRH Guidance Documents can be found at <a href="http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm">http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm</a> </td> </tr> </table>			<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], <a href="http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm">http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm</a> <sup>3</sup> <a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm">http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm</a> <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 <a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm">http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm</a> <sup>6</sup> The online search for CDRH Guidance Documents can be found at <a href="http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm">http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm</a>
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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE EN ISO 14971:2012 Medical devices - Application of risk management to medical devices		
<b>CONFORMANCE WITH STANDARD SECTIONS*</b>		
SECTION NUMBER	SECTION TITLE See attached Summary Report Table	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED ♦		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED ♦		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED ♦		
DESCRIPTION		
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<p>* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.</p> <p>♦ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.</p>		
<p>This section applies only to requirements of the Paperwork Reduction Act of 1995.</p> <p><b>*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.*</b></p> <p>The burden time for this collection of information is estimated to average 1 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:</p> <div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <p>Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff <a href="mailto:PRASStaff@fda.hhs.gov">PRASStaff@fda.hhs.gov</a></p> </div> <div style="width: 45%; text-align: right;"> <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> </div> </div>		

## Summary Report for FORM 3654

**Standard Title: BS EN ISO 14971:2012 Medical devices — Application of risk management to medical devices**

NOTE: A determination of “Yes” to conformance without a listed deviation or option selected indicates a conformance to all subsections under that section.

NOTE: A “yes” to conformance with a listed deviation will have an added entry in Table 2 for any subsections or clauses that deviate or require an option designation.

Informative Sections will be marked “Informative” for conformance since these sections do not require conformance.

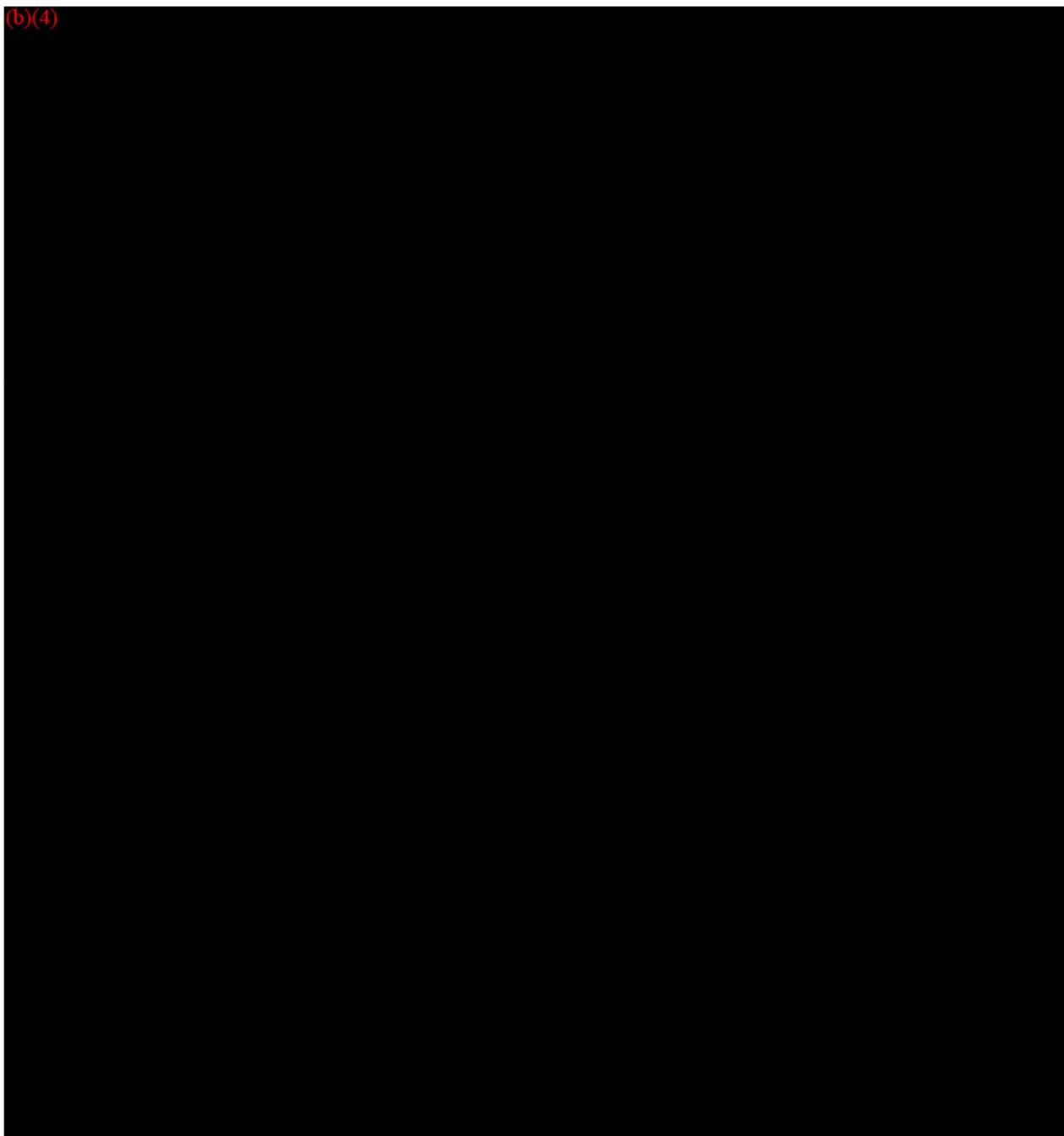
**Table 1: Conformance of Sections**

Section Number	Section Title	Conformance (Yes or No or Informative)	Type of Deviation or Option Selected (see Justification table for additional details)
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(b)(4)

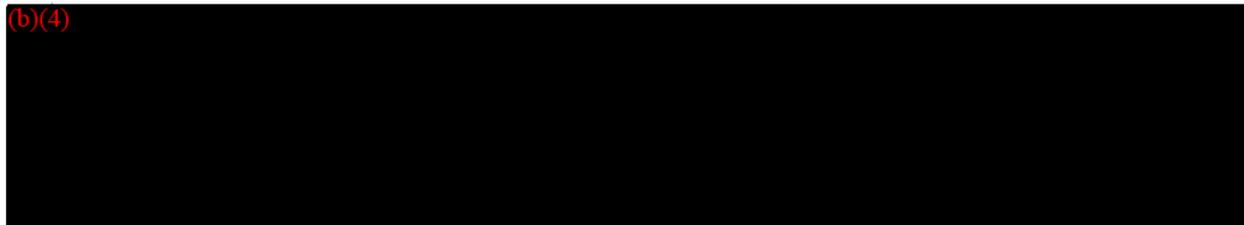


(b)(4)



**Table 2: Justifications for Deviations or Options selected**

(b)(4)





## **Section 11**

### **Device Description**

## **Device Description**

### **S2 Drill:**

The Stryker S2 Drill is a non-sterile, reusable, electric powered (40VDC) motor that directly rotates cutting accessories up to speeds of 75,000 RPM. Both the S2 Drill and its predicate, Sumex Drill are powered by the CORE console which is previously cleared under K112593 (Clearance date: 05/01/2012). The cord of the S2 Drill is integrated into the proximal end and connects directly to the CORE console.

Below is a pictorial comparison between the S2 Drill and the Sumex Drill.



