INTEGRA
LIMIT UNCERTAINTY

25 March 2016

-Via Federal Express-

510(k) Document Mail Center (WO66-G609)
Office of Device Evaluation
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

RE: Abbreviated Premarket Notification 510(k): K160811
CRW™ Stereotactic System

Payment Identification Number: (b)(4)

Dear Sir or Madam:

Integra LifeSciences Corporation hereby submits this revised eCopy for the Abbreviated 510(k) notification for its CRW™ Stereotactic System, K160811. The CRW system enables neurosurgeons to position fine instruments in the brain with sub-millimeter accuracy. The main purpose of this submission is to request permission to add MR safety information to the product labeling for certain components of the system. The CRW Stereotactic System was originally cleared on October 26, 1995 (K944463). Please see **Appendix 1** for the corresponding Substantial Equivalence letter.

Integra previously submitted an Abbreviated 510(k) to add MR safety information to the product labeling (K141671, submitted on July 1, 2014) and received a Refuse To Accept letter on July 7, 2014. It was determined that additional testing would be required to meet some of the identified deficiencies and that the resulting testing timeline would go beyond the 180 day window for completion. Hence, Integra withdrew K141671 on December 8, 2014. On March 24, 2016 Integra received an eCopy Hold Letter. This submission contains the revised eCopy.

The submission contents are in accordance with the requirements outlined in 21 CFR 807 Subpart E and formatted in accordance with FDA Guidance for Industry and FDA Staff for Traditional and Abbreviated 510(k)s (issued on August 12, 2005).

There have been other changes made to components of the system including changes of materials and minor design changes since the clearance of the original 510(k) unrelated to the main purpose of this 510(k). These changes are described in **Section 11 – Device Description.** None of the changes required the filing of a new 510(k).

To support the claim of MR conditional use, testing has been conducted according to FDA's Guidance for Industry and FDA Staff: *Establishing Safety and Compatibility of Passive Implants*

Integra • 311 Enterprise Drive, Plainsboro, NJ 08536
609-275-0500 • 800-654-2873 toll free • 609-275-9445 fax • integralife.com

in the Magnetic Resonance (MR) Environment issued August 21, 2008 and to the relevant ASTM standards listed in the FDA Guideline.

Section 18 - Performance Testing - Bench provides a summary of the testing conducted to show the device meets all applicable ASTM standards for use in an MR conditional environment. **Section 21.2 – Utilization of Standards** provides the list of standards to cover the relevant ASTM standards.

The CRW Stereotactic System is substantially equivalent to itself for design and components. As noted above, testing to support an MR conditional claim was performed in accordance with ASTM standards and in agreement with the FDA guideline covering use in the magnetic resonance environment.

CRW Stereotactic System with MR safety information added to the product labeling and the predicate device have the same intended use. Device design, technology, classification, product code and measureable parameters are unchanged with the exception of the addition of conditional MR use. There are no differences between the proposed device labeling change and the predicate device that raise any new safety and efficacy concerns; all issues related to MR conditional use have been addressed with testing, which is fully described in **Section 18 – Performance Testing - Bench**.

The design and use of CRW Stereotactic System are presented in the table below:

	CRW Stereotactic System	
Question	**Yes**	**No**
Is the device intended for prescription use?	X	
Is the device intended for over-the-counter use?		X
Does the device contain components from a tissue or biologic		X
Is the device provided sterile?	X *	
Is the device intended for single use?	X *	
Is the device a reprocessed single use device?		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 * anchor	

* **Only** the Disposable Head Ring Screws are provided sterile and are for single use only. The Disposable Head Ring Screws are used to anchor the Universal Compact Head Ring to the skull.

** The system has a software component; however, the software component is covered under a separate 510(k); neither the CRW Arc nor the software are impacted by the change covered under this 510(k) because neither is used during MR imaging.

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LIMIT UNCERTAINTY

The existence of this Premarket Notification and the data and information that it contains are Confidential, and the protection afforded to such confidential information by 21 CFR 807.95, and other applicable laws is hereby claimed.

This eCopy is an exact duplicate of the paper submission. It has been revised to address the deficiencies noted in the eCopy Hold Letter received March 24, 2016. No other changes have been made other than those to address the highlighted deficiencies.

Thank you in advance for your consideration of our application. If there are any questions, concerns or requests for additional information, please do not hesitate to contact me at 609-936-5531 or via e-mail at timothy.connors@integralife.com.

Sincerely,

Timothy J. Connors

Timothy Connors
Senior Regulatory Affairs Specialist

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24 March 2016

-Via Federal Express-

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

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The submission contents are in accordance with the requirements outlined in 21 CFR 807 Subpart E and formatted in accordance with FDA Guidance for Industry and FDA Staff for Traditional and Abbreviated 510(k)s (issued on August 12, 2005).

There have been other changes made to components of the system including changes of materials and minor design changes since the clearance of the original 510(k) unrelated to the main purpose of this 510(k). These changes are described in **Section 11 – Device Description.** None of the changes required the filing of a new 510(k).

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INTEGRA
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** The system has a software component; however, the software component is covered under a separate 510(k); neither the CRW Arc nor the software are impacted by the change covered under this 510(k) because neither is used during MR imaging.

The existence of this Premarket Notification and the data and information that it contains are Confidential, and the protection afforded to such confidential information by 21 CFR 807.95, and other applicable laws is hereby claimed.

Per the recommendations outlined in the FDA's Guidance for Industry and FDA staff issued December 3, 2015 *eCopy Program for Medical Device Submissions*, an electronic copy is being provided with this submission. The eCopy is an exact duplicate of the paper submission.

Thank you in advance for your consideration of our application. If there are any questions, concerns or requests for additional information, please do not hesitate to contact me at 609-936-5531 or via e-mail at timothy.connors@integralife.com.

Sincerely,

Timothy J. Connors

Timothy Connors
Senior Regulatory Affairs Specialist

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510(k) PREMARKET NOTIFICATION

Abbreviated 510(k)

CRW Stereotactic System

Universal Compact Head Ring (UCHR), Luminant Localizer Frame (LL01)
and Disposable Head Ring Screws (DHRSS, DHRSL)

Integra LifeSciences Corporation
311 Enterprise Drive
Plainsboro, NJ 08536, USA

TABLE OF CONTENTS

LIST OF APPENDICES

SECTION 1 – MEDICAL DEVICE USER FEE COVER SHEET (FORM FDA 3601)

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION **MEDICAL DEVICE USER FEE COVER SHEET**	PAYMENT IDENTIFICATION NUMBER: (b)(4) Write the Payment Identification number on your check.
A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html	
1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code) INTEGRA LIFESCIENCS CORP 311 ENTERPRISE DRIVE PLAINSBORO NJ 08536 US 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) (b)(4)	2. CONTACT NAME Timothy Connors 2.1 E-MAIL ADDRESS timothy.connors@integralife.com 2.2 TELEPHONE NUMBER (include Area code) 609-9365531 2.3 FACSIMILE (FAX) NUMBER (Include Area code)
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: [X] 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 [X] CDRH [ ] CBER 3.2 Select one of the types below [X] 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 [X] 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? [X] 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 submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)	

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

[ ] This application is the first PMA submitted by a qualified small business, including any affiliates

[ ] The sole purpose of the application is to support conditions of use for a pediatric population

[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only

[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

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 [X] NO

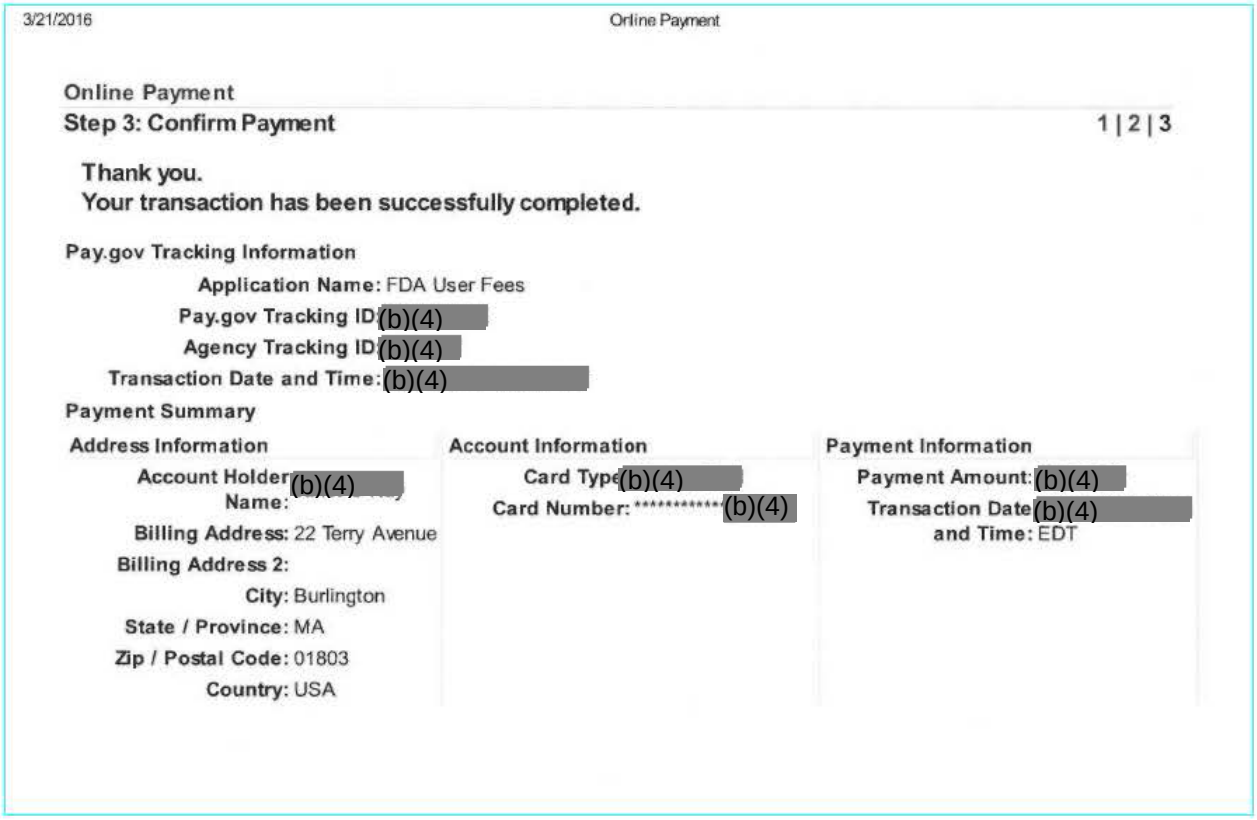
PAPERWORK REDUCTION ACT STATEMENT

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) 21-Mar-2016



3/21/2016 Online Payment

Online Payment

Step 3: Confirm Payment 1 | 2 | 3

Thank you.
Your transaction has been successfully completed.

Pay.gov Tracking Information

Application Name: FDA User Fees
Pay.gov Tracking ID: (b)(4)
Agency Tracking ID: (b)(4)
Transaction Date and Time: (b)(4)

Payment Summary

Address Information	Account Information	Payment Information
Account Holder Name: (b)(4)	**Card Type:** (b)(4)	**Payment Amount:** (b)(4)
Billing Address: 22 Terry Avenue	**Card Number:** ********** (b)(4)	**Transaction Date and Time:** (b)(4) EDT
Billing Address 2:		
City: Burlington		
State / Province: MA		
Zip / Postal Code: 01803		
Country: USA		

SECTION 2 - CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

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

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
03/24/2016	(b)(4)	not known yet

SECTION A — TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Request for Feedback
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-Submission
☐ Premarket Report	☐ Special	☐ Notice of Completion	☐ Traditional	☐ Informational Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Submision Issue Meeting
☐ Amendment	☐ 30-day Supplement		☒ Abbreviated (Complete section I, Page 5)	☐ Day 100 Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Agreement Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Determination Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Study Risk Determination
	☐ Amendment to PMA & HDE Supplement			☐ Other *(specify)*:
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission)*:
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

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	Establishment Registration Number *(if known)*		
Integra LifeSciences Corporation	(b)(4)		
Division Name *(if applicable)*	**Phone Number** *(including area code)*		
	609-936-5531		
Street Address	**FAX Number** *(including area code)*		
311 Enterprise Drive	N/A		
City	**State / Province**	**ZIP/Postal Code**	**Country**
Plainsboro	NJ	08536	USA
Contact Name			
Timothy Connors			
Contact Title	**Contact E-mail Address**		
Senior Regulatory Affairs Associate	timothy.connors@integralife.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**		

FORM FDA 3514 (1/13) Page 1 of 5 Pages

SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE

- ☐ New Device
- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site

- ☐ Change in design, component, or specification:
  - ☐ Software / Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*

- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager

- ☐ Process change:
  - ☐ Manufacturing ☐ Packaging
  - ☐ Sterilization
  - ☐ Other *(specify below)*

- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance Characteristics
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*

- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment

- ☐ Response to FDA correspondence:

- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address

- ☐ Other Reason *(specify)*:

SECTION D2 REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access

- ☐ Change in:
  - ☐ Correspondent / Applicant
  - ☐ Design / Device
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol - Feasibility
  - ☐ Protocol - Other
  - ☐ Sponsor

- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ Final

- ☐ Response to FDA Letter Concerning:
  - ☐ Conditional Approval
  - ☐ Deemed Approved
  - ☐ Deficient Final Report
  - ☐ Deficient Progress Report
  - ☐ Deficient Investigator Report
  - ☐ Disapproval
  - ☐ Request Extension of Time to Respond to FDA
  - ☐ Request Meeting
  - ☐ Request Hearing

- ☐ Other Reason *(specify)*:

SECTION D3 REASON FOR SUBMISSION - 510(k)

- ☐ New Device
- ☐ Additional or Expanded Indications
- ☐ Change in Technology

- ☒ Other Reason *(specify)*:

Labeling modification to support and "MR Conditional" claim

FORM FDA 3514 (1/13) Page 2 of 5 Pages

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	HAW	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

- [x] 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	K944463	1	CRW-1 System	1	same
2		2		2	
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

Neurological Stereotaxic Instrument

	Trade or Proprietary or Model Name for This Device		Model Number
1	CRW Stereotactic System	1	UCHRA, LL01, DHRSS, DHRSL
2		2	
3		3	
4		4	
5		5	

FDA document numbers of all prior related submissions *(regardless of outcome)*

1 K141671	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: HAW

C.F.R. Section *(if applicable)*: 882.4560

Device Class

- [ ] Class I
- [x] Class II
- [ ] Class III
- [ ] Unclassified

Classification Panel

Neurology

Indications *(from labeling)*

The CRW-1 System is a stereotactic system to be used for neurosurgical procedures that require precise target localization, such as craniotomies, biopsies, and functional stereotaxy.

FORM FDA 3514 (1/13) Page 3 of 5 Pages

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

FDA Document Number (If known)

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number: 3004608878	☒ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler	
Company / Institution Name: Integra LifeSciences Corporation		Establishment Registration Number: 3004608878		
Division Name (If applicable)		Phone Number (Including area code): 513-5337932		
Street Address: 4900 Charlemar Drive		FAX Number (Including area code): N/A		
City: Cincinnati		State / Province: OH	ZIP Code: 45227	Country: USA
Contact Name: Kerry Turner	Contact Title: Senior Director, Quality Assurance	Contact E-mail Address: kerry.turner@integralife.com		

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number: (b)(4)	☐ Manufacturer ☐ Contract Manufacturer	☒ Contract Sterilizer ☐ Repackager / Relabeler	
Company / Institution Name: (b)(4)		Establishment Registration Number: (b)(4)		
Division Name (If applicable)		Phone Number (Including area code): (b)(4)		
Street Address: (b)(4)		FAX Number (Including area code): N/A		
City: (b)(4)		State / Province: (b	ZIP Code: (b)(4)	Country: USA
Contact Name: (b)(4)	Contact Title	Contact E-mail Address		

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ 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		

FORM FDA 3514 (1/13) Add Continuation Page Page 4 of 5 Pages

SECTION I	UTILIZATION OF STANDARDS				
Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.					
1	Standards No. F2503	Standards Organization ASTM	Standards Title Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment	Version -13	Date 3/24/2016
2	Standards No.	Standards Organization	Standards Title	Version	Date
3	Standards No.	Standards Organization	Standards Title	Version	Date
4	Standards No.	Standards Organization	Standards Title	Version	Date
5	Standards No.	Standards Organization	Standards Title	Version	Date
6	Standards No.	Standards Organization	Standards Title	Version	Date
7	Standards No.	Standards Organization	Standards Title	Version	Date

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

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.

FORM FDA 3514 (1/13) Page 5 of 5 Pages

SECTION 3 - 510(K) COVER LETTER

INTEGRA
LIMIT UNCERTAINTY

25 March 2016 **-Via Federal Express-**

510(k) Document Mail Center (WO66-G609)
Office of Device Evaluation
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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Dear Sir or Madam:

Integra LifeSciences Corporation hereby submits this revised eCopy for the Abbreviated 510(k) notification for its CRW™ Stereotactic System, K160811. The CRW system enables neurosurgeons to position fine instruments in the brain with sub-millimeter accuracy. The main purpose of this submission is to request permission to add MR safety information to the product labeling for certain components of the system. The CRW Stereotactic System was originally cleared on October 26, 1995 (K944463). Please see **Appendix 1** for the corresponding Substantial Equivalence letter.

Integra previously submitted an Abbreviated 510(k) to add MR safety information to the product labeling (K141671, submitted on July 1, 2014) and received a Refuse To Accept letter on July 7, 2014. It was determined that additional testing would be required to meet some of the identified deficiencies and that the resulting testing timeline would go beyond the 180 day window for completion. Hence, Integra withdrew K141671 on December 8, 2014. On March 24, 2016 Integra received an eCopy Hold Letter. This submission contains the revised eCopy.

The submission contents are in accordance with the requirements outlined in 21 CFR 807 Subpart E and formatted in accordance with FDA Guidance for Industry and FDA Staff for Traditional and Abbreviated 510(k)s (issued on August 12, 2005).

There have been other changes made to components of the system including changes of materials and minor design changes since the clearance of the original 510(k) unrelated to the main purpose of this 510(k). These changes are described in **Section 11 – Device Description.** None of the changes required the filing of a new 510(k).

To support the claim of MR conditional use, testing has been conducted according to FDA's Guidance for Industry and FDA Staff: *Establishing Safety and Compatibility of Passive Implants*

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in the Magnetic Resonance (MR) Environment issued August 21, 2008 and to the relevant ASTM standards listed in the FDA Guideline.

Section 18 - Performance Testing - Bench provides a summary of the testing conducted to show the device meets all applicable ASTM standards for use in an MR conditional environment. **Section 21.2 – Utilization of Standards** provides the list of standards to cover the relevant ASTM standards.

The CRW Stereotactic System is substantially equivalent to itself for design and components. As noted above, testing to support an MR conditional claim was performed in accordance with ASTM standards and in agreement with the FDA guideline covering use in the magnetic resonance environment.

CRW Stereotactic System with MR safety information added to the product labeling and the predicate device have the same intended use. Device design, technology, classification, product code and measureable parameters are unchanged with the exception of the addition of conditional MR use. There are no differences between the proposed device labeling change and the predicate device that raise any new safety and efficacy concerns; all issues related to MR conditional use have been addressed with testing, which is fully described in **Section 18 – Performance Testing - Bench**.

The design and use of CRW Stereotactic System are presented in the table below:

	CRW Stereotactic System	
Question	**Yes**	**No**
Is the device intended for prescription use?	X	
Is the device intended for over-the-counter use?		X
Does the device contain components from a tissue or biologic		X
Is the device provided sterile?	X *	
Is the device intended for single use?	X *	
Is the device a reprocessed single use device?		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 * anchor	

* **Only** the Disposable Head Ring Screws are provided sterile and are for single use only. The Disposable Head Ring Screws are used to anchor the Universal Compact Head Ring to the skull.

** The system has a software component; however, the software component is covered under a separate 510(k); neither the CRW Arc nor the software are impacted by the change covered under this 510(k) because neither is used during MR imaging.

INTEGRA
LIMIT UNCERTAINTY

The existence of this Premarket Notification and the data and information that it contains are Confidential, and the protection afforded to such confidential information by 21 CFR 807.95, and other applicable laws is hereby claimed.

This eCopy is an exact duplicate of the paper submission. It has been revised to address the deficiencies noted in the eCopy Hold Letter received March 24, 2016. No other changes have been made other than those to address the highlighted deficiencies.

Thank you in advance for your consideration of our application. If there are any questions, concerns or requests for additional information, please do not hesitate to contact me at 609-936-5531 or via e-mail at timothy.connors@integralife.com.