*Image 11.1 S2 Drill (above) and CORE Sumex Drill (below)*

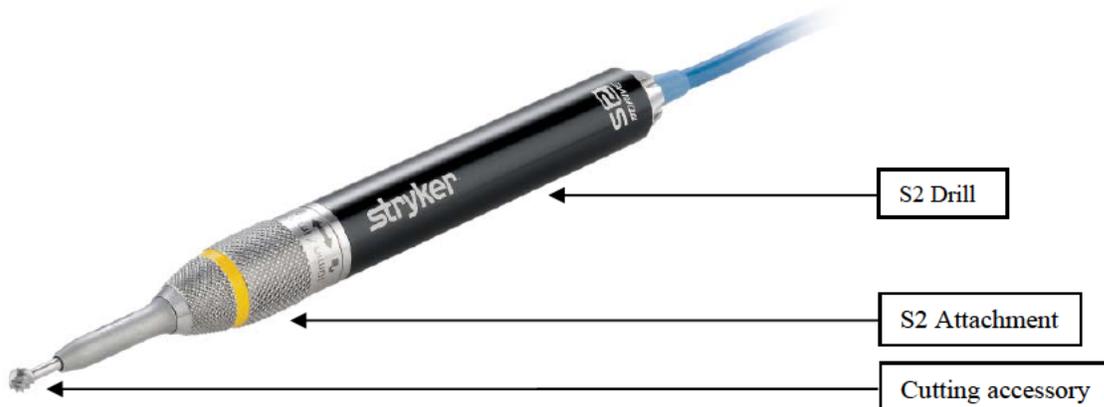


Image 11.2: S2 Drill with attachment and cutting accessory

Table 11.1 S2 Drill

Part names	Part numbers
S2 Drill	5450-400-000

The S2 Drill is used in conjunction with the following accessories that have been previously cleared and are not subject to the review of this 510(k) submission

- S2 Attachments
- S2 Cutting accessories
- Irrigation clips
- CORE Console
- Footswitch

Attachments:

The attachments fit over the distal end of the S2 drill (b)(4)

[Redacted] Each attachment will accept an assortment of cutting accessories.

There are two types of attachments that function with the S2 drill: Straight Attachments and Angled Attachments

With Straight Attachments, the burs are inserted into the distal end of the attachment and locked to the drill (b)(4)

With Angled Attachments, the burs are inserted into the distal end of the attachment and locked to the attachment (b)(4)

(b)(4)

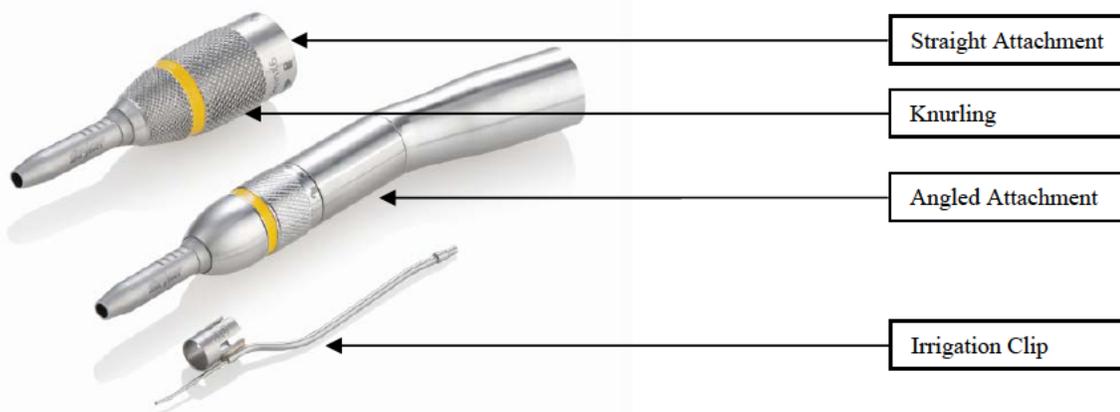
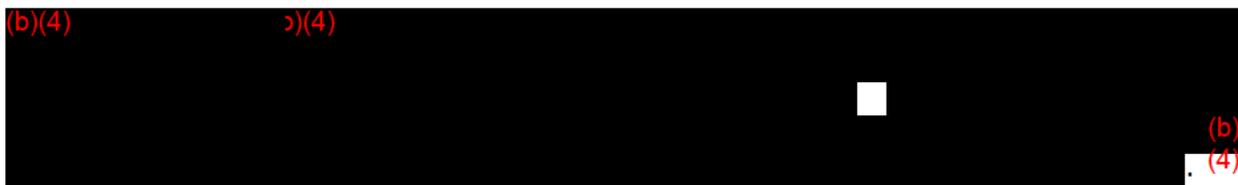


Image 11.3: Straight attachment, Angled attachment and Irrigation clip

Table 11.2 List of S2 attachments

Part names	Part numbers
4.0 cm Straight Attachment	5450-040-000
4.0cm Straight Irrigating Attachment	5450-040-001
4.0cm Angled Attachment	5450-040-002
4.0cm Angled Irrigating Attachment	5450-040-003

Cutting Accessories

Cutting accessories are single use, sterile devices which has a mount or notch machined at its proximal end and a sharp cutting edge at its distal end.

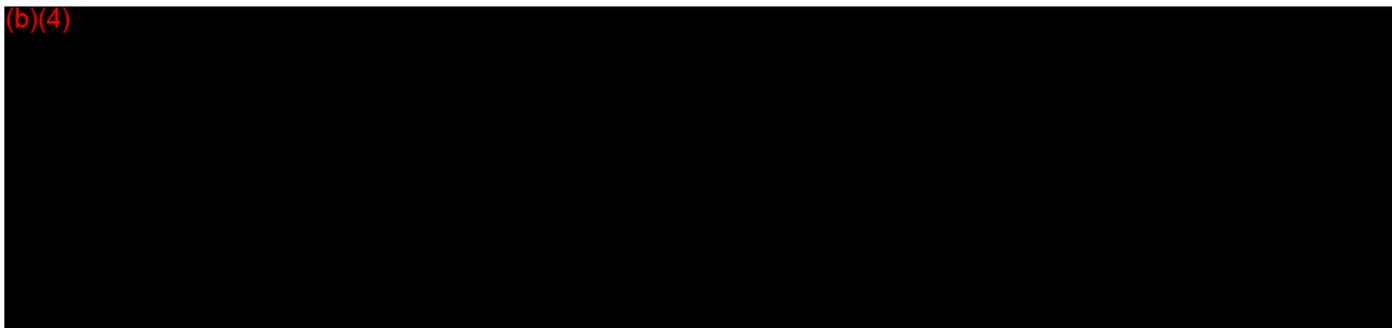




Image 11.4: Cutting accessories

The laser mark on the shank of the bur indicates the insertion depth of the bur in the attachment, and thus determines the distal bur extension from the tip of the attachment. The user can adjust the bur extension by modifying the insertion depth of the bur in the attachment. Depending on the bur size, there are 3 to 5 laser mark positions available, equivalent to 19 notch positions.

**Note:** The laser mark depth marking serves only as a guide and not an absolute measurement.

The cutting accessories are cleared as accessories to the CORE System 510(k) submission in 2011(K112593).

Table 11.3 List of cutting accessories

Part number series	Part name series	Size Range
5540-009-XXX	Precision Round – 2 Flute	1.0mm-9.0mm
5540-010-XXX	Round Fluted	3.0mm-6.0mm
5540-011-XXX	Fine Diamond	1.0mm-6.0mm
5540-012-XXX	Diamond	2.0mm-6.0mm
5540-013-XXX	Coarse Diamond	2.0mm-6.0mm

### Irrigation Clips

The irrigation clips attach to the Attachments and the Irrigation Cassette. They are simply a conduit for irrigation to flow from the Irrigation Cassette to the distal end of the attachment. Please see Image 11.2 for reference.

The irrigation clips are cleared as accessories to the CORE System 510(k) submission in 2011(K112593).

### CORE Console

The Stryker CORE Console supplies power to a variety of devices, including small and large bone handpieces, and footswitches while, allowing the user to program a number of customized settings via a touch screen graphical.

The CORE Console has three handpiece connectors and two footswitch connectors which allow the console to connect and operate multiple devices simultaneously via a cord connection. The CORE Console is cleared through the CORE System 510(k) submission in 2011 (K112593).

Footswitch

The footswitch is comprised of (b)(4) used to control handpiece selection, handpiece variable speed, handpiece direction, and irrigation (b)(4).  
(b) It is connected to the CORE Console (b)(4).  
(b)(4).

The Footswitch is cleared as an accessory to the CORE System 510(k) cleared in 2012 (K112593).