Sincerely,

Timothy J. Connors

Timothy Connors
Senior Regulatory Affairs Specialist

Integra ▪ 311 Enterprise Drive, Plainsboro, NJ 08536
609-275-0500 ▪ 800-654-2873 toll free ▪ 609-275-9445 fax ▪ integralife.com

ADMINISTRATIVE INFORMATION

Type of 510(k):	Abbreviated 510(k)
Trade Name:	CRW Stereotactic System
Classification:	Neurological Stereotaxic Instrument
Device Class:	Class II, under 21 CFR 882.4560
Classification Panel:	Neurology
Product Code:	HAW
Predicate Devices:	CRW-1 SYSTEM; K944463 Product Code: HAW
Contact Person:	Timothy Connors Senior Regulatory Affairs Specialist Integra LifeSciences Corporation Office: 609-936-5531 E-mail: timothy.connors@integralife.com
Alternate Contact:	Matthew Hibbert Senior Manager, Regulatory Affairs Integra LifeSciences Corporation Telephone: 781-565-1307 E-mail: matthew.hibbert@integralife.com

Owner:	Integra LifeSciences Corporation 311 Enterprise Drive Plainsboro, NJ 08536 USA Telephone: 609-936-5447 Establishment Registration Number: 9004007
Manufacturing Site:	Integra LifeSciences Corporation (Ohio) 4900 Charlemar Drive Building A Cincinnati, OH 45227 Tele: 513-533-7979 Establishment Registration Number: 3004608878
Sterilization Facility:	Sterigenics 84 Park Road Queensbury, NY 12804 Office: 518-743-9272

SECTION 4 - INDICATIONS FOR USE STATEMENT

Indications for Use

510(k) Number (if known): _____

Device Name: **CRW-1 System**

Indications For Use:

The CRW-1 System is a stereotactic system to be used for neurosurgical procedures that require precise target localization, such as craniotomies, biopsies, and functional stereotaxy.

Prescription Use ___X___ **AND/OR** **Over-The Counter Use_____**
(Per 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

SECTION 5 - 510(K) SUMMARY

510(k) SUMMARY

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92.

807.92(a)(1) – Submitter information	
Name	Integra LifeSciences Corporation
Address	311 Enterprise Drive Plainsboro, NJ 08536 USA
Phone Number	609-936-5531
Fax Number	NA
Establishment Registration Number	3003418325
Name of Contact Person	Timothy Connors, Senior Regulatory Affairs Specialist
Date Prepared	March 24, 2016
807.92(a)(2) – Name of device	
Trade or Propriety Name	CRW™ Stereotactic System
Common or Usual Name	Universal Compact Head Ring Luminant Localizer Frame Disposable Head Ring Screws
Classification Name	Neurological Stereotaxic Instrument
Classification Panel	Neurology
Regulation	882.4560
Product Code(s)	HAW
807.92(a)(3) - Legally marketed device(s) to which equivalence is claimed	
CRW-1 SYSTEM; K944463	
807.92(a)(4) - Device description	

Part of the CRW™ Stereotactic System is comprised of the following components:

- Universal Compact Head Ring (UCHR),
- Luminant Localizer Frame (LL01)
- Disposable Head Ring Screws (DHRSS- Short, DHRSL- long)

The Universal Compact Head Ring is placed on the patient and secured with the Disposable Head Ring Screws. The Luminant Localizer Frame is then attached to the base ring and the patient is taken to the neuroradiology department where a CT or MR imaging is performed. The image obtained in conjunction with the localizer allows the neurosurgeon to compute the exact three dimensional position of the region of interest.

807.92(a)(5) – Intended use of the device	
Indications for Use	The CRW-1 System is a stereotactic system to be used for neurosurgical procedures that require precise target localization, such as craniotomies, biopsies, and functional stereotaxy.

807.92(a)(6) Summary of the technological characteristics of the device compared to the predicate

The CRW™ Stereotactic System design is not changing as a result of this submission; this submission is primarily for a labeling change.

CRW Stereotactic System and the predicate device have the same device classification, product code and measureable parameters as outlined within the submission.

807.92(b)(1-2) – Nonclinical tests submitted

CRW Stereotactic System was tested in accordance with FDA's Guidance: *Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance Environment* (August 21, 2008 and the relevant ASTM Standards covered in the guidance document. Testing includes Magnetic Resonance testing only to support an MR conditional claim for components used in the MR environment.

Additional tests to support sterilization information, shelf life information and biocompatibility have also been included.

807.92(b)(3) – Conclusions drawn from non-clinical data

All necessary testing has been conducted per ASTM standards for the relevant CRW Stereotactic System components to be used in an MR environment (1.5 T and 3.0 T) and the test results support the addition of an MR conditional claim to the device labeling. All other testing performed raised no additional concerns of safety or efficacy. In conclusion, the components are safe and effective for use under conditions specified in the product labeling and the device is substantially equivalent to the predicate device.

SECTION 6 - TRUTHFUL AND ACCURATE STATEMENT

Truthful and Accurate Statement

Premarket Notification 510(k) Submission

TRUTHFUL AND ACCURATE STATEMENT
[As Required by 21 CFR 807.87 (k)]

I certify that, in my capacity as Senior Regulatory Affairs Specialist at Integra LifeSciences Corporation, 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.

Timothy D. Connors

Date: 24MAR2016

Timothy Connors
Senior Regulatory Affairs Specialist

SECTION 7 - CLASS III SUMMARY AND CERTIFICATION

This Section Does Not Apply

SECTION 8 - FINANCIAL CERTIFICATION OR DISCLOSURE STATEMENT

This Section Does Not Apply

SECTION 9 - DECLARATIONS OF CONFORMITY AND SUMMARY REPORTS

DECLARATIONS OF CONFORMITY AND SUMMARY REPORTS

The proposed Abbreviated 510(k) relies on the use of guidance documents and recognized standards.

The MR testing plan and execution took place in late 2013 and early 2014, respectively. Since that time, there were two updates made to items referenced in the testing documentation:

- The FDA Guidance document issued August 21, 2008 *Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment* was updated on December 11, 2014
- The ASTM F2052 standard *Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment* was updated from revision "-06e1" to the current version of "-14."

The revised versions of the documents were reviewed against the previous versions that were tested against in this submission. Integra believes that the revisions to the two documents do not affect the testing results and conclusions drawn, meaning the devices within the scope of this submission are compliant with ASTM F2052-14 and the updated FDA Guidance document issued December 11, 2014. However, to remain transparent throughout the submission, the actual versions of the documents tested to have been left in place.

Guidance Document

Guidance for Industry and FDA Staff: Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment – August 21, 2008

- This guidance addresses testing and labeling of passive implants for safety and compatibility in the magnetic resonance (MR) environment.

The FDA Guidance for Industry and FDA Staff: *Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment* issued August 21, 2008 refers to ASTM Standards for testing to determine safety in a magnetic resonance environment and the relevant ASTM standards are listed below.

FDA Recognized Standards

Standard Number	Standard Organization	Standard Title
F2052-06el	ASTM	Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment

Standard Number	Standard Organization	Standard Title
F2119-07	ASTM	Test Method for Evaluating MR Image Artifacts from Passive Implants
F2182-11a	ASTM	Test Method For Measuring Radio Frequency Induced Heating On or Near Passive Implants During Magnetic Resonance Imaging
F2213-06	ASTM	Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment.
F2503-13	ASTM	Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment

Protocol (b)(4) - Experimental Test Protocol: MR Safety Testing of the DHRS, UCHRA, and LL0l Devices (**Appendix 3.1**)

Final Report (b)(4) - Magnetic Resonance Imaging Safety Testing of the CRW Stereotactic System: DHRS, UCHRA, and LL01 (**Appendix 3.2**)

Accessory Memo (b)(4) - Displacement Force Testing of the UCHREBA, HRW, and Cleaning Tap (**Appendix 3.3**)

A summary of the test methods and test results are provided in **Section 18 – Performance Testing – Bench**.

Name and address of the test laboratory or certification body

(b)(4)

SECTION 10 - EXECUTIVE SUMMARY

EXECUTIVE SUMMARY

10.1 Background Information and Purpose of This Submission

The Cosman-Roberts Wells (CRW™ 1) System is a stereotactic system used to aid in neurosurgical procedures that require precise target localization, such as craniotomies, biopsies, and functional Stereotaxy for Deep Brain Stimulation and electrode placement. The system utilizes various components, such as a head ring, head ring screws, localizer frame, CRW Arc and stereotactic planning software, to aid in accurate, precise target localization to achieve access to targeted regions in the brain. A cranial stabilization Head Ring is instrumented on the patient's head utilizing self-penetrating Head Ring screws that are screwed into the skull for rigid fixation. Planning and localization of the target is achieved by a combination of radiographic imaging with a localizer frame attached to the Head Ring, and planning software (StereoCalc™, covered under a separate 510(k)) to provide stereotactic coordinates and settings for the CRW Arc part of the system.

The CRW 1 is comprised of the CRW Stereotactic System and the CRW Arc System. The CRW Arc is used during surgery only and is not part of this 510(k). This 510(k) covers the CRW Stereotactic System which is comprised of the below-listed components that are used prior to surgery and would be the components used in an MR environment. The components include:

- Universal Compact Head Ring Assembly (UCHR/UCHRA)
- Luminant Localizer Frame (LL01)
- Disposable Head Ring Screws (DHRSS- Short, DHRSL- Long)

Accessory components are provided for the system and have been covered in the original 510(k). These accessories are not required for use in an MR environment. However, to err on the side of caution, three of the accessories that a user might inadvertently bring to an MR environment were also tested. These include the Ear Bar Assembly, the Head Ring Wrench and the Cleaning Tap.

10.2 Integra Cosman-Roberts-Wells (CRW) Stereotactic System

10.2.1 The Universal Compact Head Ring and accessories (Figure 10.1)

Head Rings serve as the general stereotactic treatment platform. Head Rings are used to provide a reference frame for instrumentation used for precise spatial localization and treatment of physiologic targets for stereotactic neurosurgical procedures such as craniotomies, biopsies, functional neurosurgery, and radiation therapy. Head Rings are delivered to the user non-sterile, and are reusable.

Figure 10.1 Universal Compact Head Ring Assembly

10.2.2 Luminant Localizer Frame

The Luminant Localizer Frame is a universal localizer designed for use in both MR and CT imaging. The Luminant Localizer is shown below in **Figure 10.2**. The localizer frames are delivered to the user non-sterile and are reusable.

Figure 10.2 – Localizer Frame

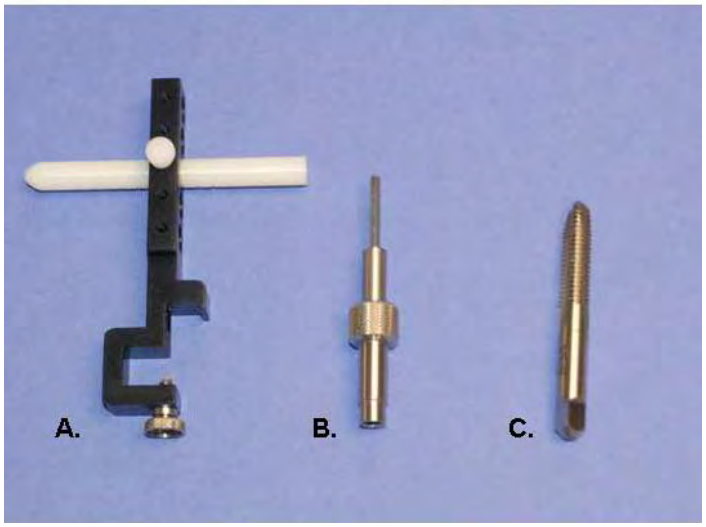
10.2.3 Disposable Head Ring Screws (DHRSS- Short, DHRSL- Long)

The Disposable Head Ring Screws (DHRS) are used with the CRW Stereotactic System to assist in anchoring the head ring to the patient's skull. The screws are provided in two sizes: long head ring screws are 48mm and short head ring screws are 36mm. The screws contain an inner aluminum pin to provide strength. The screws are provided sterile and for single use. The screws are shown below in **Figure 10.3**.

Figure 10.3 – Disposable Head Ring Screws

10.2.4 The accessories that were tested are shown below in Figure 10.4.

Figure 10.4 Test samples: (A.) Ear Bar Assembly, (B.) Head Ring Wrench, and (C.) Cleaning Tap.



10.3 Testing

The components described above (Disposable Head Ring Screws (DHRS), the Universal Compact Head Ring Assembly (UCHRA) System, and the Luminant Localizer (LL01)) were evaluated to support a claim of Magnetic Resonance Imaging (MRI) Conditional. As stated previously, these are the components that are used in the MR environment. These devices were evaluated as a single assembled construct. The ultimate objective of the evaluations was to recommend the appropriate MR Conditional labeling for the Instructions for Use.

The test program included magnetically induced displacement force, magnetically induced torque, radiofrequency (RF)-induced heating and magnetic resonance image artifact of the DHRS, UCHRA, and LL01 devices. Testing was in accordance with *Guidance for Industry and FDA Staff: Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment* – August 21, 2008 and the ASTM standards referenced in this FDA guidance document (note: see paragraph below). Details of the tests and summary result are provided in **Section 18 – Performance Testing - Bench**. The components passed all test requirements indicating they are safe to use in an MR environment (1.5 T – 3.0 T) under described conditions.

The MR testing plan and execution took place in late 2013 and early 2014, respectively. Since that time, there were two updates made to items referenced in the testing documentation:

- The FDA Guidance document issued August 21, 2008 *Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment* was updated on December 11, 2014
- The ASTM F2052 standard *Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment* was updated from revision "-06e1" to the current version of "-14."

The revised versions of the documents were reviewed against the previous versions that were tested against in this submission. Integra believes that the revisions to the two documents do not affect the testing results and conclusions drawn, meaning the devices within the scope of this submission are compliant with ASTM F2052-14 and the updated FDA Guidance document issued December 11, 2014. However, to remain transparent throughout the submission, the actual versions of the documents tested to have been left in place.

Additional specific accessories used with the assembled components were evaluated for magnetically induced displacement force in accordance with ASTM F2052. Further details are provided in **Section 18 – Performance Testing – Bench.** The accessories did not pass testing and will be labeled MR Unsafe**.**

10.4 Modifications to Components

Some modifications have been made to the following components since the clearance of the original 510(k) and the changes are described below.

Head Ring Screws

The Head Ring Screws are now disposable and supplied sterile; they are terminally sterilized by ethylene oxide. Formerly, the screws were non-disposable and the user had to sterilize the screws. Supporting testing information for the terminally sterilized screws can be found in **Section 14 – Sterilization and Shelf Life**. The present screws are made of acetal polymer, Celcon M-90 with an aluminum rod and were formerly made of Delrin with a stainless steel rod. The Celcon M-90 is not in patient contact. The aluminum used is 7075-T6 grade aluminum. This change was made in 1993 by the previous owner and prior to FDA's guideline covering changes to a product. Supporting testing information regarding biocompatibility can be found in **Section 15 – Biocompatibility**.

Luminant Localizer

The Luminant Localizer (LL01) is a replacement for the original component UCLF. The fiducial rods for the UCLF required the user to fill the rods with water. This required the user to ensure that the rods were filled without air bubbles. To address customer concerns, a modification was made to this component. The rods of the LL01, unlike the UCLF, do not need to be refilled. They are sealed glass rods filled with a proprietary gel formulation that is visible in MRI scanners and the glass portion of the rod is visible in CT. The arrangement of the rods in the LL01 is identical to the arrangement in the UCLF allowing the LL01 to be used with the same treatment planning software. (The software is used during surgery only and not during imaging and is covered under a separate 510(k).

Universal Compact Head Ring Post, Anterior (UCHRPA) and Universal Compact Head Ring Post, Posterior (UCHRPP)

The UCHRPA and UCHRPP are carbon fiber posts which are used to attach the head ring to the patient. The posts are attached to the head ring using a nut and bolt. The post is slotted to allow adjustment of the height of the post on the head ring. Head ring screws are threaded through the tops of the post and into the patient's skull. A Head Ring Cross Bar, which attaches to the UCHRPA, is also available for use when the patient's head is small or when it is difficult to properly place the anterior Head ring screws.

The physical modifications of the posts include:

1) Capture of the nut in slot to ease assembly for the user;
2) Changing the alignment of the threaded hole on the posts to 90 degrees from the body of the post
3) Threaded holes on the crossbar were modified to match the change to anterior post;
4) The resin in the carbon fiber has a slightly higher melting/glass transition point.

The basic design and function of the head posts has not changed. The nut is now captured in the post instead of being separate. The alignment of the threaded holes matches the design of the predicate posts. Capturing the nut in the post is an added convenience for the user when assembling the device. There was a change in the resin used with the carbon fiber; however, the posts do not have direct patient contact.

There will also be an amendment to a subset of the sterilization parameters for the posts. The posts are reusable and may be sterilized using either ethylene oxide or using a Sterrad machine. The system configuration using the Sterrad 100S system has been modified and an additional cycle, using the Sterrad 100NX system, has been added. Supporting testing information can be found in Section **14 – Sterilization and Shelf Life** and the changes are reflected in the proposed labeling which can be found in Section **13 – Proposed Labeling**.

10.5 Substantial Equivalence

The CRW Stereotactic System is substantially equivalent to itself because it has the same basic design and technological characteristics as described in K944463. There are no changes to the indications for use, technology, device classification, or 510(k) classification product code. Testing has been performed according to ASTM standards as provided in the FDA Guidance for Industry and FDA Staff: *Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment* issued August 21, 2008. Testing has not raised any new safety or efficacy concerns.

SECTION 11 - DEVICE DESCRIPTION

Device Description

11.1 System Overview

For stereotactic neurosurgery, the surgeon must have a method for accurately and rapidly calculating the coordinates of a given target (operative site) located in the brain. During a stereotactic procedure a neurosurgeon uses 2 dimensional coordinates taken from a patient's scanned images (CT, MR, etc.) to generate 3 dimensional coordinates for a target within a patient's head. The surgeon then uses a guide to drive an instrument to the target and then biopsy/resect, ablate, or stimulate the tissue at target. The guide can be a frame-based stereotactic system (supported by target and instrument trajectory planning software) or a frame-less stereotactic system.

A frame-based stereotactic system consists of a head ring, head ring screws and localizer frame (CRW Stereotactic System). The frame-based system is used in conjunction with the guidance arc (CRW Arc System, covered under the original 510(k)) and software (StereoCalc target planning software, originally cleared under K946252)), which are the systems used during surgery to direct instruments into the brain with sub-millimeter accuracy. Only the CRW Stereotactic System is covered in this Abbreviated 510(k) because these are the only components to be used during MR imaging.

The CRW Stereotactic System is designed to facilitate the performance of stereotactic procedures. Components described below are the pre-surgery components used during CT or MR imaging. The planning software employed consists of the StereoCalc software that is designed with capabilities to visualize critical structures of the brain and aid the surgeon in planning the appropriate trajectory for access to the target tissue. The software allows the surgeon to pre-plan a stereotactic procedure, but also devise an optimal plan prior to entering the operating room. Again, StereoCalc software has been cleared under separate 510(k) application. These additional components are mentioned here only to provide an understanding of the stereotactic system and they are not used in the MR environment. Drawings with dimensions for in-scope components and/or accessories are included in **Appendix 4**.

11.2 System Components

The components of the CRW Stereotactic System include:

- Universal Compact Head Ring Assembly
- Luminant Localizer Frame
- Disposable Head Ring Screws (DHRSS- Short, DHRSL- Long)

The Universal Compact Head Ring is placed on the patient and secured with the Disposable Head Ring Screws – See **Figures 11.1 and 11.2**. The Luminant Localizer Frame, **Figure 11.3,** is then attached to the base ring and the patient is taken to the neuroradiology department where a CT or MR imaging is performed.

The image obtained in conjunction with the localizer allows the neurosurgeon to compute the exact three dimensional position of the region of interest. The surgeon enters data from the localized scan in target planning software to obtain the Anterior/Posterior, Lateral and Vertical target coordinates. (Alternatively, these coordinates are computed manually). Then the Luminant Localizer Frame is removed and the patient is then taken to the operating room.

Figure 11.1 Universal Compact Head Ring Assembly

Figure 11.2 Disposable Head Ring Screws

Figure 11.3 Luminant MR/CT Localizer

11.3 Environment of Use

The CRW Stereotactic System is designed for use in a neuroradiology department for CT and MR imaging and in an operating room environment.

This submission provides information to support an MR conditional claim. The claim is supported by testing in accordance with the FDA Guidance for Industry and FDA Staff: *Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR)* Environment issued August 21, 2008 and to the ASTM Standards referenced in the guidance document.

The CRW Stereotactic System will be labeled MR Conditional for use in 1.5 Tesla (T) and 3.0 T MR Environments. Non-clinical testing has demonstrated that the DHRS, UCHRA, and LL01 devices, when assembled, are safe to use in an MR environment when the prescribed conditions are followed. This construct can be scanned safely under the following conditions:

- Static magnetic field of 1.5-Tesla (1.5 T) or 3.0-Tesla (3.0 T).
- Spatial gradient field of up to:
  - 11,440 G/cm (114.40 T/m) for 1.5 T systems.
  - 5,720 G/cm (57.20 T/m) for 3.0 T systems.
- Do not exceed a MR System reported, whole body averaged specific absorption rate (SAR) of 2.0 W/kg at 1.5 T and 3 T. Normal Operating Mode only.

Device Design

The device design has largely remained consistent with what was provided in the original 510(k) for the device.

However, some modifications have been made to the following components since the clearance of the original 510(k) and the changes are described below.