Sumex Drill Device Modifications

The Sumex Drill (5400-130-000) was cleared as an accessory in 2012 as part of the Consolidated Operating Room Equipment System 510(k), K112593. (b)(4)

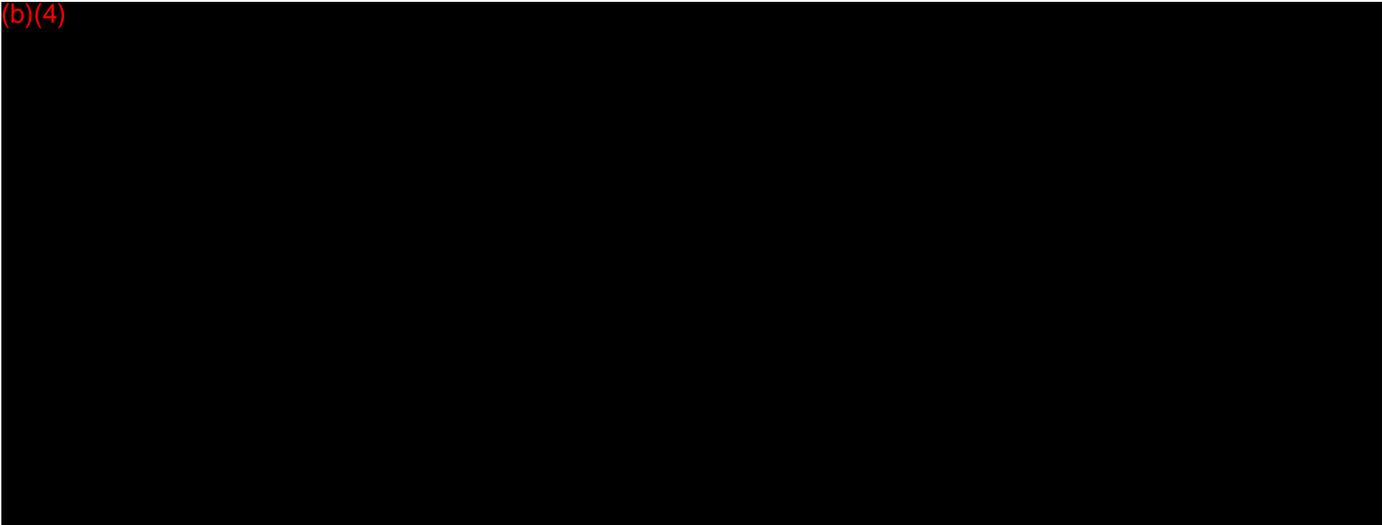
Table 11.4 Driveshaft change

Modification	Justification
(b)(4) (b)(4)	(b)(4)

(b)(4)

Modification	Justification
(b)(4)	(b)(4)

(b)(4)



**Dimensions:**

The S2 Drill has the following dimensions:

Length: 123.5mm

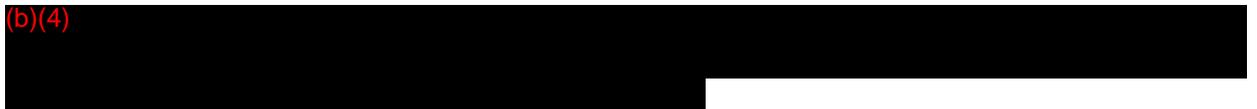
Diameter: 17mm

Weight: 0.313kg

(b)(4)  
(b)(4). The S2 Drill is driven by Pi-Drive motor as compared to Sumex Drill (predicate) which is driven by a conventional electric motor. (b)(4)



(b)(4)



**Material:**

The predicate device, CORE Sumex Drill is made of (b)(4) Stainless Steel, whereas the S2 Drill is made of the following materials:

1. (b)(4) Stainless Steel (b)(4)
2. (b)(4) Aluminum  
a. (b)(4) Hardcoat Anodize – (b)(4)

3. (b) Stainless Steel (b)(4)

(b)(4)

The S2 Drill is not a patient contacting device. It is a handheld device used by a surgeon. The attachments and cutting accessories that attach to the distal end of the drill are considered to be patient contacting devices. Hence, biocompatibility testing was not performed on the Stryker S2 Drill.

**Performance Specifications:**

Maximum speed of rotation: 75,000 rotations per minute (rpm)

Maximum power output: 110 watts

(b)(4)

(b)(4)

**Sterilization:**

The Stryker S2 Drill is reusable and must be sterilized before first and every subsequent use. The predicate device, Stryker CORE Sumex Drill is also reusable and must be sterilized before first and every subsequent use. Both the devices are sterilized by (b)(4) to a sterility assurance level of (b)(4)

**Packaging:**

For both the S2 Drill and its predicate device, CORE Sumex Drill, the packaging is exactly the same. Below is a brief description of the packaging.

The S2 Drill uses a two component packaging system that includes a (b)(4) Insert and a corrugated Tuck Folding Carton. The (b)(4) Insert is a combination of a (b)(4) (b)(4) to encapsulate and protect the drill assembly. The (b)(4) Insert containing the S2 Drill is then placed into a (b)(4) Die Cut Tuck Carton.

# **Attachment 11.1**

## **Engineering Print**







# **Attachment 11.2**

## **Detail A**



## **Section 12**

# **Substantial Equivalence Discussion**

This section of the 510(k) premarket notification demonstrates the substantial equivalence of the subject device to the predicate device, i.e. Stryker CORE Sumex Drill which was cleared as an accessory in the Stryker Consolidated Operating Room Equipment (CORE) System 510(k) submission in 2011 (K112593). The Stryker S2 Drill falls within the same classification regulation, has an identical Intended Use, and share the same fundamental scientific technology as the predicate device.

The similarities and differences between the Stryker S2 Drill and the Stryker CORE Sumex Drill are described in regard to the Indications for Use and the technological characteristics, including features, materials and principles of operation.

Stryker claims substantial equivalence because the Stryker S2 Drill has an equivalent intended use, technology and performance specifications as compared to the predicate device, Stryker CORE Sumex Drill. The differences between the Stryker S2 Drill and the predicate device do not introduce new issues of safety and effectiveness. Therefore, we consider the Stryker S2 Drill to be substantially equivalent to the previously cleared predicate device. See the following comparison matrix for detail

Table 12.1 Substantial Equivalence table

Description	Stryker CORE Sumex Drill (Predicate)	Stryker S2 Drill (Subject)	Explanation of Difference
<b>Classification/ Regulation</b>	Class II	Class II	Identical
<b>Regulation</b>	21 CFR 874.4250	21 CFR 874.4250	Identical
<b>Product Code</b>	ERL	ERL	Identical
<b>INTENDED USE</b>			
<b>Intended Use</b>	The Stryker Consolidated Operating Room Equipment (CORE) System is intended for use in cutting, drilling, reaming, decorticating, shaping, and smoothing of bone, bone cement and teeth in a variety of surgical procedures, including but not limited to, dental, ENT (ear, nose, and throat), neuro, spine, and endoscopic applications. It is also usable in the placement or cutting of screws, metal, wires, pins, and other fixation devices.	The S2 Drill System is intended for use with the Stryker Consolidated Operating Room Equipment (CORE) System. When used with a variety of attachments and cutting accessories, the drill is intended for use in cutting, drilling, reaming, decorticating, shaping and smoothing of bone, bone cement and teeth in a variety of surgical procedures, including but not limited to ENT, neuro, spine and Endoscopic applications. It is also usable in the placement or cutting of screws, metal, wires, pins, and other fixation devices.	Identical
<b>MATERIAL</b>			
<b>Housing Material</b>	(b) Stainless Steel (b)(4)	1. (b) Stainless Steel (b)(4) 2. (b)(4) Aluminum a. (b)(4) (b)(4) Hardcoat Anodize 3. (b) Stainless Steel (b)(4) (b)	(b)(4)

				(b)(4)
				(b)(4) do not raise new questions of safety and effectiveness.
DIMENSIONS				
Motor Diameter	20mm	17mm	The difference in	
Length of the drill	105mm	123.5mm	(b)(4)	
Weight of the drill	399g	313g	(b)(4)	
				(b)(4) does not raise new questions of safety and effectiveness.
PERFORMANCE				
Power source	40 V_DC Electric Motor connected via cable to CORE console	40 V_DC Electric Motor connected via cable to CORE console	Identical	
Operating Speed	0-75,000 rotations per minute	0-75,000 rotations per minute	Identical	
Maximum Power Output	Approximately 120 W	Approximately 110 W	Equivalent	
Torque at maximum speed	(b)(4)	(b)(4)	(b)(4)	

			(b)(4) does not impact the safety and effectiveness of the product.
<b>COMPATIBILITY</b>			
<b>Cutting Accessories (Burs)</b>	<ul style="list-style-type: none"> <li>Size: Ranging from 0.5 –11 mm</li> <li>(b)(4)</li> <li>Variety of cutting geometries, fluted and diamond</li> </ul>	<ul style="list-style-type: none"> <li>Size: Ranging from 0.5 – 11 mm</li> <li>(b)(4)</li> <li>Variety of cutting geometries, fluted and diamond</li> </ul>	Equivalent
<b>Accessories</b>	<ul style="list-style-type: none"> <li>Straight and Angled Attachments</li> <li>Irrigation Clips</li> <li>Cutting Accessories</li> </ul>	<ul style="list-style-type: none"> <li>Straight and Angled Attachments</li> <li>Irrigation Clips</li> <li>Cutting Accessories</li> </ul>	Identical
<b>Bur Retention Method by Drill</b>	(b)(4)		Equivalent
<b>Attachment Retention Method by Drill</b>	(b)(4)		Identical
<b>Mode of activation</b>	Footswitch and Handswitch	Footswitch	(b)(4) does not raise new questions of safety and effectiveness.
<b>Sterilization Method</b>	(b)(4)		

<b>Packaging Material</b>	<b>Insert</b> (b)(4)	<b>Insert</b> (b)(4)	(b)(4)
	<b>Carton</b> (b)(4)	<b>Carton</b> (b)(4)	

## **Section 13 Proposed Labeling**







## **Attachment 13.1**

### **Instructions for Use**

# stryker<sup>®</sup>

## S2 Drill

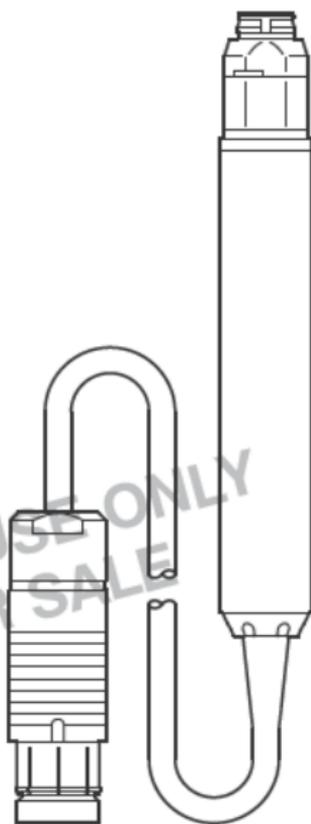
**REF** 5450-400-000

### Instructions For Use

### R<sub>x</sub> ONLY

CE 0197

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## Introduction

This *Instructions For Use* manual is the most comprehensive source of information for the safe and effective use of your product. This manual may be used by in-service trainers, physicians, nurses, surgical technologists, and biomedical equipment technicians. Keep and consult this reference manual during the life of the product.

The following conventions are used in this manual:

- A **WARNING** highlights a safety-related issue. **ALWAYS** comply with this information to prevent patient and/or healthcare staff injury.
- A **CAUTION** highlights a product reliability issue. **ALWAYS** comply with this information to prevent product damage.
- A **NOTE** supplements and/or clarifies procedural information.

For additional information, especially safety information, or in-service training, contact your Stryker sales representative or call Stryker customer service. Outside the US, contact your nearest Stryker subsidiary.

## Indications For Use

The Stryker S2 Drill (handpiece) is intended for use with the Stryker Consolidated Operating Room Equipment (CORE™) System. When used with a variety of attachments and cutting accessories, the drill is intended for use in cutting, drilling, reaming, decorticating and smoothing of bone, bone cement and teeth in a variety of surgical procedures including but not limited to Neuro, Spine, ENT (Ear, Nose, and Throat), Dental and Endoscopic applications. It is also usable in the placement or cutting of screws, metal, wires, pins, and other fixation devices.

## Contraindications

None known.

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## For Use With

This section describes system components that must be used with the equipment described in this manual to create a safe and effective system.

DESCRIPTION	REF
CORE Powered Instrument Driver (console) with software version 5.7 or higher	5400-050-000
CORE or TPS™ Footswitch	5400-007-000
	5100-008-000
	5100-007-000
Drill Attachments	5450-040-XXX series
Burs (cutting accessories)	5540-XXX-XXX series

## User/Patient Safety



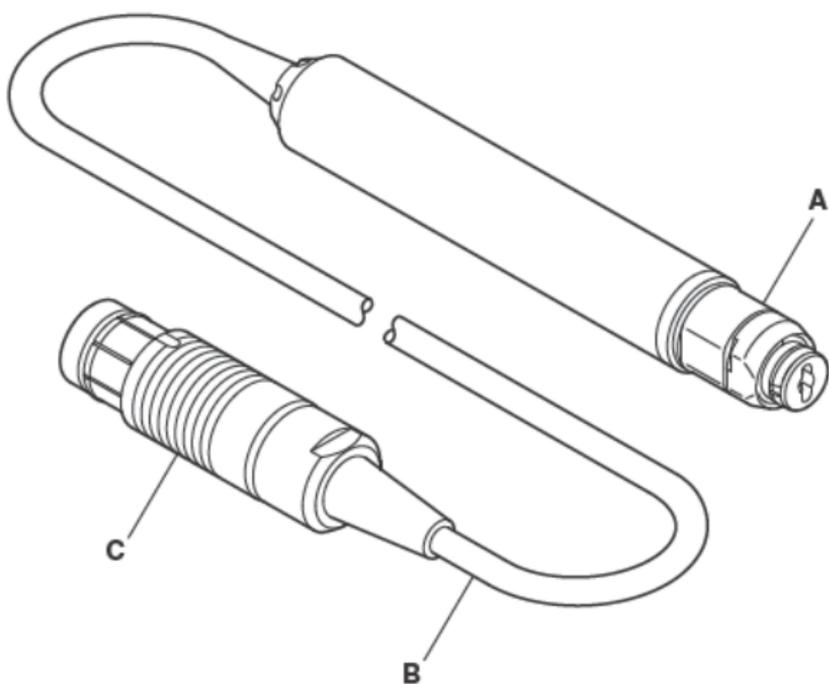
### WARNINGS:

- Before using any system component, or any component compatible with this system, read and understand the instructions. Pay particular attention to WARNING information. Become familiar with the system components prior to use.
- Only trained and experienced healthcare professionals should use this equipment.
- The healthcare professional performing any procedure is responsible for determining the appropriateness of this equipment and the specific technique used for each patient. Stryker, as a manufacturer, does not recommend surgical procedure or technique.
- Upon initial receipt and before each use, clean and sterilize the equipment as indicated. For processing instructions, see the care instructions manual supplied with the handpiece.
- Upon initial receipt and before each use, operate the equipment and inspect each component for damage. DO NOT use any equipment if damage is apparent. For inspection criteria, see the care instructions manual supplied with the handpiece.

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## Features



<b>A</b>	Attachment Interface
<b>B</b>	Cord
<b>C</b>	Plug

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## Definitions

The symbols located on the equipment and/or labeling are defined in this section or in the *Symbol Definition Chart*. See the *Symbol Definition Chart* supplied with the equipment.