Head Ring Screws

The Head Ring Screws are now disposable and supplied sterile; they are sterilized by ethylene oxide. Formerly, the screws were non-disposable and the user had to sterilize the screws. Supporting testing information for the terminally sterilized screws can be found in **Section 14 – Sterilization and Shelf Life**. The present screws are made of acetal polymer, Celcon M-90 with an aluminum rod and were formerly made of Delrin with a stainless steel rod. The Celcon M-90

is not in patient contact. The aluminum used is 7075-T6 grade aluminum. This change was made in 1993 by the previous owner and prior to FDA's guideline covering changes to a product. Supporting testing information regarding biocompatibility can be found in **Section 15 – Biocompatibility**.

Luminant Localizer

The Luminant Localizer (LL01) is a replacement for the original component UCLF. The fiducial rods for the UCLF required the user to fill the rods with water. This required the user to ensure that the rods were filled without air bubbles. To address customer concerns, a modification was made to this component. The rods of the LL01 unlike the UCLF do not need to be refilled. They are sealed glass rods filled with a proprietary gel formulation that is visible in MRI scanners and the glass portion of the rod is visible in CT. The arrangement of the rods in the LL01 is identical to the arrangement in the UCLF allowing the LL01 to be used with the same treatment planning software. (The software is used during surgery only and not during imaging and is covered under a separate 510(k).

Universal Compact Head Ring Post, Anterior (UCHRPA) and Universal Compact Head Ring Post, Posterior (UCHRPP)

The UCHRPA and UCHRPP are carbon fiber posts which are used to attach the head ring to the patient. The posts are attached to the head ring using a nut and bolt. The post is slotted to allow adjustment of the height of the post on the head ring. Head ring screws are threaded through the tops of the post and into the patient's skull. A Head Ring Cross Bar, which attaches to the UCHRPA, is also available for use when the patient's head is small or when it is difficult to properly place the anterior Head ring screws.

The physical modifications of the posts include:

1) Capture of the nut in slot to ease assembly for the user;
2) Changing the alignment of the threaded hole on the posts to 90 degrees from the body of the post, this matches the alignment of the posts used with the Brown Roberts Well (BRW) system
3) Threaded holes on the crossbar were modified to match the change to anterior post;
4) The resin in the carbon fiber has a slightly higher melting/glass transition point.

The basic design and function of the head posts has not changed. The nut is now captured in the post instead of being separate. The alignment of the threaded holes matches the design of the

predicate posts. Capturing the nut in the post is an added convenience for the user when assembling the device. There was a change in the resin used with the carbon fiber; however, the posts do not have direct patient contact.

There will also be an amendment to a subset of the sterilization parameters for the head posts. The head posts are reusable and may be sterilized using either ethylene oxide or a Sterrad machine. The system configuration using the Sterrad 100S system has been modified and an additional cycle, using the Sterrad 100NX system, has been added. Supporting testing information can be found in Section **14 – Sterilization and Shelf Life** and the changes are reflected in the proposed labeling which can be found in Section **13 – Proposed Labeling**.

Description of Accessories

Accessory components are available and have been covered in the original 510(k). No accessory components are required for use in an MR environment.

Packaging

The following provides a brief description of how the devices within scope are packaged. The word "Radionics" refers to the name of the previous owner of the device which was purchased by Integra LifeSciences.

Universal Compact Head Ring

This unit is packaged in a blue, Radel R-5100 sterilization case to allow the end user to handle the sterilization process while protecting the unit from damage. Schematics of the sterilization case are shown below in **Figures 11.4 -11.7**.

Figure 11.4 Components within sterilization case

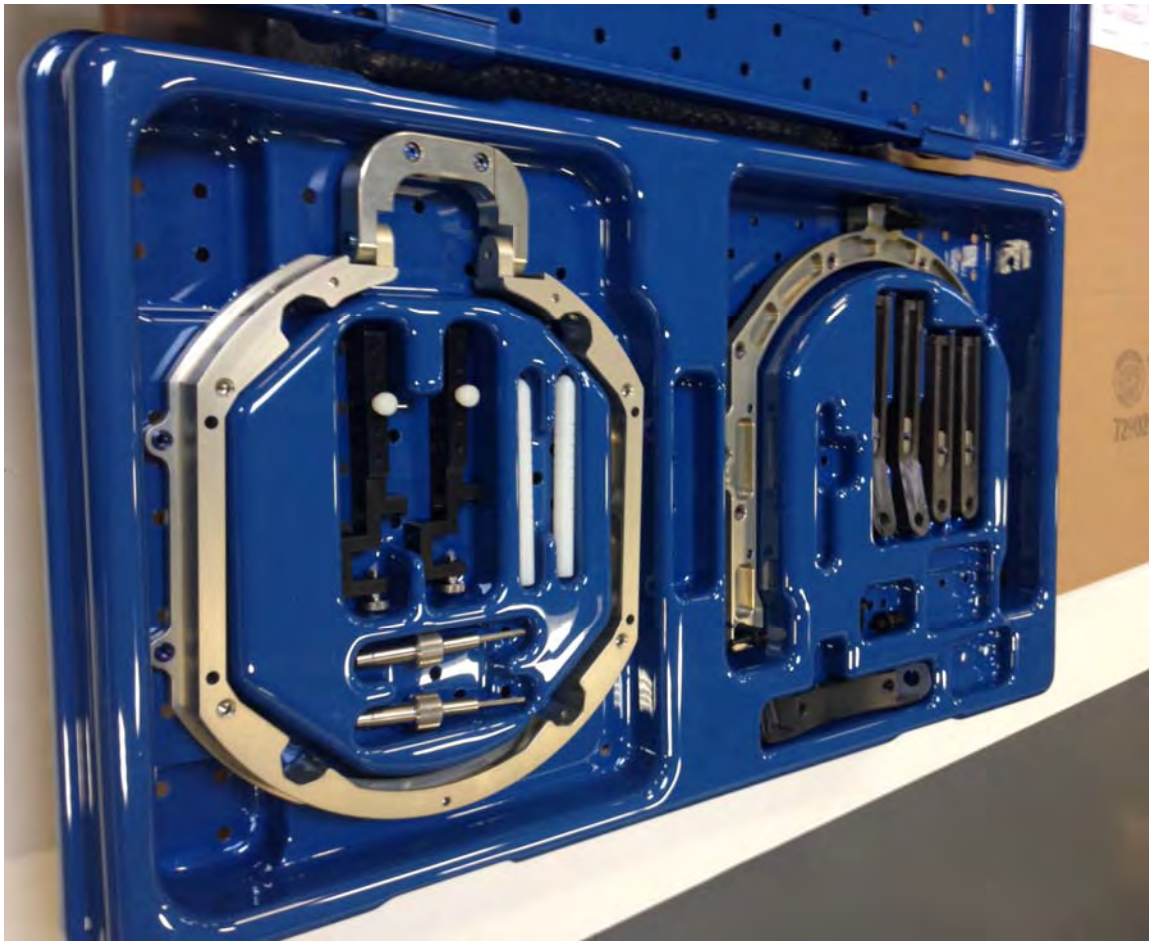


Figure 11.5 Instapak placement and plastic bag packaging

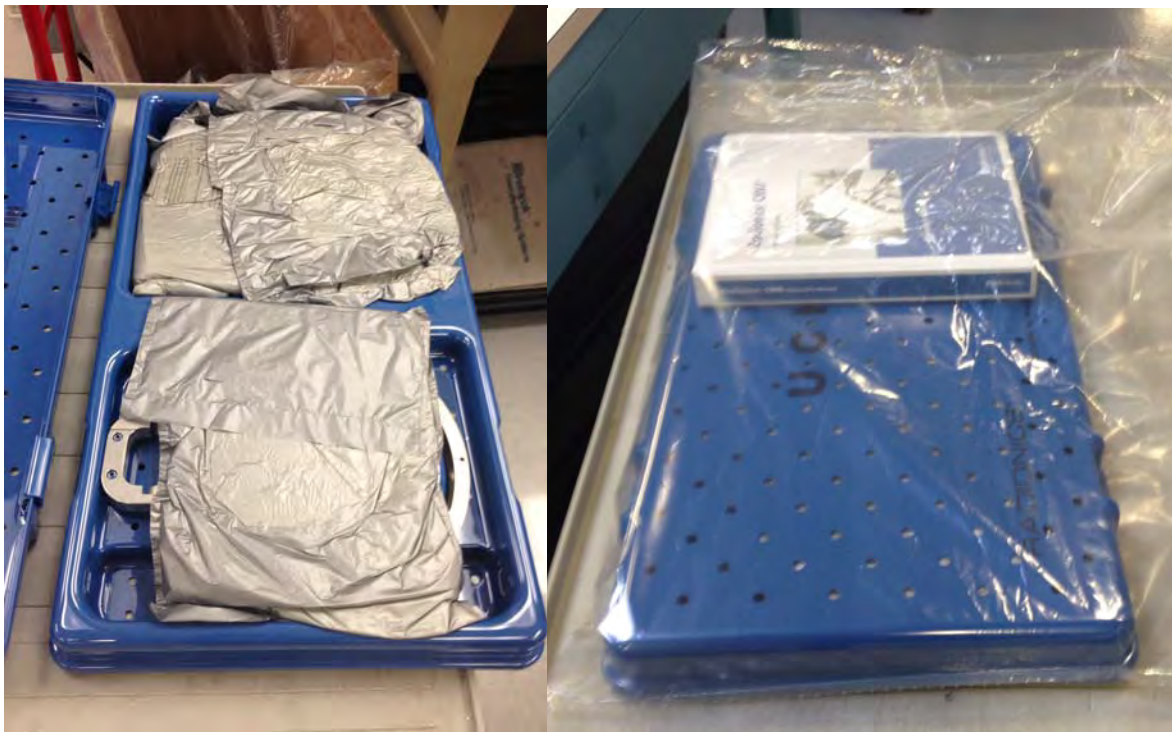


Figure 11.6 Case is placed into a corrugated cardboard shipping box along with instapak

Figure 11.7 Corrugated cardboard shipping box is sent to customers/distribution centers

Luminant Localizer Frame

The Luminant Localizer Frame is placed in a rigid plastic case that is foam lined to protect the unit during transport and between uses. The case features latches for a secure closure during transport and storage at the user facility. The case is shipped in a corrugated cardboard box that is also instapak lined to provide further protection for the unit. See **Figure 11.8,** below.

Figure 11.8 – Luminant Localizer is placed in Luminant Localizer Shipping and Storage Case (Molded Silver Gemini Case)

Figure 11.9 – Luminant Localizer Shipping and Storage Case is placed into a corrugated cardboard shipping box along with instapak

Figure 11.10– Luminant Localizer corrugated cardboard shipping box is sent to customers/distribution centers

Disposable Head Ring Screws

The Disposable Head Ring Screws are the only component provided sterile. The screws are packaged in a PETG tray with a Tyvek® lid; two screws are packaged in each tray and there are five trays per dispenser box. The dispenser box is then placed in a shipping box and then placed in multiples into a shipper box to be sent to the sterilizer and then to the distribution centers.

Figure 11.11- Disposable Head Ring Screws in Tyvek Lid with PETG Tray

Figure 11.12- Disposable Head Ring Screws are then put into Solid Bleach Sulfate Dispenser Boxes (contains 5 trays)

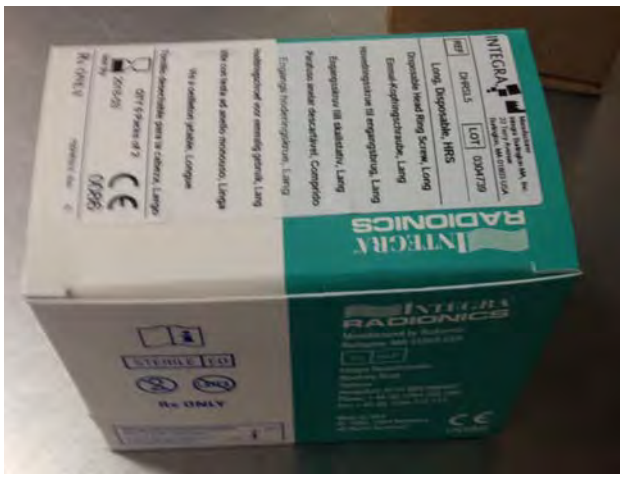


Figure 11.13- Disposable Head Ring Screws Dispenser Box is then placed in Corrugated Cardboard Shipper Box

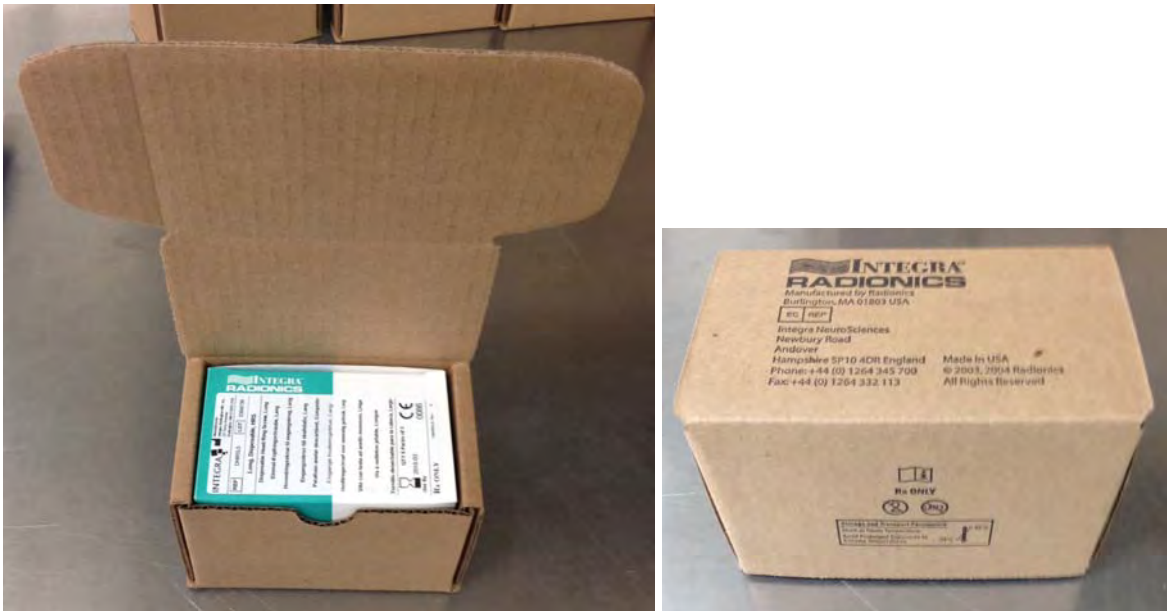


Figure 11.14- Disposable Head Ring Screws in Corrugated Cardboard Shipper Box that is sent to the sterilizer and then to the distribution centers

Sterilization

Only the head ring screws are provided sterile. These are terminally sterilized by ethylene oxide and the process has been validated to assure a sterility assurance level of 10^{-6}. Providing this component as a sterilized component is a change from the original 510(k) whereby no components were provided sterile. This change was made in 1993 when the previous owner changed the reusable head ring screws to disposable head ring screws. Please see **Section 14 – Sterilization and Shelf Life** for further details and supporting testing information.

Some components in the system are reusable and may be sterilized between uses. The sterilization cycles and the validation information can be found in **Section 14 – Sterilization and Shelf Life**.

Biocompatibility

Only the Disposable Head Ring Screws and the Ear Bar Assembly have direct patient contact. Additional biocompatibility testing has been performed and the results indicate that the devices meet the appropriate biocompatibility requirements**.** Please see **Section 15 – Biocompatibility** for further details.

SECTION 12 - SUBSTANTIAL EQUIVALENCE DISCUSSION

Substantial Equivalence Discussion

12.1 Substantial Equivalence Introduction

The CRW Stereotactic System including the components covered in this Abbreviated 510(k) is substantially equivalent to the system and components covered in the original 510(k). Although some changes have been made, these changes did not affect the function of the components or the technological characteristics as described in K944463. There are no changes to the indications for use, technology, device classification, or 510(k) classification product code.

The main purpose of this Abbreviated 510(k) is to cover a labeling change to add MR Conditional information to the labeling. Testing has been performed according to ASTM standards as provided in the FDA Guidance for Industry and FDA Staff: *Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment* issued August 21, 2008. Testing has not raised any new safety or efficacy concerns. Information derived from the tests has been added to the proposed labeling. The proposed labeling is included in this submission; please see **Section 13 – Proposed Labeling**.

Comparative information is provided in the Substantial Equivalence table below.

Table 12.1: Universal Compact Head Ring (UCHR), Luminant Localizer Frame (LL01) and the Disposable Head Ring Screws (DHRSS, DHRSL) Substantial Equivalence Chart

Characteristic	New Device	Predicate	Comments
Intended Use	Stereotactic Procedures, e.g., biopsies, frame guided resection and functional frame guided resection and functional stereotactic procedures	Stereotactic Procedures, e.g., biopsies, frame guided resection and functional frame guided resection and functional stereotactic procedures	Same
Indications for Use	The CRW-1 System is a stereotactic system to be used for neurosurgical procedures that require precise target localization, such as craniotomies, biopsies, and functional stereotaxy.	The CRW-1 System is a stereotactic system to be used for neurosurgical procedures that require precise target localization, such as craniotomies, biopsies, and functional stereotaxy.	Same
Product Classification	Class II	Class II	Same
Product Code	HAW	HAW	Same
Component Use	Universal Compact Head Ring is placed on the patient and secured with the Disposable Head Ring Screws. The Luminant Localizer Frame is then attached to the base ring and the patient is taken to the neuroradiology department.	Universal Compact Head Ring is placed on the patient and secured with the Disposable Head Ring Screws. The Luminant Localizer Frame is then attached to the base ring and the patient is taken to the neuroradiology department.	Same
Single Use	Disposable Head Ring Screws are the only component that is single use and	Head Ring Screws were provided as re-usable components and were	This does not negatively impact the safety and

Characteristic	New Device	Predicate	Comments
	provided sterile.	sterilized by the user.	effectiveness of the device system. Sterilization testing information to support the change can be found in **Section 14 – Sterilization and Shelf Life**.
Terminal Sterilization Method for Single Use Components	Ethylene Oxide (for Disposable Head Ring Screws only)	No components were provided sterile.	This difference does not negatively impact the safety and effectiveness of the device system. Sterilization testing information to support the change can be found in **Section 14 – Sterilization and Shelf Life**.
MR Conditional Use (1.5 and 3.0T)	Yes (Providing conditions for MR Conditional)	MR Compatible and CT use was covered in the original 510(k)	Updating MR safety language to align with current standards/practice

12.2 Substantial Equivalence Conclusion

CRW Stereotactic System has the same intended use as the system described in the original 510(k). The regulatory classification and code are unchanged. Three system components would be used in an MR environment and these components have the same intended uses and function in the same manner as described in the original 510(k).

Testing on these components has been performed according to ASTM standards as provided in the FDA Guidance for Industry and FDA Staff: *Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment* issued August 21, 2008. Testing has not raised any new safety or efficacy concerns. Information derived from testing has been incorporated in the proposed labeling.

Functionality of the components is unchanged. Thus, the components of the CRW Stereotactic System are substantially equivalent to themselves as described in the original 510(k) with the added use in a conditional MR environment.

SECTION 13 - PROPOSED DRAFT LABELING

13 Proposed Draft Labeling

The proposed draft labeling for the CRW Stereotactic System is provided. The Instructions for Use documents for the components are included in this submission and contain relevant information from the MR testing to support an MR conditional claim.

Labels for the system components are provided and bear the MR Conditional symbol as applicable.

Labels for the accessories are also provided and bear the MR Unsafe Symbol where applicable.

Appendix 5.1

Instructions for Use

Appendix 5.2

Product/Packaging Labeling

Information Included in MR Marking

For physical product markings the UCHR and the UHRAP will be marked for the MR Conditional symbol, see **Figure 13.1**. The markings will be machined into the raw aluminum part, then the finished machined part is sent for anodization, and lastly the anodized part will be painted using high-temperature black paint. This process is already established for the gradient markings on the side of the UCHR.

Per ASTM 2503 *Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment*, the direction is given in Section 7 *Information Included in MR Marking* that for implants, the MR marking should be included in the packing labeling (including the instructions for use and package inserts). For non-implanted items intended to be used in the MR environment, the MR markings will be positioned in a prominent location on the item as well as in the item label. For some of the items that are small or do not provided any surfaces which can be marked practically the MR marking will be included in the product labeling. **Table 13.1** provides the level in which MR information will be contained.

Figure 13.1 Identification of MR Conditional Markings

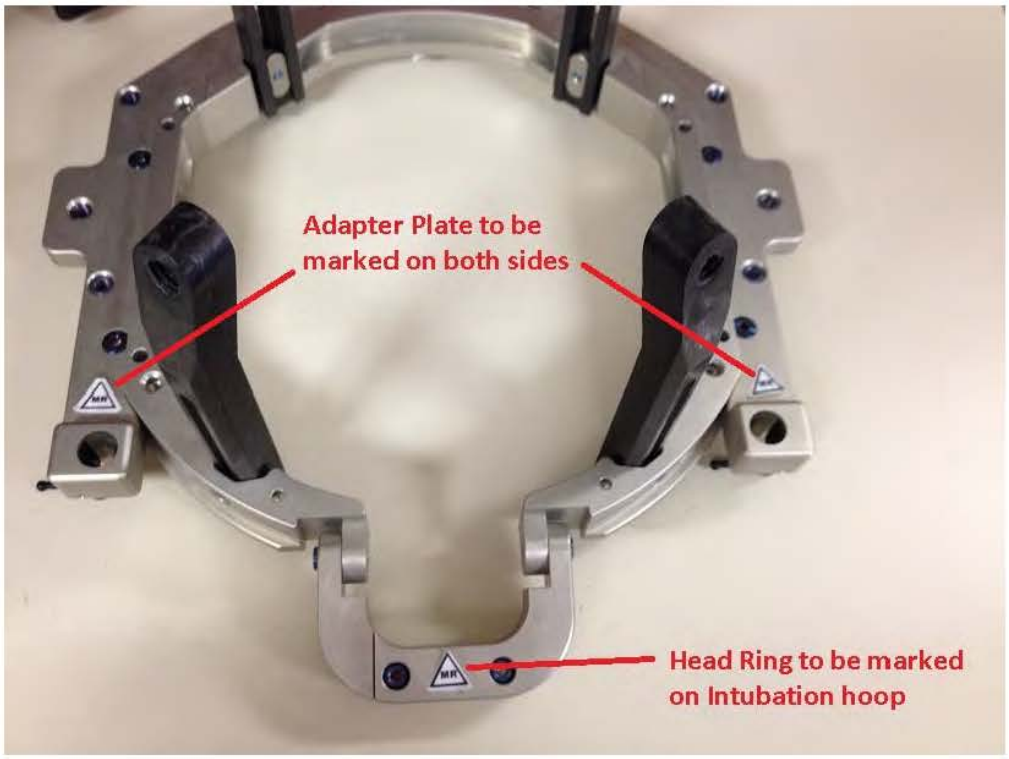


Table 13.1 Identification of MR Indication Labeling

Component	MR Direct Mark (Y/N)	Applicable MR Labeling
UCHRA	N/A	Both MR Unsafe and MR Conditional – labeling to identify based on component
UCHR - Head Ring	Y	MR Conditional
UCHRAP - Adapter Plate	Y	MR Conditional
UCHREBA - Assembly	N	MR Unsafe
UCHREBA - Ear Bar	N	
UCHREBA - Ear Bar Post	N	
UCHREBA - Ear Bar Screw	N	
UCHRP	N	MR Conditional
UCHRCB1 - Cross Bar	N	
UCHRCBS - Cross Bar Screws	N	
UCHRPA - Anterior Posts	N	
UCHRPP - Posterior Posts	N	
HRW - Wrench	N	MR Unsafe
UCHRCASE	N	
TAP - Cleaning Tap	N	
UCHRHK	N	Both MR Unsafe and MR Conditional – labeling to identify based on component
LL01 - Luminant	Y	MR Conditional
LL02 - Luminant Case	N	N/A
DHRS - Head Ring Screws	N	MR Conditional

SECTION 14 - STERILIZATION & SHELF LIFE

14.1 Sterilization

14.1.1 Sterile Products

Only the Disposable Head Ring Screws Long and Short are provided sterile.

They are terminally sterilized via ethylene oxide. The process has been validated to assure a sterility assurance level of 10^{-6}.

(b)(4)

The results of the validation study concluded the following:

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

14.1.2 Non-Sterile Products

The Universal Compact Head Ring and accessories and the Luminant Localizer Frame are provided to the end user non-sterile and are reusable. Cleaning, Sterilizing and Maintaining for the Universal Compact Head Ring and Luminant Localizer Frame are provided in their respective Instructions for Use (IFU).

Cleaning the Universal Compact Head Ring

Note: The use of Betadine® and other related fluids containing iodine may stain the surface of the stereotactic system. To minimize discoloration, wipe off any traces of Betadine® and similar solutions as soon as a possible during or following the surgery.

Use the following guidelines when cleaning the Universal Compact Head Ring (UCHR) components (head ring, posts, and screws):

Caution: Do not use saline, as it will attack the metal surface. Do not use corrosive agents, such as Clorox® or Cidex®. Do not use alcohol or hydrogen peroxide on any black composite materials.

- After each procedure, clean components with de-ionized distilled water to remove any residue of Betadine®, blood, CSF or other debris.
- Thoroughly dry and wrap components for sterilization.
- Remove any liquids from components as soon as possible after surgery to prevent corrosion or tarnishing of the surfaces.
- The cleaning tap (TAP) may be used to remove debris from inside the head ring post threads. Insert fully and remove the tap to cleanse the thread.

Packing the UCHR Components

Pack the UCHR components into the sterilization trays after cleaning and before sterilization.

Sterilizing the UCHR Components

Whenever virus–contact with the instrumentation is possible, proper sterilizing measures must be followed. It is the responsibility of hospital personnel to review sterilization procedures for susceptible components and to implement procedures addressing such hazards.

Caution: Do not sterilize the localizer frame. Sterilization may damage the component and render it inoperable.

Parameters for Sterilizing the UCHR Components

The following tables provide recommended sterilization parameters for the UCHR components. Due to variations in sterilization chambers and load configurations, it is the responsibility of the facility to determine a sterilization protocol that ensures sterility of the device.

EtO(100% EtO)	
Parameters:	Cycle 1
Concentration:	883 mg/L
Temperature:	131°F / 55°C
Exposure Time:	≥ 60 minutes
Humidity:	≥ 50% RH

Steam AutoClave (Pre-Vacuum)			
Parameters:	Option 1	Option 2	Option 3
Temperature:	270°F / 132°C	275°F / 135°C	273°F / 134°C
Exposure Time:	4 minutes	3 minutes	18 minutes
Dry Time:	20 minutes	16 minutes	20 minutes

Sterrad®		
Parameters:	Option 1	Option 2
System:	100S	100NX
Position of Slider Screw on Composite Post (UCHRP):	Lock into center of slot prior to sterilization	Any position
Containment:	Single self-seal sterilization pouch	Single self-seal sterilization pouch
Cycle :	Standard	Standard

Description of the Methods Used to Validate the Sterilization Parameters

(b)(4)

(b)(4)

References:

ISO 11135:1994 Medical devices – Validation and routine control of ethylene oxide sterilization

AAMI TIR 39:2009 Guidance on selecting a microbial challenge and inoculation sites for sterilization validation of medical devices

Steam AutoClave

(Pre-Vacuum)

(b)(4)

(Dry Time)

(b)(4)

References:

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

AAMI TIR 39:2009 Guidance on selecting a microbial challenge and inoculation sites for sterilization validation of medical devices

Sterrad®

Note: The UCHRPA/UCHRPP carbon fiber posts are the only components within the scope of this submission that are sterilized using the Sterrad machine. This section is specific to these posts.

Two different Sterrad systems were validated:

- The Sterrad 100S system using the Standard Cycle (K991999)
- The Sterrad 100NX system using the Standard Cycle (cleared via K042116)

(b)(4)

References:

ANSI/AAMI TIR12:2010 Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers

ANSI/AAMI ST79:2010/A4:2013 Comprehensive guide to steam sterilization and sterility assurance in health care facilities

ANSI/AAMI/ISO 14937:2009 Sterilization of healthcare products – General requirements for characterization of a sterilizing agent and development, validation and routine control of a sterilization process

Table 14.1.2.1 Summary of UCHR Sterilization Procedures

Component	Description	EtO	Steam Autoclave	Sterrad®
UCHR	Universal Compact Head Ring	Yes	Yes	No
UCHRPA, UCHRPP	Composite Head Ring Posts, Cross Bar & attached screws	Yes	No	Yes
HRW	Head Ring Wrench	Yes	Yes	No
UCHRAP	UCHR Adapter Plate	Yes	Yes	No
UCHREBA	Ear Bar Assembly Kit	Yes	Yes	No
UCHREB	Ear Bar	Yes	Yes	No

Cleaning the Luminant Localizer Frame

Grease or other dirt may accumulate on the frame in the course of normal use. In such cases, wipe the localizer frame with distilled water only, and dry it promptly.

14.2 Shelf Life

Table 14.1.2.2 depicts the shelf life for the products subject to this Abbreviated 510(k)

Table 14.1.2.2 Shelf Life

Component	**Description**	**Shelf Life**
UCHR	Universal Compact Head Ring	N/A
UCHRPA, UCHRPP	Composite Head Ring Posts, Cross Bar & attached screws	N/A
HRW	Head Ring Wrench	N/A
UCHRAP	UCHR Adapter Plate	N/A
UCHREBA	Ear Bar Assembly Kit	N/A
UCHREB	Ear Bar	N/A
LL01	Luminant Localizer	Shelf Life Date: 48 Months from date of manufacture Quarantine Date: 25 Months before expiration date
DHRSS	Disposable Head Ring Screws, Short	3 years
DHRSL	Disposable Head Ring Screws, Long	3 years

Summary of Methods Used to Establish Shelf Life

(b)(4)

(b)(4) All acceptance criteria established were met per the results of the testing. Based on meeting the requirements, the DHRS can be labeled for a three-year shelf life. Please see **Appendix 6** for the protocol and report for the aging studies.

SECTION 15 – BIOCOMPATIBILITY

Biocompatibility

Biocompatibility testing has been performed and the results indicate that the Disposable Head Ring Screws meet the biocompatibility requirements for devices that are classified as "Implant Devices" that are in contact with patient "Tissue/Bone" for a duration of “Limited Duration <24 hours.” The Ear Bar accessory was tested to and met the biocompatibility requirements of devices classified as “Surface Devices” that are considered contacting only “Skin” for a duration of “Limited Duration <24 hours.” See **Table 15.1.1: 510(k) Memorandum -** (b)(4) **Table 1 Initial Evaluation Tests for Consideration** below.

Table 15.1.1: 510(k) Memorandum - #G95-1 Table 1 Initial Evaluation Tests for Consideration

(b)(4)

The tests conducted and corresponding summaries:

DHRS

- **Cytotoxicity**

The test article, DHRSL - Disposable Head Ring Screw, Long, was evaluated for potential cytotoxic effects using an in vitro mammalian cell culture test. This study was conducted following the guidelines of ISO 10993-5, Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity. (b)(4)

(b)(4)

(b)(4)

- **Intracutaneous**

The test article, DHRSL - Disposable Head Ring Screw, Long, was evaluated for the potential to cause irritation following intracutaneous injection in rabbits. This study was conducted based on ISO 10993-10, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization. (b)(4)

(b)(4)

(b)(4)

- **Sensitization Maximization**

(b)(4)

(b)(4)

- **Systemic Toxicity**

(b)(4)

(b)(4)

Ear Bar

- **Cytotoxicity**

(b)(4)

(b)(4)

(b)(4)

- **Intracutaneous**

(b)(4)

(b)(4)

- **Sensitization Maximization**

(b)(4)

(b)(4)

(b)(4)

The test results performed at the time of the change confirmed that no new issues of safety or effectiveness are raised with the previously described modifications- see **Section 11 – Device Description**. Reports for the tests discussed above are provided in **Appendix 7**.

SECTION 16 - SOFTWARE

This Section Does Not Apply

SECTION 17 - ELECTROMAGNETIC COMPATIBILITY AND ELECTRICAL SAFETY

This Section Does Not Apply

SECTION 18 - PERFORMANCE TESTING - BENCH

Performance Testing- Bench

TESTING TO SUPPORT CONDITIONAL MR USE

18.1 Background Information

The purpose of the evaluation was to perform magnetic resonance imaging (MRI) compatibility testing focusing on three specific components within the CRW Stereotactic System that are used in the MR environment. The three devices captured in the matrix are the Disposable Head Ring Screws (DHRS), the Universal Compact Head Ring Assembly (UCHRA) System, and the Luminant Localizer (LL01). These devices were evaluated as a single assembled construct. The ultimate objective of the evaluations was to recommend the appropriate MR safety information to support an MR conditional claim within the device labeling.

The test program included magnetically induced displacement force, magnetically induced torque, radiofrequency (RF)-induced heating and magnetic resonance image artifact of the DHRS, UCHRA, and LL01 devices. Testing was in accordance with *Guidance for Industry and FDA Staff: Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment* – August 21, 2008 and the ASTM standards referenced in this FDA guidance document.

The MR testing plan and execution took place in late 2013 and early 2014, respectively. Since that time, there were two updates made to items referenced in the testing documentation:

- The FDA Guidance document issued August 21, 2008 *Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment* was updated on December 11, 2014
- The ASTM F2052 standard *Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment* was updated from revision "-06e1" to the current version of "-14."

The revised versions of the documents were reviewed against the previous versions that were tested against in this submission. Integra believes that the revisions to the two documents do not affect the testing results and conclusions drawn, meaning the devices within the scope of this submission are compliant with ASTM F2052-14 and the updated FDA Guidance document issued December 11, 2014. However, to remain transparent throughout the submission, the actual versions of the documents tested to have been left in place.

Testing was conducted by (b)(4) under a protocol approved by Integra. The protocol is included in this submission and can be found in **Appendix 3.1**.

Accessory components are not required in an MR environment. However, to err on the side of caution, three of the accessories that a user might inadvertently bring to an MR environment were also tested. These include the Ear Bar Assembly, the Head Ring Wrench and the Cleaning Tap. The specific accessories were evaluated for magnetically induced displacement force in accordance with ASTM F2052.

18.2 Test Plan - CRW Stereotactic System Components

18.2.1 Magnetically Induced Displacement Force

Magnetically induced displacement force was conducted in accordance with ASTM F2052. According to the standard, "any magnet with a horizontal magnetic field that produces a large spatial gradient may be used for the test." (b)(4)

(b)(4)

(b)(4)

18.2.2 Magnetically Induced Torque

Magnetically induced torque was conducted using ASTM F2213 as a guide to conduct a qualitative assessment. (b)(4)

(b)(4)

1. (b)(4)
2. (b)(4)

(b)(4)

18.2.3 RF-Induced Heating

(b)(4)

1. (b)(4)

(b)(4)

2. (b)(4)

(b)(4)

(b)(4)

(b)(4)

18.2.4 MR Image Artifact

MR image artifact is dependent upon device geometry, size, and material. For devices of the same material and geometry, larger devices result in larger overall artifact, but approximately the same radial artifact. Therefore, a representative configuration was tested in a 1.5 T Siemens Espree and a 3.0 T Siemens Trio scanner in order to assess the maximum image artifact due to the device materials and geometry. MR image artifact testing was conducted using ASTM F2119 as a guide. Specifically, the following deviations from the standard were implemented:

1. (b)(4)
(b)(4)

2. (b)(4)
(b)(4)

3. (b)(4)
(b)(4)

(b)(4)

(b)(4)

(b)(4) – see **Section 13 – Proposed Labeling**.

18.3 Test Samples – Treatment and Selection Rationale

18.3.1 Sample Treatment

The test sample(s) were subjected to all manufacturing steps including sterilization, although they did not need to be maintained as sterile for testing.

18.3.2 Sample Selection Rationale

The DHRS, UCHRA, and LL01 devices are comprised of several components and a range of materials. These are summarized in the protocol. Variables such as component size and the relative position of parts within the assembled construct were noted, and selections were made to establish the parts and positions which would result in the expected worst-case construct configuration for a given test. The protocol summarizes the variables relevant to each test, the selection made, and the rationale associated with each selection.

With regard to induced displacement force and torque testing, part sizes as well as optional parts within the system were considered in order to maximize the mass ratio of metallic to non-metallic components within the construct. All parts within the subject devices are offered in a single size with the exception of the disposable head screws, which are available in long and short. A total of four disposable head screws are required in the assembly, and they are constructed of aluminum and other non-metallic materials. Since the mass ratio of aluminum to non-metallic materials is the same for both the long and short sizes, the long screws were included in the construct for testing in order to maximize the amount of metallic materials present overall. The cross bar and associated cross bar screws are optional components within the system which are not always used clinically. They are composed solely of non-metallic materials; therefore, in order to maximize the mass ratio of metallic to non-metallic components, these parts were not included in the construct for induced displacement force and torque testing.

With regard to heating testing, part sizes as well as the relative position of parts within the system were considered in order to increase the likelihood of induced currents within the construct, resulting in worst-case heating. It can be expected that minimizing the distance between metallic components will promote the potential for an induced current to arise. As discussed above, only the disposable head screws are offered in more than a single size. Therefore, the long screws were included in the construct for testing and were fully threaded into the posts (such that the hex head is flush with the posts), thereby minimizing the distance between the screws. Similarly, the optional cross bar (and associated cross bar screws) were

included in the construct since by utilizing these components the anterior disposable head screws are relocated to a position closer to the midline of the patient. This further minimizes the distance between the anterior screws. Finally, the vertical travel as allowed by the design of the anterior and posterior posts was set such that the anterior posts were placed at the furthest allowable position in the cranial direction, and the posterior posts were placed at the same vertical position as the anterior posts. This post configuration minimizes the distance between the anterior and posterior sets of screws.

Finally, with regard to artifact testing, part sizes were predominantly considered since by increasing the part sizes and number of parts within the construct the overall image artifact will also increase. Therefore, the largest disposable head screws and the optional cross bar (and associated cross bar screws) were included in the construct for testing. Additionally, the imaging field of view was established such that all 9 gel rods could be visualized.

18.4 Test Results - CRW Stereotactic System Components

The test protocol, described above, was executed by (b)(4) in accordance with the relevant ASTM standards. MRI compatibility was evaluated for 1.5 T and 3.0 T. The final report, issued by (b)(4) is provided in **Appendix 3.2** and the results are summarized below.

18.4.1 Deviations from ASTM Standards

The ASTM standards for evaluating the MRI compatibility and safety of passive implantable devices were used as a guide for the subject testing. Deviations from these standards were implemented in order to adapt the methods to be applicable to an external headframe device. These deviations are listed explicitly in the test protocol. Rationale for the relative position of parts and the presence of optional parts within the test construct is provided in the test protocol as well as Sections 2.1.1 through 2.1.3 of the final report issued by (b)(4). Three minor deviations from the protocol were noted:

1. (b)(4)
(b)(4)

(b)(4)

2. (b)(4)
(b)(4)

3. (b)(4)
(b)(4)

18.4.2 Magnetically Induced Displacement Force

(b)(4)

18.4.3 Magnetically Induced Torque

(b)(4)

18.4.4 RF-Induced Heating

(b)(4)

18.4.5 MR Image Artifact

(b)(4)

(b)(4) Photographs documenting this testing and representative images of the artifact for the test samples are provided in appendices to the final report – **see Appendix 3.2.**

18.5 Testing - Accessories

(b)(4)

(b)(4) All devices were captured in this matrix. Testing was in accordance with ASTM F2052.

18.6 Test Results - Accessories

(b)(4)

(b)(4)

(b)(4) The report for this testing is located in **Appendix 3.3**.

18.8 - Conclusion

(b)(4)

(b)(4)

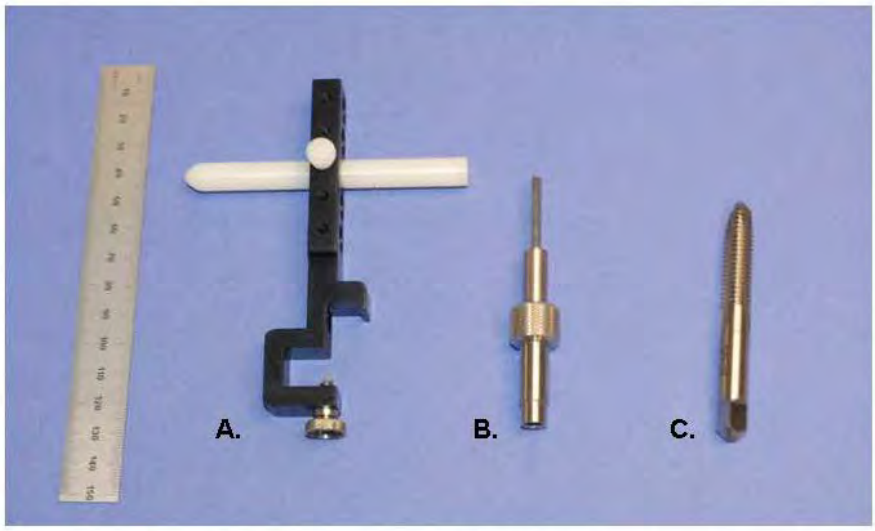
(b)(4)

TABLE 18.1 SUMMARY RESULTS

EVALUATION	FIELD STRENGTH	DHRS, UCHRA, LL01 COMPONENTS
(b)(4)		

***** MAXIMUM WHOLE-BODY SAR OF 2.0 W/KG

No accessories are required in an MR environment; however, to err on the side of caution, three accessories that a user might bring into the MR area were also tested. These accessories did not pass testing and will be labeled as MR Unsafe (See Figure below).



Test samples: (A.) Ear Bar Assembly, (B.) Head Ring Wrench, and (C.) Cleaning Tap.