SYMBOL	LOCATION	DEFINITION
	Attachment Interface	Alignment mark
	Plug	Alignment mark
	Handpiece/ Labeling	Consult instructions for use
	Labeling	General warning sign

## Instructions

### To Operate the Handpiece



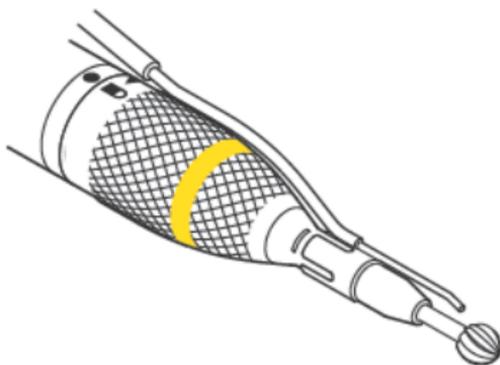
#### WARNINGS:

- DO NOT operate the handpiece without an attachment, or with the attachment partially installed in the unlocked position.
- Before operating the handpiece, gently tug the attachment and cutting accessory to verify they are securely installed onto the handpiece.
- Delicate structures in proximity to dissection must be thoroughly protected to prevent injury.
- DO NOT grasp or touch any rotating component while the handpiece is operating.
- DO NOT let the spinning bur come into contact with the irrigation clip, retractors, or other metal tools. Metal shavings could detach from the equipment and fall into the surgical site.
- DO NOT operate fluted burs in the reverse (counterclockwise) direction. Failure to comply may cause the bur to overheat. Five audible beeps from the console notify the user that a cutting accessory is rotating in the reverse direction.
- DO NOT rotate and unlock the attachment while operating the handpiece. Unlocking the attachment may cause unintended material to be cut or removed.

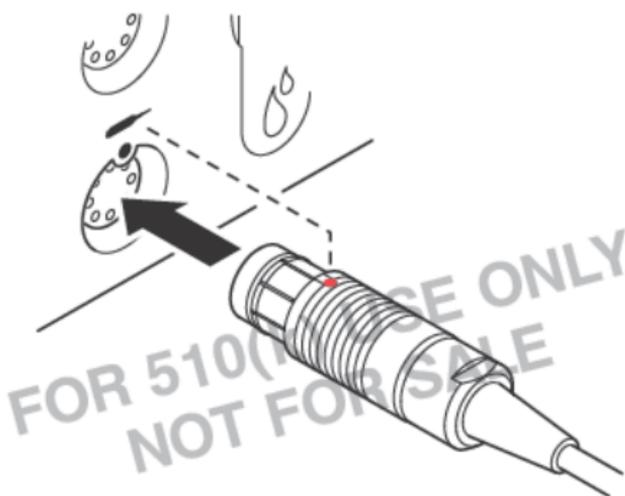
- DO NOT apply excessive pressure, such as bending or prying, with the cutting accessory. Excessive pressure may bend or fracture the cutting accessory.
- ALWAYS operate the equipment within the specified environmental condition values. See the *Specifications* section.
- ALWAYS follow the recommended duty cycle to prevent the equipment from overheating. See the instructions for use supplied with the attachment.

**NOTES:**

- Using irrigation while operating burs will help reduce the possibility of thermal necrosis.
  - See the instructions for use supplied with the console for additional information about handpiece operation.
1. Securely install an attachment and cutting accessory onto the handpiece. See the instructions for use supplied with the attachment.



2. Align the marks and connect the plug to a handpiece port on the console.



3. Use the console to program the operational settings of the handpiece and footswitch as required. See the instructions for use supplied with the console.
4. Apply pressure to a footswitch pedal to activate the handpiece.
5. After operation, disconnect the plug from the console receptacle.
6. Remove the attachment and cutting accessory from the handpiece. See the instructions for use supplied with the attachment.

## Cleaning and Disinfection

See the care instructions manual supplied with the handpiece.

## Inspection and Testing

See the care instructions manual supplied with the handpiece.

## Sterilization

See the care instructions manual supplied with the handpiece.

## Storage and Handling

See the care instructions manual supplied with the handpiece.

## Disposal/Recycle

See the care instructions manual supplied with the handpiece.

## Troubleshooting



**WARNING:** DO NOT disassemble or service this equipment, unless otherwise specified.

**NOTE:** For service, contact your Stryker sales representative or call Stryker customer service. Outside the US, contact your nearest Stryker subsidiary.

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## Specifications



**WARNING:** ALWAYS consult any documentation that accompanies attachments and cutting accessories for product-specific duty cycles and instructions for use.

**CAUTION:** ALWAYS store the equipment within the specified environmental condition values throughout its useful life.

**NOTE:** When in use, portions of the Drill Attachments are applied parts. See the instructions for use supplied with the attachments for information specific to applied parts.

<b>Model:</b>	S2 Drill (REF 5450-400-000)
<b>Dimensions:</b>	123.5 mm length 17 mm diameter
<b>Cord Length:</b>	4.6 m
<b>Mass:</b>	0.313 kg
<b>Speed:</b>	75,000 rpm
<b>Mode of Operation:</b>	Non-continuous
<b>Duty Cycle:</b>	For duty cycle information, see the instructions for use supplied with the attachment.
<b>Ingress Protection:</b>	IPX0 Ordinary Equipment
<b>Equipment Type:</b>	 Type BF Applied Part

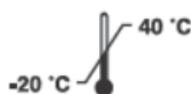
### Environmental Conditions:

Temperature Limitation:

#### Operation



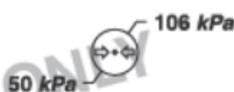
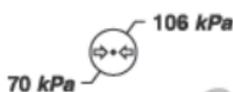
#### Storage and Transportation



Humidity Limitation:



Atmospheric Pressure Limitation:



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## **Attachment 13.2**

### **Care Instructions**

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# S2 Drill and Drill Attachments

Care Instructions

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## Introduction

This *Care Instructions* manual is the most comprehensive source of information for the maintenance and sterile processing of your product. This manual may be used by in-service trainers, biomedical equipment technicians, and central supply/sterile processing technicians. Keep and consult this reference manual during the life of the product.

The following conventions are used in this manual:

- A **WARNING** highlights a safety-related issue. ALWAYS comply with this information to prevent patient and/or healthcare staff injury.
- A **CAUTION** highlights a product reliability issue. ALWAYS comply with this information to prevent product damage.
- A **NOTE** supplements and/or clarifies procedural information.

If additional information or in-service training is required, contact your Stryker sales representative or call Stryker customer service. Outside the US, contact your nearest Stryker subsidiary.

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## User/Patient Safety



### WARNINGS:

- Only individuals trained and experienced in the processing of reusable medical devices should process this equipment.
- Before processing any equipment, read and understand the instructions. Pay particular attention to WARNING information. Become familiar with the equipment prior to processing.
- DO NOT reuse, reprocess, or re-package single use cutting accessories. All cutting accessories are intended for a single use only. Reuse may create a serious risk of contamination and lead to infection or cross-infection. Reprocessing may compromise the structural integrity of the cutting accessory and result in fragmentation during use. Critical product information may be lost if the cutting accessory is re-packaged.

## Accessories



**WARNING:** Use only Stryker-approved system components and accessories, unless otherwise specified. DO NOT modify any system component or accessory, unless otherwise specified.

**NOTE:** For a complete list of accessories, contact your Stryker sales representative. Outside the US, contact your nearest Stryker subsidiary.

The following Stryker-approved accessories are sold separately:

DESCRIPTION	REF
ProClean Instrument Detergent	3000-002-000
CORE™ Sterilization Cases	5400-276-000
	5400-277-000

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## Processing Instructions

Processing equipment, operators, detergents, and procedures all contribute to the efficacy of medical device processing. The healthcare facility should make sure that the combination used results in a medical device that is safe for use. Alternative methods of processing may be equally suitable.

### 1.0 Point of Use

**CAUTION:** DO NOT use saline to wet or soak the equipment before transport to the decontamination processing area.

**NOTE:** If transport to the decontamination processing area is delayed, cover the equipment with a damp cloth or spray the equipment with a pre-cleaning foam. The pre-cleaning foam will minimize the drying of soil and facilitate later decontamination processing.