SECTION 19 - PERFORMANCE TESTING - ANIMAL

This Section Does Not Apply

SECTION 20 – PERFORMANCE TESTING - CLINICAL

This Section Does Not Apply

SECTION 21 – OTHER

21.1 Kit Certification

To the best of my knowledge, the CRW Stereotactic System is not a convenience kit as described in the FDA Guidance document, "Convenience Kits Interim Regulatory Guidance" issued May 20, 1997.

Timothy D. Connors
Senior Regulatory Affairs Specialist

24MAR2016
Date

21.2 Utilization of Standards

Conformance to the following standards has been cited within this 510(k) submission to support MR Conditional use.

Standard Number	Standard Organization	Standard Title	Version/ Date	FDA Standard Recognition Number
F2052-06el	ASTM	Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment	2013	8-381
F2119-07	ASTM	Test Method for Evaluating MR Image Artifacts from Passive Implants	2013	8-153
F2182-11a	ASTM	Test Method For Measuring Radio Frequency Induced Heating On or Near Passive Implants During Magnetic Resonance Imaging	2013	8-227
F2213-06	ASTM	Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment.	2011	8-128
F2503-13	ASTM	Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment	2013	8-349

For each of the standards listed, FDA Form 3654 – Standards Data Report for 510(k)s has been completed (see **Appendix 8**).

Standards Conformance Summary Report:

Standard/Part	Statement
ASTM F2503-13 Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment	This international standard applies to the practice of marking of items that might be used in the magnetic resonance (MR) environment. The purpose of this practice is to mark items that might be brought into the MR environment and to recommend information that should be included in the marking. The full test report: Report: Magnetic Resonance Imaging Safety Testing of the CRW Stereotactic System: DHRS, UCHRA, and LL01 Final Report are located in **Appendix 3.2** and the protocol is an appendix to the full report.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 26 1995

Ms. Linda Jalbert
Manager, Regulatory Affairs
Radionics, Inc.
P.O. Box 438
22 Terry Avenue
Burlington, Massachusetts 01803-2591

Re: K944463
CRW-1 Stereotactic Arc System
Regulatory Class: II (two)
Product Code: 84 HAW
Dated: September 18, 1995
Received: September 19, 1995

Dear Ms. Jalbert:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

This letter will immediately allow you to begin marketing your device as described in your 510(k) premarket notification. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), promotion, or advertising please contact the Office of Compliance, Promotion and Advertising Policy Staff (HFZ-300) at (301) 594-4639. Other general information

on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

Thomas J. Callahan

Thomas J. Callahan, Ph.D.
Acting Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

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Acceptance Checklist for Abbreviated 510(k)s

(Should be completed within 15 days of DCC receipt)

The following information is not intended to serve as a comprehensive review.
FDA recommends that the submitter include this completed checklist as part of the submission.

510(k)#: K **Date Received by DCC:**

Lead Reviewer:

Branch: **Division:** **Center/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 the RTA review and that the element will be assessed during substantive review.

Preliminary Questions

Answers in the shaded blocks indicate consultation with a Center advisor is needed. (Boxes checked in this section represent FDAs preliminary assessment of these questions at the time of administrative review.)

	Yes	No	N/A
1. Is the product a device (per section 201(h) of the FD&C Act) or a combination product (per 21 CFR 3.2(e)) with a device constituent part subject to review in a 510(k)? If it appears not to be a device (per section 201(h) of the FD&C Act) or such a combination product, or you are unsure, consult with the CDRH Jurisdictional Officer or the CBER Product Jurisdiction Liaison to determine the appropriate action, and inform division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If the product does not appear to be a device or such a combination product, mark "No."	☑	☐	
Comments:			
2. Is the submission with the appropriate Center? If the product is a device or a combination product with a device constituent part, is it subject to review by the Center in which the submission was received? If you believe the submission is not with the appropriate Center or you are unsure, consult with the CDRH Jurisdictional Officer or the CBER Product Jurisdiction Liaison to determine the appropriate action and inform your division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If submission should not be reviewed by your Center mark "No."	☑	☐	
Comments: CDRH			

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3. If a Request for Designation (RFD) was submitted for the device or combination product with a device constituent part and assigned to your center, identify the RFD # and confirm the following: **a) Is the device or combination product the same (e.g., design, formulation) as that presented in the RFD submission?** **b) Are the indications for use for the device or combination product identified in the 510(k) the same as those identified in the RFD submission?** If you believe the product or the indications presented in the 510(k) have changed from the RFD, or you are unsure, consult with the CDRH Jurisdictional Officer or the CBER Product Jurisdiction Liaison to determine the appropriate action and inform your division management. *Provide summary of Jurisdictional Officer's/Liaison's determination.* If the answer to either question above is no, mark "No." If there was no RFD, mark "N/A."	☐	☐	☑
Comments:			
4. Is this device type eligible for a 510(k) submission? If a 510(k) does not appear to be appropriate (e.g., Class III type and PMA required, or Class I or II type and 510(k)-exempt), you should consult with the CDRH 510(k) Program Director or appropriate CBER staff during the acceptance review. If 510(k) is not the appropriate regulatory submission, mark "No."	☑	☐	
Comments:			
5. Is there a pending PMA for the same device with the same indications for use? If yes, consult division management and the CDRH 510(k) Program Director or appropriate CBER staff to determine the appropriate action.	☐	☑	
Comments:			
6. If clinical studies have been submitted, is the submitter the subject of an Application Integrity Policy (AIP)? If yes, consult with the CDRH Office of Compliance/Division of Bioresearch Monitoring (OC/DBM) or CBER Office of Compliance and Biologics Quality/Division of Inspections and Surveillance/Bioresearch Monitoring Branch (OCBQ/DIS/BMB) to determine the appropriate action. Check on web at http://www.fda.gov/ICECI/EnforcementActions/ApplicationIntegrityPolicy/ucm134453.htm. If no clinical studies have been submitted, mark "N/A."	☐	☐	☑
Comments:			

- **If the answer to 1 or 2 appears to be "No," then stop review of the 510(k) and issue the "Original Jurisdictional Product" letter.**
- **If the answer to 3a or 3b appears to be "No," then stop the review and contact the CDRH Jurisdictional Officer or CBER Office of Jurisdiction Liaison.**

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- **If the answer to 4 is "No", the lead reviewer should consult division management and other Center resources to determine the appropriate action.**
- **If the answer to 5 is "Yes," then stop review of the 510(k), contact the CDRH 510(k) Staff and PMA Staff, or appropriate CBER staff.**
- **If the answer to 6 is "Yes," then contact CDRH/OC/DBM or CBER/OCBQ/DIS/BMB, provide a summary of the discussion with DBM or BMB Staff, and indicate their recommendation/action.**

Abbreviated 510(k) Criteria

(See "The new 510(k) Paradigm – Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications – Final Guidance" and "Format for Traditional and Abbreviated 510(k)s")

In order to qualify for review as an Abbreviated 510(k), one of the following criteria (1 or 2 or 3) should be met. Submission should be converted and reviewed as a Traditional 510(k) if one of these criteria is not met. Complete the Refuse to Accept Checklist for a Traditional 510(k) if submission is converted.

			Yes	No	N/A
1.		**Submission relies on a device-specific guidance document, other than a special controls guidance document, and a summary report is provided that:** *Select "N/A" if submission does not rely on any device-specific guidance document(s). If "Yes," address parts a and b below.*	☐		☑
	a.	Includes a description of adherence to the relevant guidance document to support substantial equivalence.	☐	☐	
	b.	Includes a description of how the guidance document was used to satisfy the requirements of 21 CFR 807.87 (e.g., data to support substantial equivalence) and lists any deviations. *Select "No" if the sponsor does not address whether there were deviations.*	☐	☐	
Comments:					
2.		**Submission relies on a special control(s), either in a device-specific regulation or special controls document, as defined in Section 513(a)(1)(B) of the FD&C Act, to demonstrate substantial equivalence and a summary report is provided that:** *Select "N/A" if submission does not rely on any special controls. If "Yes," address parts a-d below.*	☐		☑
	a.	Includes a description of adherence to the special control(s) to support substantial equivalence	☐	☐	
	b.	Includes a description of how the special control(s) was used to satisfy the requirements of 21 CFR 807.87 (e.g., data to support substantial equivalence) and lists any deviations	☐	☐	

		Select "No" if the sponsor does not address whether there were deviations.				
Comments:						
3.		**Submission relies on FDA-recognized consensus standard(s) (See section 514(c)).** *Select "N/A" if submission does not rely on any FDA-recognized standard(s). If "Yes," address part a below.*		☑		☐
		For each cited standard:				
	a.	Submission includes: - The device specific conformity statement as specified in device-specific guidance document (e.g., latex condoms), or - a declaration for conformity to the device specific standard. **OR** The items below for use of FDA-recognized consensus standards.		☑	☐	☐
		i.	An identification of the applicable FDA-recognized consensus standards (full citation including version number)	☑	☐	☐
		ii.	An identification, for each consensus standard, of any adaptations of the standard for evaluation of the device under review (e.g., an identification of an alternative series of tests that were performed)	☑	☐	☐
		iii.	An identification, for each consensus standard, of any items (e.g., normative requirements of the standard) applicable to your device	☑	☐	☐
		iv.	A specification of any deviations from each applicable standard (e.g., deviations from international standards which are necessary to meet U.S. infrastructure conventions such as the National Electrical Code (ANSI/NFPA 70))	☑	☐	☐
		v.	A specification of the differences that may exist, if any, between the tested device and the device to be marketed and a justification for the applicability of the test results in these areas of differences.	☑	☐	☐
Comments:						

Does the submission meet one of the criteria above?

☑ Yes, submission meets criteria for an Abbreviated 510(k). Continue with the remainder of this checklist below.

☐ No, submission does not meet criteria for an Abbreviated 510(k). Discontinue this RTA checklist, convert to a Traditional and apply the Traditional checklist.

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Organizational Elements Failure to include these items should not result in an RTA designation.				
***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**		**Yes**	**No**	***Page #**
1.	Submission contains a Table of Contents.	☑	☐	2
2.	Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.).	☑	☐	N/A
3.	All pages of the submission are numbered. *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...).*	☑	☐	N/A
4.	Type of 510(k) is identified (i.e., Traditional, Abbreviated, or Special) *If type of 510(k) is not designated, review as a Traditional 510(k).*	☑	☐	1, 15, 18
Comments:				

Elements of a Complete Submission (RTA Items) **(21 CFR 807.87 unless otherwise indicated)** Submission should be designated RTA if not addressed
• Any "No" answer will result in a "Refuse to Accept" decision.; however, FDA staff has discretion to determine whether missing items are needed to ensure that the submission is administratively complete to allow the submission to be accepted or to request missing checklist items interactively from submitters during the RTA review. • 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.

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.				Yes	No	N/A	*Page #
A.	**Administrative**						
	1.	All content used to support the submission is written in English (including translations of test reports, literature articles, etc.).		☑	☐		N/A
		Comments:					
	2.	Submission identifies the following (FDA recommends use of the CDRH Premarket Review Submission Cover Sheet form [Form 3514]):					
		a.	Device trade/proprietary name	☑	☐		18
		b.	Device class and panel or Classification regulation or Statement that device has not been classified with rationale for that conclusion	☑	☐		18
		Comments:					
	3.	Submission contains an Indication for Use Statement with Rx and/or OTC designated (see also 21 CFR 801.109, and FDA's guidance "Alternative to Certain Prescription Devices Labeling Requirements.") *See recommended format (http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM360431.pdf).*		☑	☐		21
		Comments:					
	4.	Submission contains a 510(k) Summary or 510(k) Statement. *Refer to 21 CFR 807.92 and 21 CFR 807.93 for contents of 510(k) Summary and Statement, respectively. Adequacy of the content will be assessed during substantive review.*		☑	☐		23
		Comments:					
	5.	Submission contains a Truthful and Accuracy Statement per 21 CFR 807.87(k). *See recommended format (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142707.htm).*		☑	☐		26
		Comments:					

Contains Nonbinding Recommendations

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.				Yes	No	N/A	*Page #
	6.		Submission is a Class III 510(k) Device. *Select "N/A" only if submission is not a Class III 510(k).*	☐		☑	
		a.	Contains Class III Summary and Certification *See recommended content (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142662.htm). Select "N/A" only if submission is not a Class III 510(k).*	☐	☐	☑	
		Comments:					
	7.		Submission contains clinical data. *Select "N/A" if the submission does not contain clinical data. If "N/A"is selected, parts a and b below are omitted from the checklist.*	☐		☑	
		a.	Submission includes completed Financial Certification (FDA Form 3454) or Disclosure (FDA Form 3455) information for each covered clinical study included in the submission. *Select "N/A" if the submitted clinical data is not a "covered clinical study" as defined in the Guidance for Industry-Financial Disclosures by Clinical Investigators.*	☐	☐	☑	
		b.	Submission includes completed Certification of Compliance with requirements of ClinicalTrials.gov Data Bank (FDA Form 3674) (42 U.S.C. 282(j)(5)(B)) for each applicable device clinical trial included in the submission. *Select "N/A" if the submitted clinical data is not an "applicable device clinical trial" as defined in Title VIII of FDAAA, Sec. 801(j)*	☐	☐	☑	
		Comments:					
	8.		The submission identifies prior submissions for the same device included in the current submission (e.g., submission numbers for a prior not substantially equivalent [NSE] determination, prior deleted or withdrawn 510(k), Pre-Submission, IDE, PMA, etc.). **OR** States that there were no prior submissions for the subject device. *Prior submissions (or no prior submissions) for this device should be included in Section F (prior related submissions) of the CDRH Premarket Review Submission Cover Sheet form (Form 3514).*	☑	☐		p15

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.				Yes	No	N/A	*Page #
			This information may also 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).				
		a.	If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence from prior submissions for this device are addressed. *To address this criterion, it is recommended that the submission 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 adequacy of how the feedback was addressed will be assessed during the substantive review.* *Select "N/A" if the submitter states there were no prior submissions.*	☑	☐	☐	15
		Comments:					
B.	**Device Description**						
	9.	The device has a device-specific guidance document, special controls document, and/or requirements in a device-specific regulation regarding device description that is applicable to the subject device. *If "N/A"is selected, parts a and b below are omitted from the checklist.*		☐		☑	
		a.	The submission addresses device description recommendations outlined in the device-specific guidance. **OR** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria. *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.*	☐	☐	☑	

Contains Nonbinding Recommendations

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.				Yes	No	N/A	*Page #
		b.	The submission includes device description information that addresses relevant mitigation measures set forth in a special controls document or device-specific regulation applicable to the device. **OR** The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness. *Select "N/A" if there is no applicable special controls document or device-specific regulation. 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 such mitigation measures have been addressed should be assessed during the substantive review.*	☐	☐	☑	
		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).		☑	☐		42
		Comments:					
	11.	The submission includes descriptive information for the device, including the following:					
		a.	A description of the principle of operation or mechanism of action for achieving the intended effect.	☑	☐		42
		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.	☑	☐		42
		c.	A list and description of each device for which clearance is requested. *Select "N/A" if there is only one device or model. "Device" may refer to models, part numbers, various sizes, etc.*	☑	☐	☐	42
		d.	Submission contains representative engineering drawing(s), schematics, illustrations, photos and/or figures of the device. **OR**	☑	☐		Appendix 4

Contains Nonbinding Recommendations

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.				Yes	No	N/A	*Page #
			Submission includes a statement that engineering drawings, schematics, etc. are not applicable to the device (e.g., device is a reagent and figures are not pertinent to describe the device). *In lieu of engineering 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.*				
		Comments:					
	12.	Device is intended to be marketed with multiple components, accessories, and/or as part of a system. *Select "N/A" if the device is not intended to be marketed with multiple components, accessories, and/or as part of a system. If "N/A"is selected, parts a-c below are omitted from the checklist.*		☑	☐	☐	
		a.	Submission includes a list of all components and accessories to be marketed with the subject device.	☑	☐		42
		b.	Submission includes a description (as detailed in item 11a., 11b., and 11d. above) of each component or accessory. *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.*	☑	☐	☐	42
		c.	A 510(k) number is provided for each component or accessory that received a prior 510(k) clearance **AND** A statement is provided that identifies components or accessories that have not received prior 510(k) clearance.	☑	☐		42
		Comments:					
C.	**Substantial Equivalence Discussion**						
	13.	Submitter has identified a predicate device(s), including the following information:					
		a.	Predicate device identifier provided (e.g., 510(k) number, de	☑	☐		57

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.				Yes	No	N/A	*Page #
			novo number, reclassified PMA number, regulation number if exempt or statement that the predicate is a preamendment device). For predicates that are preamendments devices, information is provided to document preamendments status. *Information regarding documenting preamendment status is available online (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/MedicalDeviceQualityandCompliance/ucm379552.htm).*				
		b.	The identified predicate(s) is consistent throughout the submission (e.g., 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.	☑	☐		
		Comments:					
	14.	Submission includes a comparison of the following for the predicate(s) and subject device and a discussion why any differences between the subject and predicate(s) do not impact safety and effectiveness [see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f)] *See "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]" guidance document for more information on comparing intended use and technological characteristics.*					
		a.	Indications for use *If there are no differences between the subject device and the predicate(s) with respect to indications and intended use, this should be explicitly stated.*	☑	☐		58
		b.	Technology, including features, materials, and principles of operation *Examples of technological characteristics include, but are not limited to design, features, materials, energy source, and principle of operation.* *FDA recommends a tabular format for comparing technological characteristics. Any characteristic that is the*	☑	☐		58, 59

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.				Yes	No	N/A	*Page #
			same as the predicate(s) should be explicitly stated. Differences in technological characteristics should be identified and a rationale provided why they do not raise different questions of safety and effectiveness.				
		Comments:					
D.	**Proposed Labeling (see also 21 CFR parts 801 and 809 as applicable)**						
	15.	Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual).		☑	☐		Appendix 5
		a.	Indications for use are stated in labeling and are identical to Indications for Use form and 510(k) Summary (if 510(k) Summary provided)	☑	☐		Appendix 5
		b.	Labeling includes: - Statements of conditions, purposes or uses for which the device is intended (e.g., hazards, warnings, precautions, contraindications) (21 CFR 801.5) **AND** - Includes adequate directions for use (see 21 CFR 801.5) **OR** - Submission states that device qualifies for exemption per 21 CFR 801 Subpart D	☑	☐		Appendix 5
		Comments:					
	16.	Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1)		☑	☐		Appendix 5
		Comments:					
	17.	Labeling includes the prescription statement (see 21 CFR 801.109(b)(1)) or Rx Only symbol (see also Section 502(a) of the FD&C Act and FDA's guidance "Alternative to Certain Prescription Device Labeling Requirements"). *Select "N/A" if not indicated for prescription use.*		☑	☐	☐	Appendix 5
		Comments:					
	18.	The device has a device-specific guidance document, special controls document, and/or requirements in a device-specific		☐		☑	

Contains Nonbinding Recommendations

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.				Yes	No	N/A	*Page #
			regulation regarding labeling that is applicable to the subject device. *If "N/A" is selected, parts a and b below are omitted from the checklist.*				
		a.	The submission addresses labeling recommendations outlined in the device-specific guidance. **OR** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria. *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.*	☐	☐	☑	
		b.	The submission includes labeling information that addresses relevant mitigation measures set forth in a special controls document or device-specific regulation applicable to the device. **OR** The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness. *Select "N/A" if there is no applicable special controls document or device-specific regulation. 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 such mitigation measures have been addressed should be assessed during the substantive review.*	☐	☐	☑	
		Comments:					
	19.		If the device is an in vitro diagnostic device, provided labeling includes all applicable information required per 21 CFR 809.10. Select "N/A" if not an in vitro diagnostic device.	☐	☐	☑	
		Comment:					

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.			Yes	No	N/A	*Page #
E.	**Sterilization** *If an in vitro diagnostic (IVD) device and sterilization is not applicable, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.*				☐	
	Submission states that the device, and/or accessories, and/or components are: (*one of the below must be checked*) ☑ Provided sterile, intended to be single-use ☐ Requires processing during its use-life ☑ Non-sterile when used (and no processing required) ☐ Information regarding the sterility status of the device is not provided (if this box is checked, please also check one of the two boxes below) ☐ Sterility status not needed for this device (e.g., software-only device) ☐ Sterility status needed or need unclear This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *If "non-sterile when used" or "not provided and not needed" is selected, the sterility-related criteria below are omitted from the checklist.* *If information on sterility status is not provided, and it is needed or the need for this information is unclear, select "No."* *The "Requires processing during its use-life" option refers to devices falling into one of the four categories below:* • *Supplied sterile and requires reprocessing prior to subsequent patient use* • *Supplied non-sterile and requires user to process the device for initial use, as well as to reprocess the device after each use* • *Reusable medical device (single-user) reprocessed between each use* • *Single-use medical devices initially supplied as non-sterile to the user, and requiring the user to process the device prior to its use* *Please refer to the guidance document titled "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling" for additional information.*			☐		66, 67
	Comments:					
	20.	Assessment of the need for cleaning and subsequent disinfection or sterilization information.				

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
		a.	Identification of device, and/or accessories, and/or components that are provided sterile. *Select "N/A" if no part of the device, accessories, or components is provided sterile.*	☑	☐	☐	66
		b.	Identification of device, and/or accessories, and/or components that are end user sterilized or disinfected. *Select "N/A" if no part of the device, accessories, or components is end user sterilized or disinfected.*	☑	☐	☐	67
		c.	Identification of device, and/or accessories, and/or components that are reusable. *Select "N/A" if no part of the device, accessories, or components is reusable.*	☑	☐	☐	67
		Comments:					
	21.	If the device, and/or accessory, and/or a component is provided sterile: *Select "N/A" if no part of the device, accessories, or components is provided sterile, otherwise complete a-f below.*				☐	
		a.	Sterilization method is stated for each component (including dose for radiation sterilization)	☑	☐		66
		b.	A description of method to validate the sterilization parameters is provided for each proposed sterilization method (e.g., half-cycle method and full citation of FDA-recognized standard, including date). *Note: the sterilization validation report is not required.*	☑	☐		66
		c.	For devices sterilized using chemical sterilants such as ethylene oxide (EO) and hydrogen peroxide, submission states maximum levels of sterilant residuals remaining on the device and sterilant residual limits. *Select "N/A" if not sterilized using chemical sterilants.*	☑	☐	☐	66
		d.	Sterility Assurance Level (SAL) stated	☑	☐		66
		e.	Submission includes description of packaging	☑	☐		~~66~~ 53
		f.	For products labeled "non-pyrogenic," a description of the method used to make the determination stated (e.g., limulus amebocyte lysate [LAL]).	☑	☐	☐	66

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.				Yes	No	N/A	*Page #
			Select "N/A" if not labeled "non-pyrogenic."				
		Comments:					
	22.	If the device, and/or accessory, and/or a component is reusable or end user sterilized or disinfected: *Select "N/A" if no part of the device, accessories, or components are reusable or end user sterilized or disinfected, otherwise complete a-d below.*				☐	
		a.	Cleaning method is provided in labeling for each device, and/or accessory, and/or component. *Select "N/A" if not reusable and does not need cleaning prior to disinfection or sterilization*	☑	☐	☐	67,71
		b.	Disinfection method is provided in labeling for each device, and/or accessory, and/or component. *Select "N/A" if not disinfected (i.e., undergoes terminal sterilization) prior to use*	☐	☐	☑	
		c.	Sterilization method is provided in labeling for each device and/or accessory, and/or component. *Select "N/A" if not sterilized (i.e., undergoes disinfection) prior to use*	☑	☐	☐	67,68,71
		d.	Device types in this submission are listed in Appendix E of the FDA's guidance "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling." *Device types identified in Appendix E of the reprocessing guidance represent devices posing a greater likelihood of microbial transmission and represent a high risk of infection. Select "N/A" if the device type in the submission is not included in Appendix E of the reprocessing guidance.*	☐		☑	
			i. If device types in this submission are included in Appendix E of the reprocessing guidance, the submission includes protocols and test reports for validating the reprocessing instructions. *Select "N/A" if the device type in the submission is not included in Appendix E of the reprocessing guidance.*	☐	☐	☑	
		Comments:					
	23.	The device has a device-specific guidance document, special		☐		☑	

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.				Yes	No	N/A	*Page #
		controls document, and/or requirement in a device-specific regulation regarding sterility and/or reprocessing that is applicable to the subject device *If "N/A" is selected, parts a and b below are omitted from the checklist.*					
		a.	The submission addresses sterility and/or reprocessing recommendations outlined in the device-specific guidance. **OR** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria. *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.*	☐	☐	☑	
		b.	The submission includes sterility and/or reprocessing information that addresses relevant mitigation measures set forth in a special controls document or device-specific regulation applicable to the device. **OR** The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness. *Select "N/A" if there is no applicable special controls document or device-specific regulation. 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 such mitigation measures have been addressed should be assessed during the substantive review.*	☐	☐	☑	
		Comments:					
F.	**Shelf-Life**						
	24.	Proposed shelf life/ expiration date stated **OR**		☑	☐		71

Contains Nonbinding Recommendations

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.			Yes	No	N/A	*Page #
		Statement that shelf-life is not applicable because of low likelihood of time-dependent product degradation				
		Comments:				
	25.	For a sterile device, submission includes summary of methods used to establish that device packaging will maintain a sterile barrier for the entirety of the proposed shelf-life. *Select "N/A" if the device is not provided sterile.*	☑	☐	☐	72
		Comments:				
	26.	Submission includes summary of methods used to establish that device performance is maintained for the entirety of the proposed shelf-life (e.g., mechanical properties, coating integrity, pH, osmolality, etc.). **OR** Statement why performance data is not needed to establish maintenance of device performance characteristics over the shelf-life period.	☑	☐		72
		Comments:				
G.	**Biocompatibility** *If an in vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.*				☐	
	Submission states that there: (*one of the below must be checked*) ☑ Are direct or indirect patient-contacting components ☐ Are no direct or indirect patient-contacting components ☐ Information regarding patient contact status of the device is not provided (if this box checked, please also check one of the two boxes below) ☐ Patient contact information not needed for this device (e.g., software-only device) ☐ Patient contact information is needed or need unclear This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *If "are no" or "not provided and not needed" is selected, the biocompatibility-related criteria below are omitted from the checklist. If information on the*			☐		75

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.			Yes	No	N/A	*Page #
	patient-contact status is not provided, and contact information is needed or its contact status is unclear, select "No." *An example of a direct patient-contacting device would be an implant that has direct contact with patient tissues during use. An example of an indirect patient-contacting device would be fluid entering the patient's body following passing through device/device components not in direct contact with the patient.*					
	Comments:					
	27.	Submission includes a list identifying each patient-contacting device component (e.g., implant, delivery catheter) and associated materials of construction for each component, including identification of color additives, if present.	☑	☐		75
		Comments:				
	28.	Submission identifies contact classification (e.g., surface-contacting, less than 24 hour duration) for each patient-contacting device component (e.g., implant, delivery catheter).	☑	☐		75
		Comments:				
	29.	Biocompatibility assessment of patient-contacting components Submission includes: Test protocol (including identification and description of test article), methods, pass/fail criteria, and results provided for each completed test. **OR** A statement that biocompatibility testing is not needed with a rationale (e.g., materials and manufacturing/processing are identical to the predicate).	☑	☐		76
		Comments:				
H.	**Software**					
	Submission states that the device: (*one of the below must be checked*) ☐ Does contain software/firmware ☑ Does not contain software/firmware ☐ Information on whether device contains software/firmware is not provided			☐		80

			Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	*Page #
			(if this box checked, please also check one of the two boxes below) ☐ Software/firmware information not needed for this device (e.g., surgical suture, condom) ☐ Software/firmware information is needed or need unclear This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *If "does not contain" or "not provided and not needed" is selected, the software-related criteria below are omitted from the checklist. If information on software is not provided, and this information is needed or the need is unclear, select "No."*				
	Comments:						
	30.		Submission includes a statement of software level of concern and rationale for the software level of concern	☐	☐		
			Comments:				
	31.		All applicable software documentation provided based on level of concern identified by the submitter, as described in Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, or the submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through an alternative approach (i.e., the submitter has identified an alternate approach with a rationale). *Note: This element is also applicable to non-internally generated or off-the-shelf (OTS) software used in the device.*	☐	☐		
			Comments:				
I.	**Electrical Safety and EMC**						
	Electrical Safety: Submission states that the device: (*one of the below must be checked*) ☐ Does require electrical safety evaluation ☑ Does not require electrical safety evaluation ☐ Information on whether device requires electrical safety evaluation not provided (if this box checked, please also check one of the two boxes below)				☐		81

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.			Yes	No	N/A	*Page #
		☐ Electrical safety information not needed for this device (e.g., surgical suture, condom) ☐ Electrical safety information needed or need unclear This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *If "does not require" or "not provided and not needed" is selected, the electrical safety criteria below are omitted from the checklist. If information on electrical safety is not provided, and it is needed or the need for this information is unclear, select "No."*				
		Comments:				
	32.	Submission includes evaluation of electrical safety (e.g., per IEC 60601-1, or equivalent FDA-recognized standard, and if applicable, a device-specific standard). **OR** Submission includes electrical safety evaluation using methods or standards that are not FDA-recognized and submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternate methods or standards with a rationale).	☐	☐		
		Comments:				
	EMC: Submission states that the device: (*one of the below must be checked*) ☐ Does require EMC evaluation ☐ Does not require EMC evaluation ☐ Information on whether device requires EMC evaluation not provided (if this box checked, please also check one of the two boxes below) ☐ EMC information not needed for this device (e.g., surgical suture, condom) ☐ EMC information needed or need unclear This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *If "does not require" or "not provided and not needed" is selected, the EMC*			☐		

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.			Yes	No	N/A	*Page #
	criteria below are omitted from the checklist. If information on EMC is not provided, and it is needed or the need for this information is unclear, select "No."					
	Comments:					
	33.	Submission includes evaluation of electromagnetic compatibility (e.g., per IEC 60601-1-2 or equivalent FDA-recognized standard and if applicable, a device-specific standard). **OR** Submission includes electromagnetic compatibility evaluation using methods or standards that are not FDA-recognized and submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternate methods or standards with a rationale).	☐	☐		
		Comments:				
J.	**Performance Data General** *If an in vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected. Performance data criteria relating to IVD devices is addressed in Section K.*				☐	
	Comments:					
	34.	Full test report is provided for each completed test. A full test report includes: objective of the test, description of the test methods and procedures, study endpoint(s), pre- defined pass/fail criteria, results summary, conclusions. *Full test reports provided for all completed tests/evaluations (e.g., bench evaluations, comparative performance tests, etc.). Select "N/A" if the submission does not include performance data.*	☑	☐	☐	Appendix 3.2
	a.	Submission includes an explanation of how the data generated from each test report supports a finding of substantial equivalence (e.g., comparison to predicate device testing, dimensional analysis, etc.). *Select "N/A" if the submission does not include performance data.*	☑	☐	☐	Appendix 3.2
		Comments:				

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.				Yes	No	N/A	*Page #
	35.	The device has a device-specific guidance document, special controls document, and/or requirement in a device-specific regulation regarding performance data that is applicable to the subject device *If "N/A"is selected, parts a and b below are omitted from the checklist.*		☐		☑	
		a.	The submission addresses performance data recommendations outlined in the device-specific guidance. **OR** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria. *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.*	☐	☐	☑	
		b.	The submission includes performance data that addresses relevant mitigation measures set forth in a special controls document or device-specific regulation applicable to the device. **OR** The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness. *Select "N/A" if there is no applicable special controls document or device-specific regulation. 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 such mitigation measures have been addressed should be assessed during the substantive review.*	☐	☐	☑	
		Comments:					
	36.	If literature is referenced in the submission, submission includes: *Select "N/A" if the submission does not reference literature. If "N/A"is selected, parts a and b below are omitted from the*				☐	

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.				Yes	No	N/A	*Page #
			checklist. *Note that the applicability of the referenced article to support a substantial equivalence finding should be assessed during the substantive review; only the presence of a discussion is required to support acceptance.*				
		a.	Legible reprints or a summary of each article.	☑	☐		Appendix 3.4
		b.	Discussion of how each article is applicable to support the substantial equivalence of the subject device to the predicate.	☑	☐		Appendix 3.2, 3.4
			Comments:				
	37.		For each completed animal study, the submission provides the following: *Select "N/A" if no animal study was conducted. If "N/A"is selected, parts a-c below are omitted from the checklist. Note that this section does not address biocompatibility evaluations, which are assessed in Section G of the checklist.*			☑	
		a.	Submission includes a study protocol which includes all elements as outlined in 21 CFR 58.120	☐	☐		
		b.	Submission includes final study report which includes all elements outlined in 21 CFR 58.185	☐	☐		
		c.	Submission contains a statement that the study was conducted in compliance with applicable requirements in the GLP regulation (21 CFR Part 58), or, if the study was not conducted in compliance with the GLP regulation, the submission explains why the noncompliance would not impact the validity of the study data provided to support a substantial equivalence determination.	☐	☐		
			Comments:				
K.	**Performance Characteristics – In Vitro Diagnostic Devices Only (see also 21 CFR 809.10(b)(12))**						
	Submission indicates that device: (*one of the below must be checked*) ☐ Is an in vitro diagnostic device ☑ Is not an in vitro diagnostic device *If "is not" is selected, the performance data-related criteria below are omitted from the checklist.*						

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.				Yes	No	N/A	*Page #
	38.	Submission includes the following studies, as appropriate for the device type, including associated protocol descriptions, study results and line data:					
		a.	Precision/reproducibility	☐	☐	☑	
		b.	Accuracy (includes as appropriate linearity; calibrator or assay traceability; calibrator and/or assay stability protocol and acceptance criteria; assay cut-off; method comparison or comparison to clinical outcome; matrix comparison; and clinical reference range or cutoff.	☐	☐	☑	
		c.	Sensitivity (detection limits, LoB, LoD, LoQ where relevant for the device type).	☐	☐	☑	
		d.	Analytical specificity	☐	☐	☑	
		Comments:					
	39.	The device has a device-specific guidance document, special controls document, and/or requirement in a device-specific regulations regarding performance data that is applicable to the subject device. *If "N/A" is selected, parts a and b below are omitted from the checklist.*		☐	☐	☑	
		a.	The submission addresses performance data recommendations outlined in the device-specific guidance. **OR** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria. *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.*	☐	☐	☑	
		b.	The submission includes performance data that addresses relevant mitigation measures set forth in a special controls document or device-specific regulation applicable to the device.	☐	☐	☐	

			Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	*Page #
			OR The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness. *Select "N/A" if there is no applicable special controls document or device-specific regulation. 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 such mitigation measures have been addressed should be assessed during the substantive review.*				
		Comments:					

Decision: Accept_____ Refuse to Accept_____

If Accept, notify the applicant

If Refuse to Accept, notify applicant electronically and include a copy of this checklist.

Digital Signature Concurrence Table	
Reviewer Sign-Off	
Branch Chief Sign-Off (digital signature optional)*	
Division Sign-Off (digital signature optional)*	

*Branch and Division review of checklist and concurrence with decision required. Branch and Division digital signature optional.

CONFIDENTIAL

(b)(4)

EXTERNAL MEMORANDUM

TO: Integra

FROM: (b)(4)

DATE: December 16, 2013

PROJECT: (b)(4)

SUBJECT: Experimental Test Protocol: (b)(4)
(b)(4)

(b)(4)

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Magnetic Resonance Imaging Safety Testing (b)(4)

Final Report

(b)(4)

Magnetic Resonance Imaging Safety Testing (b)(4)

(b)(4)1

Final Report

Prepared for

Integra LifeSciences
311 Enterprise Drive
Plainsboro, NJ 08536

Prepared by

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EXTERNAL MEMORANDUM

TO: Integra LifeSciences

FROM: (b)(4)

DATE: February 14, 2014

PROJECT: (b)(4)

SUBJECT: Displacement Force Testing (b)(4)

(b)(4)

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Terry O. Woods[1]

MRI Safety and Compatibility of Implants and Medical Devices

Reference: Woods, T. O., "**MRI Safety and Compatibility of Implants and Medical Devices,**" *Stainless Steels for Medical and Surgical Applications, ASTM STP 1438,* G. L. Winters and M. J. Nutt, Eds., ASTM International, West Conshohocken, PA, 2003.

Abstract: Since MRI (magnetic resonance imaging) scanners became available in the 1980's, they have rapidly become one of the most common clinical imaging tools. The MR environment produces unique safety and compatibility issues for materials used in implants and medical devices. The principal issues for MR safety and compatibility are magnetically induced displacement force and torque, radio frequency (RF) heating, and image artifact. This paper defines and discusses the potential hazards produced by implants and devices in the MR environment, with an emphasis on stainless steels. It also describes MR safety and compatibility test methods developed by ASTM and summarizes ongoing MR standards development work.

Keywords: MRI, MRI safety, MRI compatibility, implants, medical devices

Introduction

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Designation: F2052 – 06$^{\varepsilon 1}$

Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment[1]

This standard is issued under the fixed designation F2052; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

ε^1 NOTE—Paragraph X1.3 was added editorially in May 2006.

1. Scope

1.1 This test method covers the measurement of the magnetically induced displacement force produced by static magnetic field gradients on medical devices and the comparison of that force to the weight of the medical device.

1.2 This test method does not address other possible safety issues which include but are not limited to issues of magnetically induced torque, RF heating, induced heating, acoustic noise, interaction among devices, and the functionality of the device and the MR system.

1.3 This test method is intended for devices that can be suspended from a string. Devices which cannot be suspended from a string are not covered by this test method. The weight of the string from which the device is suspended during the test must be less than 1 % of the weight of the tested device.

1.4 This test method shall be carried out in a system in which the direction of the magnetically induced deflection force is horizontal.

1.5 The values stated in SI units are to be regarded as standard. Values in parentheses are for information only.

1.6 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory requirements prior to use.*

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[3] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036.

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5. Significance and Use

5.1 This test method is one of those required to determine if the presence of a medical device may cause injury to individuals during an MR examination and in the MR environment. Other safety issues which should be addressed include but may not be limited to magnetically induced torque (see Test Method F2213) and RF heating (see Test Method F2182). The terms and icons in Practice F2503 should be used to mark the device for safety in the magnetic resonance environment.

5.2 If the device deflects less than 45°, then the magnetically induced deflection force is less than the force on the device due to gravity (its weight). For this condition, it is assumed that any risk imposed by the application of the magnetically induced force is no greater than any risk imposed by normal daily activity in the Earth's gravitational field.

5.3 A deflection of less than 45° at the location of the maximum static magnetic field gradient in one MR system does not preclude a deflection exceeding 45° in a system with a higher field strength or larger static field gradients.

5.4 This test method alone is not sufficient for determining if a device is safe in the MR environment.

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Designation: F2213 – 06 (Reapproved 2011)

Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment[1]

This standard is issued under the fixed designation F2213; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This test method covers the measurement of the magnetically induced torque produced by the static magnetic field in the magnetic resonance environment on medical devices and the comparison of that torque to the equivalent torque applied by the gravitational force to the implant.

1.2 This test method does not address other possible safety issues which include but are not limited to issues of magnetically induced force due to spatial gradients in the static magnetic field, RF heating, induced heating, acoustic noise, interaction among devices, and the functionality of the device and the MR system.

1.3 The torque considered here is the magneto-static torque due to the interaction of the MRI static magnetic field with the magnetization in the implant. The dynamic torque due to interaction of the static field with eddy currents induced in a rotating device is not addressed in this test method. Currents in lead wires may induce a torque as well.

1.4 The sensitivity of the torque measurement apparatus must be greater than 1/10 the "gravity torque," the product of the device's maximum linear dimension and its weight.

1.5 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

1.6 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

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[redacted]

[1] This test method is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.15 on Material Test Methods.

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[2] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

[3] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, http://www.ansi.org.

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5. Significance and Use

5.1 This test method is one of those required to determine if the presence of a medical device may cause injury during a magnetic resonance examination and in the magnetic resonance environment. Other safety issues which should be addressed include but may not be limited to magnetically induced force (see Test Method F2052) and RF heating (see Test Method F2182). The terms and icons in Practice F2503 should be used to mark the device for safety in the magnetic resonance environment.

5.2 If the maximal torque is less than the product of the longest dimension of the medical device and its weight, then the magnetically induced deflection torque is less than the worst case torque on the device due to gravity. For this condition, it is assumed that any risk imposed by the application of the magnetically induced torque is no greater than any risk imposed by normal daily activity in the Earth's gravitational field. This is conservative; it is possible that greater torques would not pose a hazard to the patient.

5.3 This test method alone is not sufficient for determining if an implant is safe in the MR environment.

5.4 The sensitivity of the torque measurement apparatus must be greater than 1/10 the "gravity torque," the product of device weight and the largest linear dimension.

5.5 The torque considered here is the magneto-static torque due to the interaction of the MRI static magnetic field with the magnetization in the implant. The dynamic torque due to interaction of the static field with eddy currents induced in a rotating device is not addressed in this test method. Currents in lead wires may induce a torque as well.