1. Separate reusable equipment from disposable waste.
2. Discard waste into an appropriate container; use a puncture-resistant container for sharps.
3. Remove gross soil from the equipment using absorbent wipes.

### 2.0 Transport to Decontamination Processing Area



**WARNING:** During transport, pay particular attention to sharp, cutting edges to avoid injury.

**CAUTION:** Avoid mechanical damage during transport. DO NOT mix heavy devices with delicate devices.

**NOTE:** Clean the equipment as soon as practical, typically within two hours, to preclude extended or repeated cleaning procedures.

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## 3.0 Preparation for Cleaning

### 3.1 Detergents



#### WARNINGS:

- Read, understand, and follow the indications, instructions, and WARNING information supplied with the detergent for correct handling and use of the product. Pay particular attention to the concentration used and the total dispersion. Prepare the detergent solution according to the manufacturer's recommendations.
- ALWAYS provide personal protective equipment (PPE) for processing personnel according to the instructions and material safety data sheets (MSDS) supplied with the detergent.
- To clean the equipment, use specifically formulated detergents only.

#### CAUTIONS:

- To clean the equipment, a mild alkaline detergent (neutral up to pH 8.5) is preferred. If a washer-disinfector is used, see the instructions for use supplied with the washer-disinfector machine to select the recommended detergent.
- ALWAYS use a detergent that is suitable for use on aluminum and stainless steel surfaces if aluminum and stainless steel surfaces are present.

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### 3.1 Detergents (continued)

**NOTES:**

- The *Validated Detergents* table lists the detergents used by Stryker during the validation of the manual and automated (washer-disinfector) cleaning processes described in these instructions.
- Stryker does not recommend these detergents in preference to other products. Other products may perform equally well or better. However, alternative detergents must be verified by referencing the information provided by the product supplier and/or physical testing.

**VALIDATED DETERGENTS**

Supplier	Product	Suitability	Process
Stryker	ProClean Instrument Detergent	All materials	Manual Cleaning
Steris	Polystica 2x Concentrate Enzymatic and Polystica 2x Concentrate Neutral	Aluminum, stainless steel, soft metals, and plastics	Automated Cleaning

### 3.2 Water Quality



**WARNING:** Use filtered water for diluting detergents and for rinsing the equipment. Mineral residues from hard water can stain the equipment and/or prevent effective cleaning and decontamination.

**CAUTION:** Poor water quality can adversely affect the life of medical devices. ALWAYS follow the water quality requirements per AAMI TIR 34.

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## 4.0 Handpiece and Attachment Cleaning



### WARNINGS:

- Clean the equipment as indicated before first and every use.
- Prior to cleaning, remove all detachable components and single use cutting accessories from the handpieces. Detachable components include attachments and irrigation clips.
- Use the cleaning methods as indicated in these instructions. Using other cleaning methods may prevent proper sterilization of the equipment.
- Use PPE at all times during cleaning.

### CAUTIONS:

- DO NOT use solvents, lubricants, or other chemicals, unless otherwise specified.
- DO NOT use ultrasonic cleaning equipment.
- DO NOT immerse or soak any equipment in liquid. DO NOT allow moisture or liquid to soak into electrical plugs, receptacles, or openings. Moisture or liquid may enter the equipment, cause corrosion, and damage the electrical and/or mechanical components.
- DO NOT use pipe cleaners or cotton swabs to clean lumens.
- ALWAYS make sure the detergent solution is completely rinsed off before drying the equipment.
- Use of compressed air is only recommended for drying of equipment.

### NOTES:

- Equipment may be placed under running water to ensure thorough wetting and contact with liquid while actuating moving parts.
- Two methods of cleaning are described: a manual cleaning method and an automated cleaning method. Removal of all gross soil is required for both cleaning methods.

## 4.1 Manual Cleaning

### 4.1.1 Recommended Equipment

- Non-abrasive, soft, flexible, nylon-bristle brushes
- Syringe
- PPE as recommended by the detergent supplier (minimum: overalls, gloves, face/eye shield)
- Absorbent wipes
- Soft, lint-free cloth
- Warm water with an optimum temperature range of 27 to 44 °C [80 to 110 °F]. The water should not exceed 60 °C [140 °F] and should be warm to the touch.
- Medical-grade compressed air, < 140 kPa [< 20 psi]

### 4.1.2 To Clean Handpieces and Attachments

1. Remove all gross soil from the equipment using absorbent wipes or a soft, lint-free cloth moistened with the prepared detergent solution.
2. Make sure all surfaces of the equipment are thoroughly wetted using warm water.
3. Using suitable brushes, clean the equipment thoroughly. Pay particular attention to rough surfaces, crevices, and difficult-to-reach areas where soil may be shielded from brushing, such as details around a lock collar or connector. Flush difficult-to-reach areas with a syringe filled with detergent solution. See the *Special Cleaning Considerations: Handpieces and Attachments* table.

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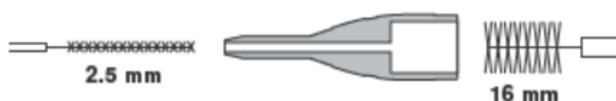
#### 4.1.2 To Clean Handpieces and Attachments (continued)

- Use soft brushes of appropriate diameters to clean lumens. If a lumen passes all the way through a device, make sure that the brush cleans the whole length of the lumen. For dead-ended lumens, use light pressure and do not force the brush any farther after you feel resistance. See the *Special Cleaning Considerations: Handpieces and Attachments* table.

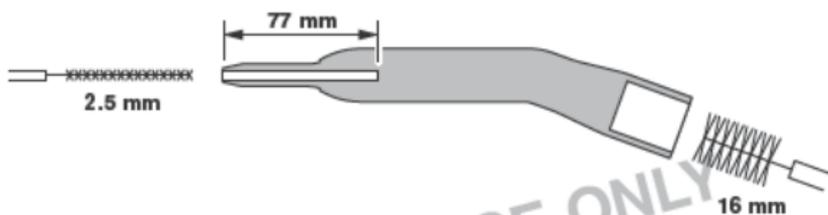
##### DRILL



##### STRAIGHT ATTACHMENTS



##### ANGLED ATTACHMENTS



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**CAUTION:** DO NOT actuate the attachment interface on the handpiece during cleaning.

- Actuate all moving parts of the equipment to clean hidden surfaces. See the *Special Cleaning Considerations: Handpieces and Attachments* table.

**SPECIAL CLEANING CONSIDERATIONS:  
 HANDPIECES AND ATTACHMENTS**

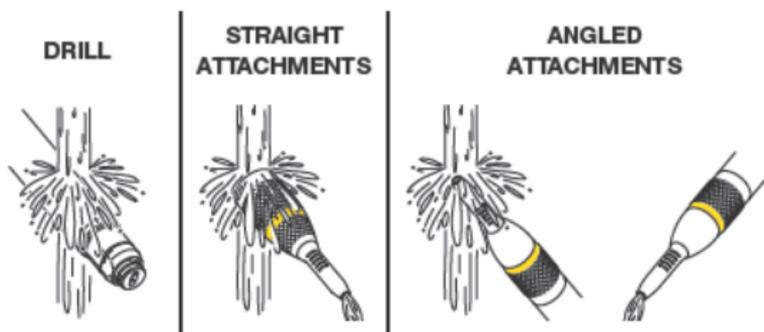
Component	Moving Parts	Critical Areas	Brush Sizes
Drill	No	Dead-ended Lumen	2.5 mm
Straight Attachments	No	Lumen, Blind Hole	2.5 mm and 16 mm
Angled Attachments	Yes	Dead-ended Lumen, Blind Hole, Lock Collar	2.5 mm and 16 mm
Irrigation Clips	No	Lumen	3 French

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#### 4.1.2 To Clean Handpieces and Attachments (continued)

6. Hold the equipment on an incline, distal end pointing down, and rinse the equipment in warm running water until all traces of detergent solution are removed. Pay particular attention to rough surfaces, lumens, hinges, blind holes, and joints between mating parts. For equipment with lumens, hold the equipment on an incline, distal end pointing up, and rinse the lumen under warm running water. For dead-ended lumens, once the water comes back out of the equipment, immediately point the distal end of the equipment down to allow the water to drain out. Repeat this step one or two more times until the water draining from the equipment is clear. Actuate all moving parts of the equipment to remove any remaining detergent solution.