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Mechanisms and prevention of thermal injury from gamma radiosurgery headframes during 3T MR imaging

Marcus C. Bennett,[1a] David B. Wiant,[1] Jacob A. Gersh,[1] Wendy Dolesh,[1] X. Ding,[1] Ryan C. M. Best,[1] J. D. Bourland[1,2,3]
Departments of Radiation Oncology,[1] Biomedical Engineering,[2] and Physics,[3] Wake Forest University School of Medicine, Winston-Salem, NC, USA
mbennett@wakehealth.edu

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Magnetic resonance imaging (MRI) is regularly used for stereotactic imaging of Gamma Knife (GK) radiosurgery patients for GK treatment planning. MRI-induced thermal injuries have occurred and been reported for GK patients with attached metallic headframes. Depending on the specific MR imaging and headframe conditions, a skin injury from MRI-induced heating can potentially occur where the four headframe screws contact the skin surface of the patient's head. Higher MR field strength has a greater heating potential. Two primary heating mechanisms, electromagnetic induction and the antenna effect, are possible. In this study, MRI-induced heating from a 3T clinical MRI scanner was investigated for stereotactic headframes used in gamma radiosurgery and neurosurgery. Using melons as head phantoms, optical thermometers were used to characterize the temperature profile at various points of the melon headframe composite as a function of two 3T MR pulse sequence protocols. Different combinations of GK radiosurgery headframe post and screw designs were tested to determine best and worst combinations for MRI-induced heating. Temperature increases were measured for all pulse sequences tested, indicating that the potential exists for MRI-induced skin heating and burns at the headframe attachment site. This heating originates with electromagnetic induction caused by the RF fields inducing current in a loop formed by the headframe, mounting screws, and the region of the patient's head located between any of the two screws. This induced current is then resistively dissipated, with the regions of highest resistance, located at the headframe screw–patient head interface, experiencing the most heating. Significant heating can be prevented by replacing the metallic threads holding the screw with electrically insulated nuts, which is the heating prevention and patient safety recommendation of the GK manufacturer. Our results confirm that the manufacturer's recommendation to use insulating nuts reduces the induced currents in the headframe nearly to zero, effectively preventing heating and minimizing the likelihood of thermal injury.

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Key words: MRI-induced heating, radiosurgery, stereotactic headframe

I. INTRODUCTION & BACKGROUND

Magnetic resonance imaging (MRI) is increasingly used in radiation oncology departments for radiation treatment planning because of the excellent contrast for soft tissues and tumors.[1-3] MRI is also considered a primary imaging modality for Gamma Knife (GK) stereotactic radiosurgery treatment planning. Important MRI safety issues that may be new to the radiation oncology clinic include potential damage and injury to property, patients and staff from several

[a] Corresponding author: Marcus C. Bennett, Department of Radiation Oncology, Wake Forest University School of Medicine, Medical Center Blvd., Winston-Salem, NC 27157 USA; phone: 336-713-6508; fax: 336-713-6622; email: mbennett@wakehealth.edu

sources: the rapid acceleration of nearby ferromagnetic objects by the high-static magnetic field (up to 3 T for clinical units);[4-11] the gradient fields, which have been shown to induce nerve stimulation in humans;[12,13] the cryogenics, which can cause severe frostbite, suffocation, and substantial explosions if the pressure relief system of the cryogen containers become defective;[14] and the radiofrequency (RF) fields, which are likely the primary source of MRI-induced thermal injury.[9,15-23]

This study is motivated by the increasing number of reports of MRI-induced patient thermal injuries, including burns,[9,13-23] and by our clinic's use of a dedicated 3T MR simulator[1,2] that serves as an integral part of an active GK radiosurgery program. The causes of reported MRI-induced thermal injuries and burns are often not well understood, are sometimes described as unknown or mysterious, and seem to originate with different heating mechanisms. In some cases, burns were associated with wires used with electronic monitoring equipment or implanted biomedical devices such as pacemakers,[8-11,15,17,20-24] while in other cases, thermal injuries have occurred with no wires present near the patient, in the extremities or around tattoos,[24] for instance. While the specific situations leading to these injuries may be difficult to pinpoint, the heating mechanisms causing them are not mysterious. They are the well-understood physical phenomena of electromagnetic induction and the antenna effect, both originating with the radiofrequency (RF) outputs of the MRI machine.

In 2003, headframe and GK manufacturer, Elekta, (Elekta AB, Stockholm, Sweden) notified users of the availability of "insulated posts", with the stated use for "high tesla MR units and high frequency MR sequences".[25] Beginning at approximately the same time, reports to the US Food and Drug Administration (FDA) documented thermal injuries due to MR-induced heating for patients wearing stereotactic headframes.[26-33]

The physical explanation of these reported thermal injuries has not been given. Thus, this study seeks to prevent MRI-induced burns in GK patients by first understanding the physical mechanisms that could lead to these injuries and, subsequently, validating the technique recommended to prevent them. The manufacturer's recommended burn prevention technique is to replace the tapped holes at the GK headframe screw–post interface, a metal-to-metal junction, with snap-in insulated nuts. The use of the insulated headframe posts is required for both 1.5 T and 3 T MRI scans.[34] The use of uninsulated posts is permitted for X-ray-only procedures, such as CT scans or biplanar projection angiography.

A. MRI-induced heating mechanisms

Previous studies of MRI-induced burns considered three potential heating mechanisms:[15,16] 1) resistive heating from currents induced by direct electromagnetic induction, 2) the unlikely coincidental presence of a conducting loop arranged perpendicular to the RF field and containing the right combination of inductance and capacitance to result in a resonant frequency equal to that of the MRI RF field (a special case of electromagnetic induction), and 3) the antenna effect, which is antinodal heating at the tips of wires or other conductors of appropriate length that act as antennas. A brief review of these potential heating mechanisms is presented.

The first mechanism, electromagnetic induction, is described by Faraday's law:

$$\oint \vec{E} \cdot d\vec{l} = -\frac{d}{dt}\left(\int \vec{B} \cdot d\vec{a}\right) \tag{1}$$

where $\vec{E}$ is the electric field, $\vec{l}$ is the distance around the loop, $\vec{B}$ is the magnetic flux density, and $\vec{a}$ is the cross-sectional area enclosed by a conducting loop. This can be stated more simply as:

$$V \propto dB/dt \tag{2}$$

where *V* is the voltage induced in the loop, *B* is the magnetic field, and *t* is time. In this case, the rapidly changing magnetic fields induce a current in loops of wire or other conducting material, with the area enclosed by the loop oriented perpendicular to the changing magnetic field. The voltage in turn induces a current:

$$i = V/R \tag{3}$$

where *V* is the voltage and *R* is the resistance of the loop. The induced current is then dissipated as heat at a rate:

$$P = i^2R \tag{4}$$

with the greatest heating occurring at locations with the highest resistance. These loops can be formed by wires, other conducting material such as the GK headframe posts, and/or loops of human tissue such as a patient with his arm forming a closed loop, or human tissue plus a section of wire forming a loop. The current will dissipate via resistive heating, the majority of which will occur at the position of highest electrical resistance which tends to occur at the skin–skin interface (e.g., loop formed by the arm), or the wire–skin interface (e.g., loop formed by a wire).

In the study by Dempsey et al.[16] different diameter loops of copper wire were placed perpendicular to the RF field and the temperature rise was recorded. Larger diameter loops resulted in more heating, consistent with Faraday's law. No resistor was placed in the loop and, therefore, the resistive heating was distributed evenly around the loop, resulting in a temperature rise along the whole loop. Had a resistor been placed in the loop, most of the heat would have been dissipated locally at and near the resistor, resulting in a higher temperature rise over a much smaller region of the loop. Whether the induced currents originated with the RF field or with the gradient field was not resolved in the Dempsey study. However, direct measurement of the induced voltage waveform in a loop of wire showed that the source of the heating is primarily the RF field.[17] Subsequent measurements confirmed this result, showing that reducing the magnitude of the RF signal reduces the induced voltage in the loop of wire.[17]

Resonance heating is a second possible heating mechanism. Dempsey et al.[16] found very high temperature rises of up to 61°C in loops with appropriately valued inductance and capacitance to cause resonance. The resonant frequency of the loop is given by:

$$f = \frac{1}{2\pi\sqrt{LC}} \tag{5}$$

In practice, it is unlikely that the loops described above will by coincidence happen to have the appropriate values of inductance (L) and capacitance (C) so that the resonant frequency matches the frequency of the MRI machine; however, if they do, there will be substantial heating.

The third mechanism that can lead to heating is the antenna effect, which occurs when a wire of appropriate length is exposed to the RF frequency and acts as an antenna. This effect is exploited in half-wavelength dipole antennas for receiving radio signals. If a length of wire or other conductor is ~ $\lambda/2$, an electromagnetic oscillation (resonance) will be produced with a node in the center of the wire and an antinode at either end. The maximum amplitude will occur at the antinodes, resulting in the ends of the wire heating to high enough temperatures for thermal injury. Dempsey and Condon[15] showed that for a 1.5 T MRI machine with operating frequency of 63.87 MHz, the antenna effect occurred in a wire length of ~ 220 cm, in rough agreement with the theoretical expectation of $\lambda/2$ approximately equal to 235 cm. Local temperature increases of up to 63°C were observed at the wire tip, high enough to cause

burns to the experimental apparatus,[16] and certainly high enough to cause severe or ablative tissue injury. This mechanism is suspected in a number of cases of MRI induced patient burns, including pulse oximeter wires.[24] It is extremely important to realize that the length of an ideal λ/2 antenna inside the human body is reduced by an order of magnitude, because the EM wavelength is significantly reduced due to the dielectric and electrical properties of human tissues. For instance, pacemaker leads in human-equivalent soft tissue will resonate at lengths of ~ 20 cm for 1.5 T (64 MHz), or ~ 10 cm for 3 T,[20] not the 220 to 235 cm in-air values reported earlier.[15]

The antenna effect in conductive tissues is explained as follows. The human body is conducting, and thus the behavior of incident EM waves is described by Maxwell's equations applied to conducting media. For this case, Ampere's law is:

$$\vec{\nabla} \times \vec{B} = \mu\varepsilon \, d\vec{E}/_{dt} + \mu\sigma\vec{E} \tag{6}$$

where $\vec{B}$ is the magnetic field, $\vec{E}$ is the electric field, μ is the permeability, ε is the permittivity, and σ is the conductivity. The solutions to the resulting wave equations are plane waves, but with a complex wave number

$$\tilde{k} = k + iK \tag{7}$$

where

$$k = \omega\sqrt{\varepsilon\mu/2}\left[\sqrt{1 + (\sigma/\varepsilon\omega)^2} + 1\right]^{1/2} \tag{8}$$

and

$$K = \omega\sqrt{\varepsilon\mu/2}\left[\sqrt{1 + (\sigma/\varepsilon\omega)^2} - 1\right]^{1/2} \tag{9}$$

The wavelength, λ, in the human body is thus given by:

$$\lambda = \frac{1}{k} \tag{10}$$

which depends primarily on the permittivity, ε, the conductivity, σ, and the frequency, ω. Another result is that the amplitude of the wave will decrease with increasing penetration depth into the human body, quantified by the skin depth, δ

$$\delta = \frac{1}{K} \tag{11}$$

which describes the depth at which the amplitude is decreased by 1/e, or to about 37% of the surface value. For given ω, the wavelength depends on ε, and σ, and the wave amplitude depends on its depth below the surface, quantified by the skin depth. Accordingly, the behavior of EM waves in the human body varies within the different organs and tissue types, based on ε and

σ values over the frequency range.[35,36] It is also important to note that antenna effect heating depends on the angle of the conductor with respect to the applied EM wave and is maximized when the length of the conductor is parallel to the direction of the EM wave.

The antenna effect for metallic implants has been studied in tissue equivalent body[20] and head[35,36] phantoms (e.g., matched ε and σ). For the brain, for 3 T, the wavelength is estimated to be 25.5 cm,[35,36] suggesting that an implant length of ~ 12.75 cm would be susceptible to antenna effect heating. At 7 T, wavelength becomes 10.6 cm leading to potential antenna effect heating for 5.3 cm implants.[35,36] These implant dimensions give an indication of possible conductor lengths of relevance for antenna effect heating for GK patients wearing headframes.

All reported MRI-induced burns likely originate in some form from either electromagnetic induction or the antenna effect. For the case of the headframe screw heating, the results of this study show that the cause is electromagnetic induction. This finding is consistent with the dimensions of the GK headframe which, with an effective unwrapped length of ~ 62 cm, is too short for antenna effect heating at 3 T (128 MHz, λ/2 approximately equal to 117 cm) or 1.5 T (64 MHz, λ/2 approximately equal to 220 cm).[16] Also, the typical ~ 5–10 mm length of the screws embedded in the head surface is less than the ~ 13 cm length expected for the antenna effect in the human head to occur. Thus, the cause of heating is most likely due to the induction of currents in loops formed by the headframe and the tissue of the patient's head, with the area of the loop oriented perpendicularly to the rapidly changing magnetic fields. Because the heat source is resistive heating, $P = i^2R$ (Eq. (4)), one needs only to increase the resistance of the part of the loop outside the patient's head (i.e., the headframe) in order to decrease the resistive heating in the tissue.

The following experimental results using melon phantoms show that heating occurs during standard MR brain scans near attached GK headframe screws, the heating mechanism is electromagnetic induction, the amount of heating depends on the material type of the headframe screws and posts, and the use of insulated headframe posts renders the induced currents and associated resistive heating negligible.

II. MATERIALS AND METHODS

A. Experimental geometry, pulse sequences, and temperature measurements

Fresh watermelons and honeydew melons were used to simulate the human head (Fig. 1). The melons ranged in weight approximately from 1.5 to 3 lbs. The electrical resistance of the surface layer of both types of melon, about 1 MΩ, is comparable to the resistance of the human head measured by point contacts on the skin. Both displayed similar resistive properties, with R ~ 1 MΩ within the outer shell of the melon, but decreasing to ~ 50–300 kΩ if the inner pulp is penetrated by the meter lead (Fig. 1). As shown in Fig. 2, the melons are mounted in the GK headframe and optical thermometers are mounted with tape at various positions on the headframe, screws, and melon. All experiments were conducted using a GE 3.0 T MR scanner (Signa EXCITE, GE Healthcare, Waukesha, WI). Two pulse sequences were investigated: 1) a standard T1-weighted GK Protocol sequence (axial T1 spin echo, with flow compensation, TE = ~ 23 ms, TR = 800 ms, NEX = 1, BW = 22.73, and a 384 × 224 matrix), and 2) in order to induce increased heating, an enhanced 13 minute fast spin echo sequence (FSCXL with flow compensation and tailored RF, TE = 16 ms, TR = 767 ms, NEX = 4, BW = 20.83, ETL = 37, and a 256 × 256 matrix). Temperature was measured using two MR-compatible fiber optic thermometers, (Veris MR Vital Signs Monitoring System, Medrad, Inc, Warrendale, PA). The temperature is determined via a temperature sensitive phosphor located at the probe tip and energized by an LED pulse.[37] Thermal connections to the headframe screws were made by careful adhesion of the more thermally conductive *side* (as opposed to the end) of the optical thermometer to the tip of the screw (arrow, Fig. 2(c)). Thermal connections to the melon were

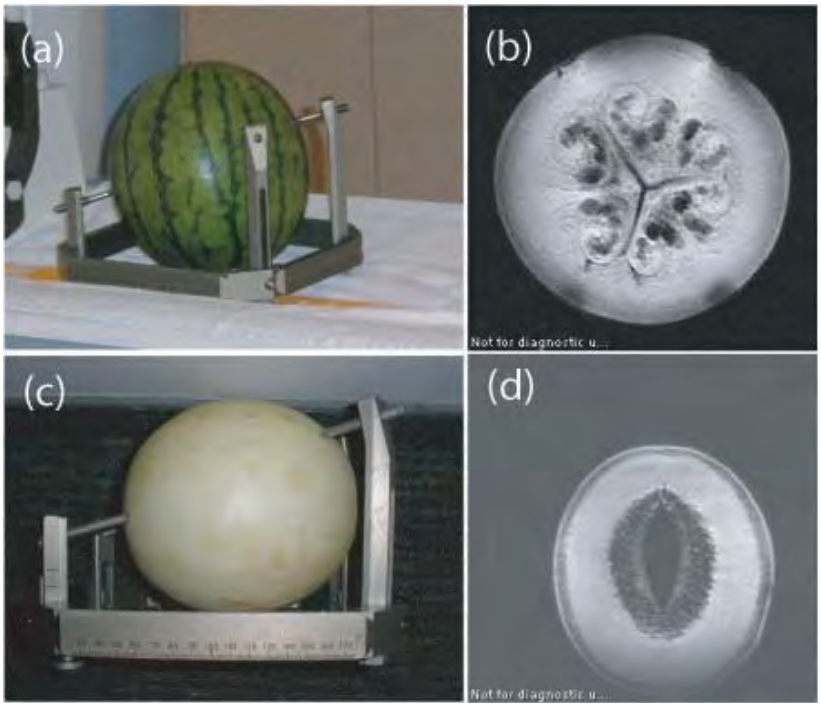

FIG. 1. Photograph and associated MRI images of a watermelon (a) and (b), and a honeydew melon ((c) and (d)). Headframe screws should be kept in the shell region as indicated in the MRI images in order to maintain resistance in the MΩ range and thus be comparable to the human head.

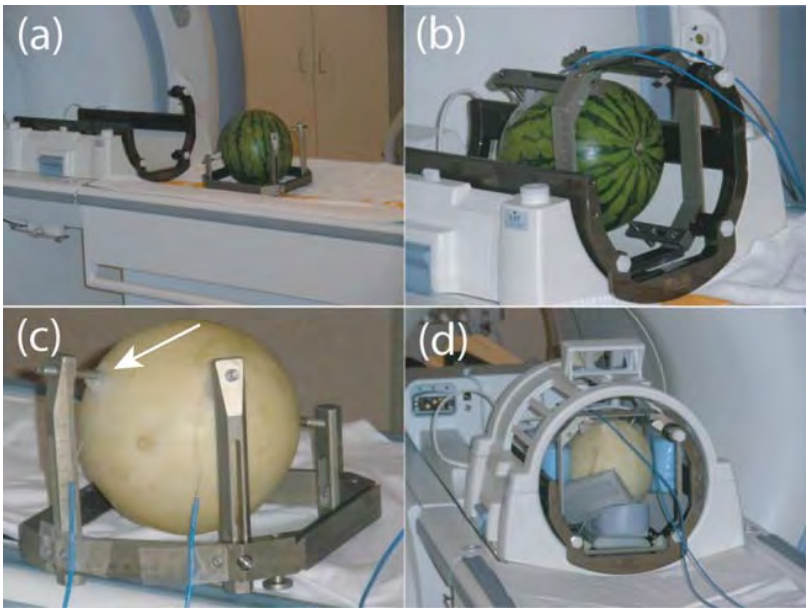

FIG. 2. Watermelon mounted in headframe (a); watermelon placed in GK head coil (b) with optical thermometers taped to the surface of the watermelon up against the screw–melon surface interface; a similar set-up for a honeydew melon (c). It is important to cushion the melon in the head coil (d) to reduce the vibration, which can lead to thermometers coming loose from the surface.

made by enclosing the optical thermometers in thin plastic wrap and inserting them directly into the melon to a depth of 5 mm, preventing air cavities and ensuring good thermal contact.

B. Antenna-effect heating

To verify the absence of antenna-effect heating, the GK headframe alone with 4 uninsulated posts and 4 tungsten tipped alumina screws (Fig. 3(a)) was placed in the GK standard four-element head coil and scanned in the MRI using the current standard T1-weighted GK protocol pulse sequence. Temperature measurements at the two anterior headframe screws were recorded every 30 seconds during the 9.5 minute pulse sequence. No heating was detected at either screw, confirming that the headframe–post–screw unit was not behaving as an antenna (Fig. 3(b), triangles). Similarly, 45 and 60 mm titanium screws alone, without the headframe or posts, were embedded in the melon to depths of 5 mm and evaluated for heating with the T1-weighted pulse sequence. Again, no heating was observed at the screw–melon interface, indicating the absence of the antenna effect for these length screws for the 0.5 mm portion of the screw within the melon.

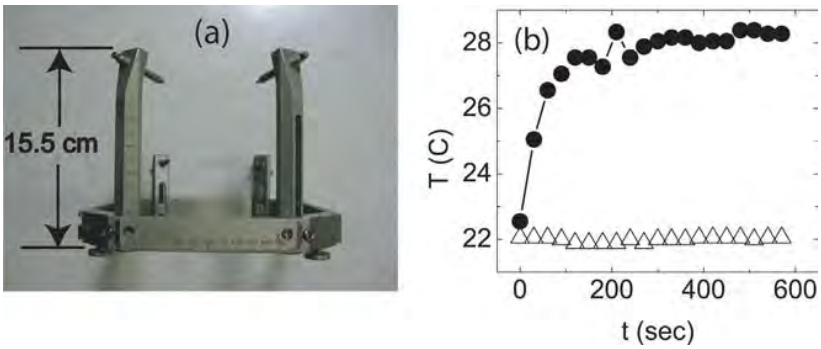

FIG. 3. Photograph of Gamma Knife headframe (a) showing that the length of the longest post is ~ 15 cm, which is much lower than the expected length required for heating via the antenna effect, which would be ~ 60 cm. Plot (b) of the time dependence of the temperature taken at the top of the headframe post, showing that there is no heating with the melon absent (triangles), but significant heating at the screw tips when the melon is mounted in the headframe (circles).

C. Electromagnetic induction heating

To determine whether there is any heating from electromagnetic induction in a loop, a watermelon was subsequently mounted on the same headframe and remeasured in the same four-element head coil using the same pulse sequence. The screws were screwed approximately 5 mm into the surface of the watermelon and the temperature was again measured every 30 seconds at the top part of the anterior screw tips at the melon surface. A temperature increase of approximately 6°C near the screw tips was observed, confirming electromagnetic induction as the source of the heating (Fig. 3(b), circles). To further characterize the temperature profile of the melon headframe composite, a watermelon was mounted on the GK headframe and with the T1 axial GK pulse sequence, the temperature was measured at the screw tip and three positions along the melon in order to determine where heating occurs. Heating was greatest along the screw surface and at two points in the melon nearest to the screw (Fig. 4).