**NOTE:** A final rinse of the equipment using deionized or filtered water is recommended.



7. Visually inspect the equipment for any remaining soil or detergent solution. If soil or detergent solution remains, repeat the cleaning and rinsing procedure using fresh detergent solution.
8. Allow the equipment to drain on absorbent wipes.
9. Dry the equipment with a soft, lint-free cloth or medical-grade compressed air.
10. After cleaning, inspect and test the equipment immediately. See the 5.0 *Inspection and Testing* section.

## 4.2 Automated Cleaning

### 4.2.1 Recommended Equipment

- Non-abrasive, soft, flexible, nylon-bristle brushes
- PPE as recommended by the detergent supplier (minimum: overalls, gloves, face/eye shield)
- Absorbent wipes
- Soft, lint-free cloth
- Washer-disinfector
- Detergents and rinsing agents as required by the washer-disinfector
- Warm water with an optimum temperature range of 27 to 44 °C [80 to 110 °F]. The water should not exceed 60 °C [140 °F] and should be warm to the touch.
- Medical-grade compressed air, < 140 kPa [< 20 psi]

### 4.2.2 To Clean Handpieces and Attachments

1. Remove all gross soil from the equipment using absorbent wipes or a soft, lint-free cloth moistened with the prepared detergent solution.
2. Make sure all surfaces of the equipment are thoroughly wetted using warm water.
3. Use soft brushes of appropriate diameters to clean lumens. If a lumen passes all the way through a device, make sure that the brush cleans the whole length of the lumen. For dead-ended lumens, use light pressure and do not force the brush any farther after you feel resistance. See the *Special Cleaning Considerations: Handpieces and Attachments* table.

**CAUTION:** DO NOT actuate the attachment interface on the handpiece during cleaning.

4. Actuate all moving parts of the equipment to clean hidden surfaces. See the *Special Cleaning Considerations: Handpieces and Attachments* table.
5. Hold the equipment on an incline, distal end of handpieces pointing down, and rinse the equipment in warm running water until all traces of detergent solution are removed. Pay particular attention to rough surfaces, lumens, hinges, blind holes, and joints between mating parts. Actuate all moving parts of the equipment to remove any remaining detergent solution.

#### 4.2.2 To Clean Handpieces and Attachments (continued)

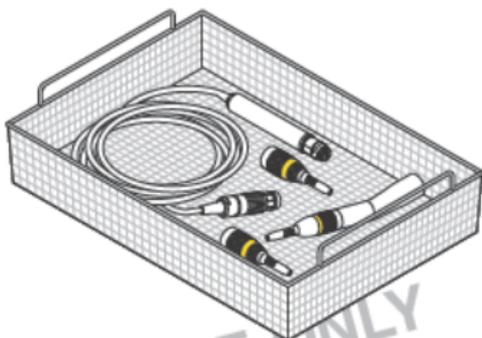
6. Visually inspect the equipment for any remaining gross soil and repeat the cleaning steps if necessary.
7. Allow the equipment to drain on absorbent wipes or load the equipment into the washer-disinfector immediately.



#### WARNINGS:

- ALWAYS load the equipment carefully to prevent movement that may inhibit proper cleaning during the automated washer-disinfector cycle.
  - DO NOT use sterilization trays to hold equipment in the washer-disinfector. Sterilization trays are for use with the sterilization process only and must be washed separately.
8. Load the equipment into the washer-disinfector in a wire basket. Always avoid contact between multiple components. If possible, orient the equipment vertically to assist in drainage. Placing the equipment in a horizontal position is also acceptable.

**NOTE:** The equipment illustrated is representational only and may not reflect the actual equipment configuration.



**CAUTION:** DO NOT use any type of lubricant in the automated washer-disinfector. Use of additional lubrication is not required and may leave residue on the equipment after cleaning.

9. Operate the washer-disinfector. The *Validated Automated Washer-Disinfector Cycle Parameters: Handpieces and Attachments* table lists the phases that should be included in the cycle.

**4.2.2 To Clean Handpieces and Attachments (continued)**

**VALIDATED AUTOMATED WASHER-DISINFECTOR CYCLE  
 PARAMETERS: HANDPIECES AND ATTACHMENTS**

Phase	Time	Water Temperature	Cleaning Agent
Pre-rinse	2 to 4 minutes	< 21 °C [< 70 °F]	Prepared detergent*
Enzyme Wash	2 to 4 minutes	43 to 60 °C [110 to 150 °F]	Prepared enzymatic detergent
Wash	2 to 4 minutes	60 to 82 °C [140 to 180 °F]	Prepared detergent
Rinse	2 to 4 minutes	43 to 82 °C [110 to 180 °F]	–
Dry Time	15 minutes	Maximum 137 °C [279 °F]	–

\*Detergent may be omitted at the pre-rinse stage if the washer-disinfector does not have this capability.

10. On completion, unload the washer-disinfector.
11. Visually inspect the equipment for remaining soil. If soil remains, repeat the cleaning process.
12. Dry the equipment with medical-grade compressed air or by heating the equipment in an oven below 110 °C [230 °F].
13. After cleaning, inspect and test the equipment immediately. See the 5.0 *Inspection and Testing* section.

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## 5.0 Inspection and Testing



### WARNINGS:

- Only individuals trained and experienced in the maintenance of reusable medical devices should inspect and test this equipment.
- Perform recommended inspection and testing as indicated in these instructions.
- DO NOT use any equipment if damage is apparent.
- DO NOT use any system component if the inspection criteria are not met.
- DO NOT disassemble or service this equipment, unless otherwise specified. If the equipment fails to meet the inspection and testing criteria, contact your Stryker sales representative or call Stryker customer service. Outside the US, contact your nearest Stryker subsidiary.

**CAUTION:** Failure to comply with the stated minor service interval may compromise the effective use of the equipment. See the *5.3 Functional Inspection* section.

### NOTES:

- The useful life of this equipment is dependent upon many factors including, but not limited to, the method and duration of each use, and the handling of the equipment between uses.
- Routine and careful inspection and functional testing of the equipment is the best method for determining the serviceable life span of the equipment.
- Maintenance documentation for this equipment is available upon request to Stryker-authorized service personnel only.

### 5.1 Limitations of Processing

Repeated processing has a minimal effect on this equipment. See the *5.2 Visual Inspection* and *5.3 Functional Inspection* sections for additional guidance on evaluating device functionality.

## 5.2 Visual Inspection

After cleaning, visually inspect the equipment before sterilization. Pay particular attention to the following:

- Locations where soil may become trapped, such as mating surfaces, hinges, and shafts
- Recessed features, such as holes and lumens
- Features where soil may be pressed into contact with the equipment

INTERVAL	ACTIVITY	CRITERIA
Before sterilization	Inspect the equipment	No visible soil, damage, signs of wear, and/or corrosion
		No missing components
		No nicks or burrs that may damage tissue, surgical gloves, and/or the sterilization wrap

## 5.3 Functional Inspection

After cleaning, check the functionality and integrity of the equipment before sterilization.

INTERVAL	ACTIVITY	CRITERIA
Before sterilization	Test the equipment	No loose components
		All moving parts move freely
		Equipment operates as expected
		No unusual sounds or vibrations
Every 12 months	Return the equipment to Stryker	Minor service interval

## 6.0 Preparation for Sterilization



**WARNING:** ALWAYS use a chemical indicator within every sterilization load to make sure the proper sterilization conditions of time, temperature, and saturated steam are achieved.

Where appropriate, load the equipment into an appropriate sterilization tray. See the *Accessories* section.

## 7.0 Packaging

Enclose the equipment using a sterilization wrap that is suitable for the equipment, such as a grade 500 or higher, before sterile processing.

Follow the Association for the Advancement of Medical Instrumentation (AAMI) and the Association of periOperative Registered Nurses (AORN) recommended guidelines for appropriate wrapping configurations.

**NOTE:** The packaging material will maintain the sterility of the equipment after exposure.

## 8.0 Handpiece and Attachment Sterilization



### WARNINGS:

- Sterilize the equipment as indicated before first and every use.
- Prior to sterilization, remove all detachable components and single use cutting accessories from the handpieces. Detachable components include attachments and irrigation clips.
- Use the sterilization methods as indicated in these instructions. Using other sterilization methods may prevent proper sterilization of the equipment and/or damage the equipment.

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## 8.0 Handpiece and Attachment Sterilization (continued)



### WARNINGS:

- Follow the recommended dry times to prevent moisture from accumulating inside the equipment. Moisture may prevent proper sterilization of the equipment and/or cause the equipment to corrode.
- After sterilization, allow the equipment to cool to room temperature prior to use. Failure to comply may result in burned patient tissue or healthcare staff, and/or damage to the equipment.

### CAUTIONS:

- ALWAYS make sure the equipment is completely dry before sterilization.
- Poor water quality can adversely affect the life of medical devices. ALWAYS follow the water quality requirements per AAMI TIR 34.

### NOTES:

- Steam sterilization (moist heat) is recommended. Stryker has validated several autoclave cycles for the sterilization of this equipment. However, autoclave design and performance can affect the efficacy of the process. Healthcare facilities should verify the process they use, employing the actual equipment and operators that routinely process the equipment.
- The final responsibility for verification of sterilization techniques lies directly with the hospital. To ensure the efficacy of hospital processing, all cycles and methods should be verified for different sterilization chambers, wrapping methods and/or various loading configurations.
- If wet trays or equipment are discovered, a change in the product load configuration or a longer dry time may be necessary.

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## 8.0 Handpiece and Attachment Sterilization (continued)

To obtain optimum performance, perform one of the following sterilization cycles validated by Stryker:

### VALIDATED<sup>1</sup> STEAM STERILIZATION CYCLE PARAMETERS<sup>2</sup>: HANDPIECES AND ATTACHMENTS

Wrapping Method	Cycle	Sterilization Temperature	Minimum Exposure Time	Minimum Dry Time
Wrapped	Dynamic Air Removal (Pre-vacuum)	132 °C [270 °F]	4 minutes	30 minutes
		134 °C [273 °F]	3 minutes <sup>3</sup>	30 minutes

<sup>1</sup> Validation is based on the AAMI protocol.

<sup>2</sup> Sterilization parameters for Australia/New Zealand per AS/NZS 4187-2003.  
Sterilization parameters for the Netherlands per Field Standard for Loaner Instruments, Revision 03.02, April 2008.  
Sterilization parameters for Europe and the United Kingdom per EN ISO 17664.  
Sterilization parameters for Canada per CSA ISO 17664.

<sup>3</sup> Minimum exposure time may be extended to 18 minutes.

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## 8.0 Handpiece and Attachment Sterilization (continued)



**WARNING:** DO NOT place equipment into an insert tray or a sterilization case for immediate-use steam sterilization.

**CAUTION:** Stryker does not recommend immediate-use steam sterilization for routine sterilization of medical devices. Immediate-use steam sterilization should only be used when individual devices require immediate sterilization and use.

### VALIDATED STEAM STERILIZATION CYCLE PARAMETERS: HANDPIECES AND ATTACHMENTS (CONTINUED)

Wrapping Method	Cycle	Sterilization Temperature	Minimum Exposure Time	Dry Time
Unwrapped	Dynamic Air Removal (Pre-vacuum)	132 °C [270 °F]	4 minutes	No dry time
	Gravity	132 °C [270 °F]	10 minutes	No dry time

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## 9.0 Storage and Handling

### 9.1 Sterile Equipment



#### WARNINGS:

- ALWAYS transport wrapped equipment with care to prevent damaging the sterile barrier.
- ALWAYS store wrapped, processed equipment in a controlled environment and avoid extremes in temperature and moisture.
- Excessive handling of wrapped equipment will increase the likelihood of damaging the sterile barrier and may lead to contamination.

**NOTE:** See the instructions for use supplied with the sterilization wrap for maximum shelf-life information.

### 9.2 Non-sterile Equipment

To ensure longevity, performance, and safety, use of the original packaging materials is recommended when storing or transporting this equipment.

## Disposal/Recycle



#### WARNINGS:

- ALWAYS follow the current local regulations governing the safe handling and disposal of sharps.
- ALWAYS follow the current local regulations governing biohazard waste to safely handle and dispose of surgical waste.

Follow the current local recommendations and/or regulations governing environmental protection and the risks associated with recycling or disposing of the equipment at the end of its useful life.

ssed under FOIA Request # 2015-7918; Released by CDRH

ct FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov

ES/DE/FR/IT 5450-001-710  
JA/ZH/KO 5450-001-720  
SV/DA/FI/PT/NO 5450-001-730  
PL/EL 5450-001-750



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Instruments

K141935/5001

August 25, 2014

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

FDA CDRH DMC

AUG 27 2014

Received

**Re: Stryker Response to FDA Additional Information Request / Telephone Hold for K141935 Stryker S2 Drill**

<b>Device Name</b>	<b>Stryker S2 Drill</b>
<b>Common Name</b>	<b>Ear, nose, and throat electric or pneumatic surgical drill</b>
<b>FDA Establishment Number</b>	<b>1811755</b>
<b>Company Name</b>	<b>Stryker Instruments</b>
<b>Company Address</b>	<b>4100 East Milham Ave. Kalamazoo, Michigan 49001 USA</b>

To whom it may concern:

Stryker Instruments is hereby submitting in duplicate this response to FDA additional information request/telephone hold for K141935 Special 510(k): Stryker S2 Drill. **The eCopy is an exact duplicate of the paper copy.**

The purpose of this response submission is to provide FDA with the requested information in order to seek clearance for K141935, Stryker S2 Drill. This response has been prepared in accordance with section 510(k) of the Federal Food, Drug and Cosmetic Act, FDA Guidance *The New 510(k) Paradigm Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications* (20Mar1998).

We consider our intent to market this device as confidential commercial information and request that FDA treat it as such. We have taken precautions to protect the confidentiality of the intent to market this device. We understand that the submission to the government of false information is prohibited by 18 U.S.C. 1001 and 21 U.S.C. 331(q).

2 copies ICT

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**Instruments**

If you have any questions regarding this submission, please contact me at (269) 389-4796, email at [vishal.kanani@stryker.com](mailto:vishal.kanani@stryker.com). In the event that I cannot be reached, please contact Jeanne Warner, Regulatory Affairs Manager, at (269) 389-5299.

Sincerely,

A handwritten signature in black ink that reads "Vishal Kanani". The signature is written in a cursive style and is underlined with two parallel lines.

Vishal Kanani  
Sr. Regulatory Affairs Representative  
Stryker Instruments  
Phone: (269) 389-4796  
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Email: [vishal.kanani@stryker.com](mailto:vishal.kanani@stryker.com)

## **SECTION 1**

### **Special 510(k) Cover Letter**

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Instruments

August 25, 2014

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

**Re: Stryker Response to FDA Additional Information Request / Telephone Hold for K141935 Stryker S2 Drill**

<b>Device Name</b>	<b>Stryker S2 Drill</b>
<b>Common Name</b>	<b>Ear, nose, and throat electric or pneumatic surgical drill</b>
<b>FDA Establishment Number</b>	<b>1811755</b>
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<b>Company Address</b>	<b>4100 East Milham Ave. Kalamazoo, Michigan 49001 USA</b>

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**Instruments**

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Sincerely,

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## **Section 2**

### **Stryker Response to FDA Additional Information Request / Telephone Hold for**

### **K141935 – Stryker S2 Drill**

**Stryker Response to FDA Additional Information Request/Telephone Hold for K141935**  
**Stryker S2 Drill**

(b)(4)