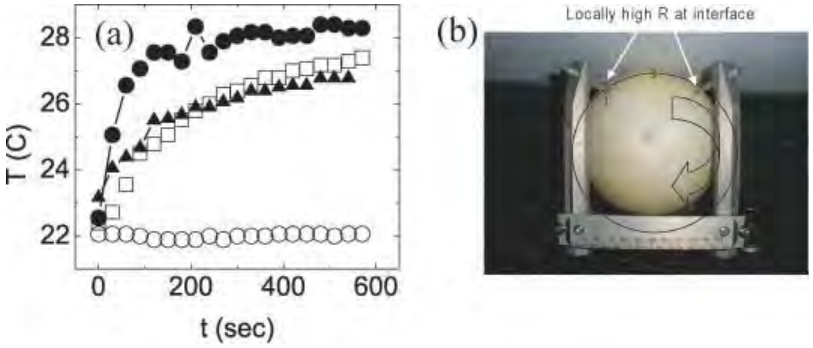

FIG. 4. The time dependence (a) of the temperature measured at each of the three positions indicated in (b) (filled triangles, hollow squares, hollow circles) and on the screw surface near the screw tip (filled circles). Photograph (b) of a honeydew melon showing three locations (red numbers 1–3) where the time dependence of the temperature was measured during a test scan. The arrow indicates the approximately circular current path of the induced current.

D. Screw–post combinations

With the heating mechanism established as electromagnetic induction, the heating characteristics of different screw and post types were measured. The temperature profiles were measured for combinations of two different screw types, and two different headframe post materials. All screw and post comparison tests were done on the same melon in immediate succession to ensure the same measurement conditions. Baseline temperature was determined by the initial temperature measured just before starting the initial scan, and subsequent scans were started only after temperatures cooled to within 1°C of baseline. Baseline temperatures varied from day to day from 18°C to 23°C, with a typical value of 20°C. Titanium- or tungsten-tipped alumina screws were measured in combination with either carbon or alumina posts, with both regular threads and insulated (plastic) nuts (Fig. 5). These combinations were chosen to represent the possible configurations available in the clinic, as well as to represent a range of safety (from "not safe" through "safe") (Table 1). To determine whether the manufacturer-recommended insulating posts prevent heating, the standard alumina headframe posts were replaced with electrically insulated posts, designed by placing snap–in insulating nuts between the screw and the post in the headframe in place of the regular threaded hole (Fig. 5(a), center). Experimental results confirm that this increased impedance prevents significant heating at the headframe screw–patient head interface. As shown in Table 1, the insulated posts are the only ones that rendered the heating negligible.

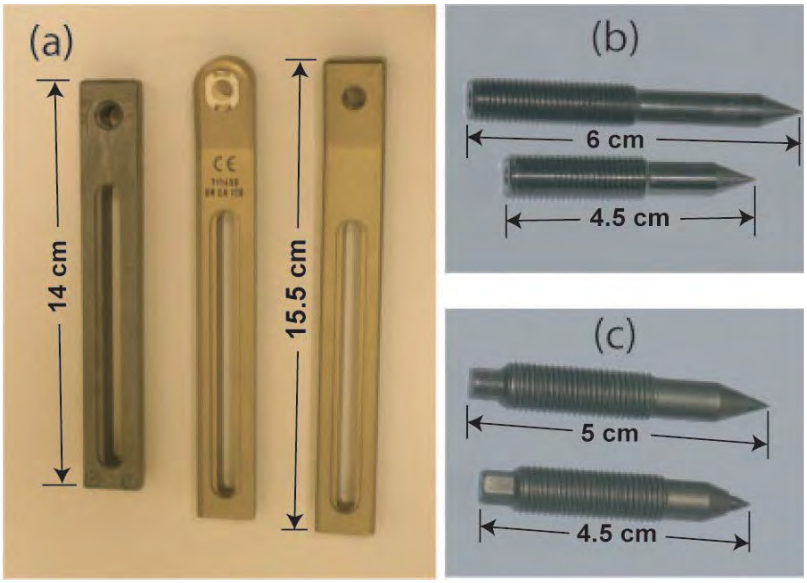

FIG. 5. The three types of headframe post (a) that were used in the experiment were from left to right, carbon, alumina with the snap in insulated threads, and uninsulated alumina; titanium screws (b); tungsten-tipped alumina screws (c).

TABLE 1. General heating characteristics for different screw-post combinations. Based on temperature profile plots (see associated figures), combinations that showed anything more than negligible heating were deemed "not safe".

	Post Type		
Screw Type	*Alumina*	*Carbon*	*Insulated Alumina*
Alumina	not safe (Fig. 11) significant heating	not safe (Fig. 12) some heating	safe (Fig. 14) negligible heating
Titanium	not safe (Fig. 11) most heating	not safe (Fig. 12) some heating	safe (Fig. 14) negligible heating

III. RESULTS

A. Electromagnetic induction responsible for MRI-induced heating

The initial experiment was designed to determine which of the two most likely heating mechanisms, the antenna effect or electromagnetic induction, is responsible for the heating that occurs at the GK headframe screw–melon interface. Antenna-effect heating can be theoretically ruled out because the dimensions of the GK headframe are not large enough for this type of heating to occur. For the 128 MHz RF field of the 3 T magnet, the RF wavelength is ~ 235 cm, which corresponds to $\lambda/2$ ~ 117 cm. The longest posts on the GK headframe are ~ 15 cm and the overall unwrapped length is ~ 62 cm, much shorter than the required ~ 117 cm necessary for antenna heating to occur in air. Antenna-effect heating was experimentally ruled out based on temperature measurements that showed: 1) no heating for the assembled headframe suspended in air, and 2 no heating for screws of various lengths embedded at depths of 0.5 cm in the melon. This latter null result is expected based on the nominal EM wavelength produced by 3 T scans for soft tissue (~ 40 cm) and for brain tissue (~ 25 cm).[35,36]

Resonance-induced heating is a remaining phenomenon that could possibly result in heating. We have measured negligible capacitances and inductances in the GK headframe–melon composite and there is no evidence of resonance heating occurring in this experiment.

B. Induced heating location

Temperature measurements versus time as a function of position between the two anterior screws show that heating is greatest at the tapered part or tip of the screw along the melon–screw interface and that heating decreases with increasing distance from the screw tip (Fig. 4). Specifically, we found that heating occurs only near the tip of the screw and not primarily at back of the screw (Fig. 6). This temperature profile is consistent with the formation of a loop with most of the heating occurring at the maximum resistance spot in the loop, which is at the screw–melon interface in the conventional frame setup.

Melon resistivity was measured at different locations on the surface and at depth to determine variability that would impact temperature measurements. Using a handheld resistance meter, we measured a resistance of 1–3 MΩ for the outer flesh of the melon. Deeper into the melon, however, where the pulp is located, there is a significant drop in resistance down to ~ 100 kΩ. Experiments repeated with the thermometers placed in this deeper region show significantly decreased heating, owing to the reduced resistance (Fig. 7). This result shows that the region of heat is resistance dependent, again confirming that the source of the heating is the induced current loop with the same current heating more in higher resistance regions. To further characterize the

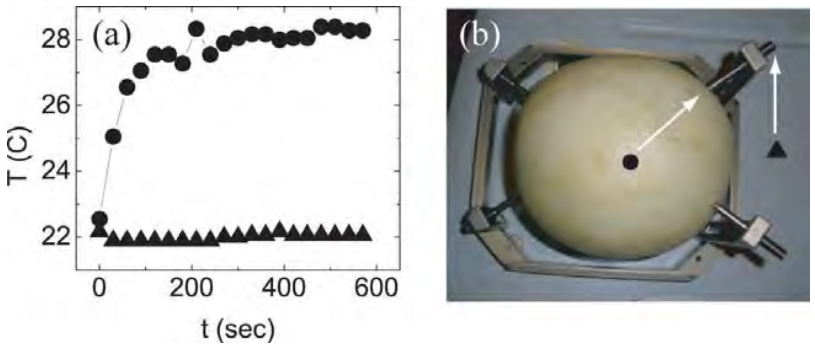

FIG. 6. Plot (a) of the time dependence of the temperature measured near the screw tip (filled circles) and at the back part of the screw (filled triangles), as indicated in the photograph of the melon headframe composite (b).

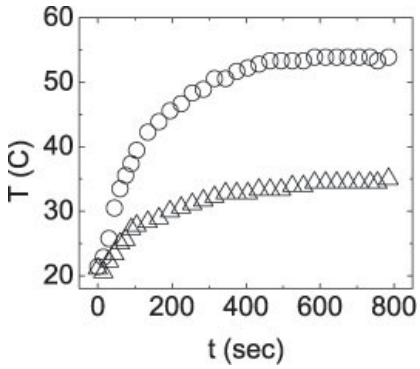

FIG. 7. The time dependence of the temperature at the melon–screw interface for the screws penetrating the standard 5 mm depth (circles) and a much deeper penetration of approximately 2 cm (triangles). The lower resistance of the pulp of the melon located > 1 cm below the melon surface results in less heat dissipated at deeper positions.

heating that occurs in the melon headframe composite, the time dependence of the temperature was measured on the posterior loop, which would be expected to have less heating than the anterior loop due to the smaller area enclosed. In Figure 8, the time dependence of the temperature of the posterior loop (Fig. 8(a), triangles) is plotted with that of the anterior loop (circles). As expected from current induced in accordance to Faraday's law, the induced current and its associated heating is less in the posterior loop because of the smaller cross sectional area. Other potential loops are separately measured to find the relative contributions to the screw heating of the composite system. Fig. 9 shows the time dependence of the temperature taken near the tip of the right anterior headframe screw at the screw–melon interface during the 13 minute FSE scan for each of the indicated loops. The anterior loop shows the most heating, with the side and diagonal loops each showing less heating (Fig. 9).

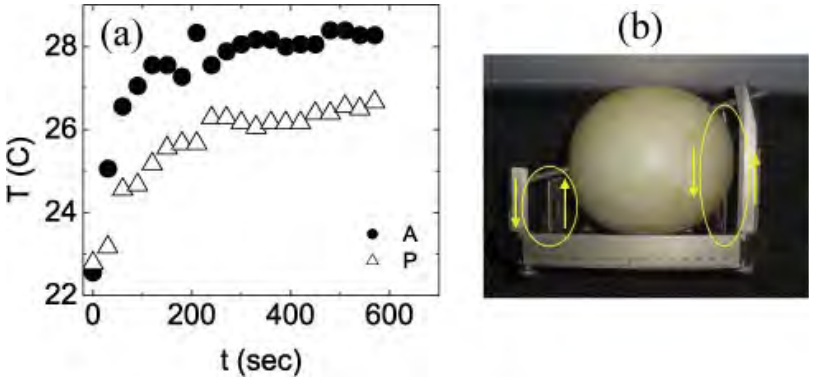

FIG. 8. The time dependence of the temperature measured near the screw tips for the larger anterior loop (circles) and the smaller posterior loop (triangles), showing that there is more heating induced in the larger loop, as noted in (b), consistent with electromagnetic inductive heating.

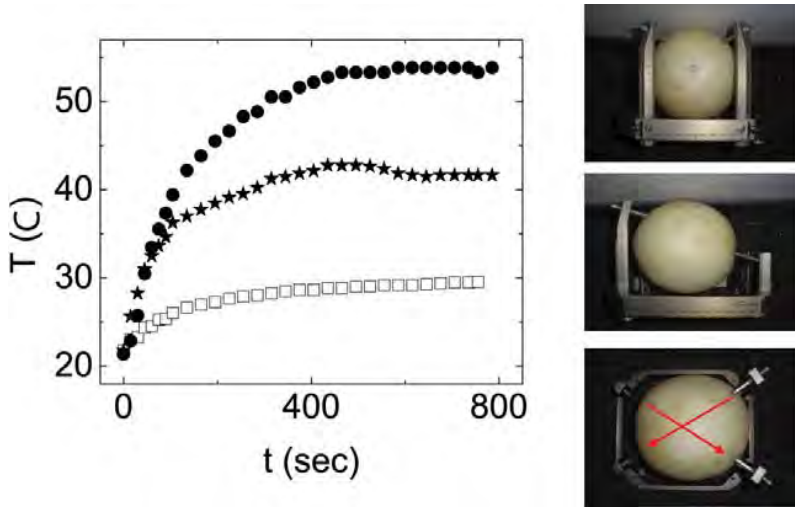

FIG. 9. The time dependence of the temperature measured with just two headframe screws attached in the configurations depicted in the photographs, isolating the anterior loop (top, filled circles), the right loop (middle, filled stars), and a diagonal loop (bottom, hollow squares).

C. Screw–post combinations

Temperature measurements for the two different screw materials, tungsten-tipped alumina and titanium, show that there is more heating at the screw–melon interface for the titanium screws (Fig. 10, filled circles), indicating a higher resistance at this interface for the titanium screws compared with the alumina screws (hollow circles). Different combinations of headframe screw and post materials show different heating characteristics associated with different resistance characteristics. Several different screw–post combinations were measured. First, using the titanium screws, the time dependence of the temperature was again measured, but with carbon posts instead of alumina posts (Fig. 11). At the screw tips, the heating decreased for the carbon posts relative to the alumina post, but the heating increased at the screw–post interface (Fig. 12). This effect is also consistent with heating by electromagnetic induction. With the alumina posts, there is very little resistance at the screw–post interface, but with the carbon posts, there is significant heating, showing that there is a significant resistance at the post–screw interface. Because the size of the loop is the same, the same voltage is induced in the loop. However, now there are two locations of significant resistance, so the heat is dissipated at two locations instead of just one. Thus the heating at the screw–melon interface decreases, but increases at the screw–post interface. This occurs only for the carbon posts. Because carbon posts may offer some advantages for CT imaging, it would be possible to use these posts with minimal heating via a similar insulated nut setup as is currently used with the alumina posts.

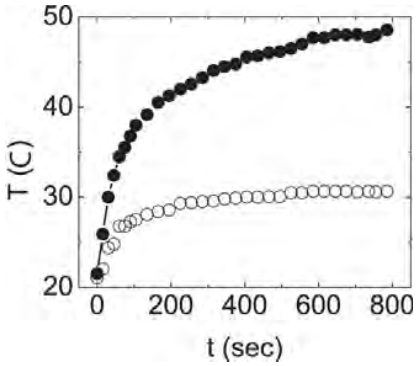

FIG. 10. The time dependence of the temperature of the headframe screw at the screw–melon interface near the screw tip for titanium screws (filled circles) and tungsten-tipped alumina screws (hollow circles), taken during the same pulse sequence.

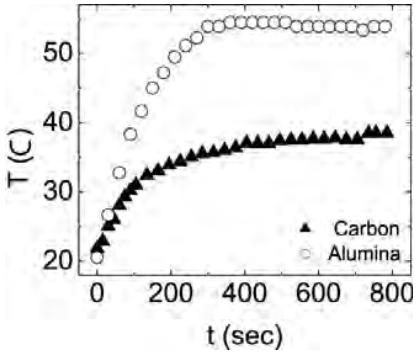

FIG. 11. The time dependence of the temperature measured at screw tip screwed into an alumina post (circles) and a carbon post (triangles), showing that more heating occurs at the screw tip in the alumina post compared with the carbon post.

Temperature measurements with the uninsulated alumina posts replaced with the insulated posts using snap-in insulated nuts prove that the insulated posts diminish heating to a negligible level (Fig. 13). A close–up view shows the small amount of heating (Fig. 13(b)). For mixed headframe–post–screw combinations, the results for one insulated alumina post and three uninsulated alumina posts are compared with the case for one insulated alumina post and three carbon posts (Fig. 14). As expected, there is less heating at the screw tips when carbon posts are used, compared with alumina posts.

In general, for the case of the GK headframe, the greatest heating occurs at the headframe screw–patient head interface, with the loop formed by the frame in contact with the skin. The results of this study show that this patient–frame loop is the only mechanism that can lead to GK patient burns that occur in the vicinity of the headframe screws.

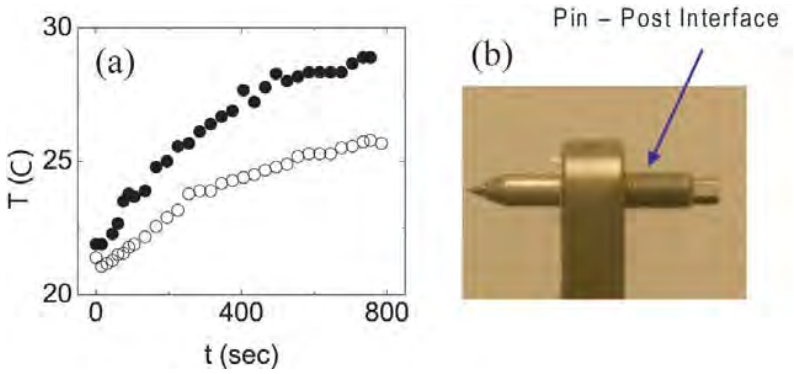

FIG. 12. Plot (a) of the time dependence of the temperature at the threaded region of the screw–post interface as indicated in (b), showing that there is more heating at this position with the carbon post than with the titanium post, which is consistent with Faraday's law.

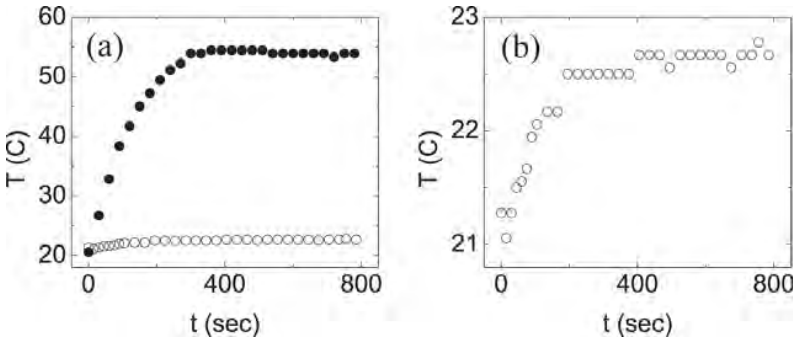

FIG. 13. The time dependence (a) of the temperature near the screw tip for the uninsulated alumina post and titanium screws (filled circles) and for the insulated alumina post with titanium screws (hollow circles), showing the prevention of significant heating by the increased resistance of the insulating nuts. Plot (b) of the time dependence of the temperature using the insulated post showing that while the heating is almost completely eliminated, there still is some heating present, which is consistent with heating by electromagnetic induction.

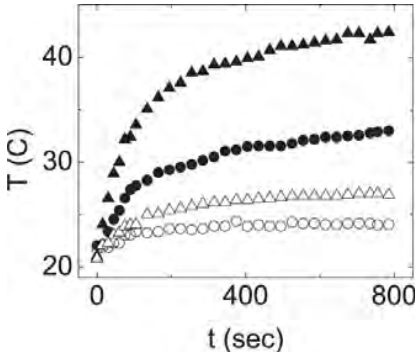

FIG. 14. Heating from mixed-post configurations, measured at the screw–melon interface. Circles show heating for carbon posts, with one insulated post (right anterior, hollow circles) and three uninsulated posts (temperatures obtained at left anterior, filled circles) at the other locations. Triangles show heating for alumina posts, with one insulated alumina post (right anterior, hollow triangles) and three uninsulated posts (temperatures obtained at left anterior, filled triangles) at the other locations. Uninsulated posts show higher temperature increases than insulated posts, and alumina posts have higher heating than carbon posts.

IV. DISCUSSION

This set of experiments was designed to determine which physical mechanism could lead to local heating of the GK headframe for patients undergoing stereotactic MR imaging, and to test the manufacturer's recommended method for heating prevention using electrically insulated posts. Additional experiments were conducted to characterize typical heating profiles of the GK headframe–patient system that occurs during MRI scans, and to learn how this profile changes when headframe post and screw materials are changed.

Initial experiments (Fig. 3) ruled out the antenna effect as a headframe heating mechanism and confirmed that the observed heating originates with the resistive dissipation of currents induced by the rapidly changing magnetic fields passing perpendicularly through the area enclosed by electrically conducting loops comprised of the headframe, headframe screws, and region of the patient's head between the two headframe screws, as described by Faraday's law. Further experiments showed that the resistive heating occurs primarily at the screw tips (Fig. 4, Fig. 6), where the electrical resistance is highest. Subsequent experiments found no antenna-effect heating in the portion of the screw embedded in the melon with no headframe attached.

The heating profile can be controlled by changing the materials of the headframe posts and screws. This was observed in the experiments comparing combinations of alumina, insulated alumina, and carbon posts, and titanium- and tungsten-tipped alumina screws (Figs. 10-14). Figures 11 and 12 compare the heating characteristics of the headframe composite with alumina screws and alumina posts with that of same setup, but with carbon posts in place of the alumina posts. While additional heating occurs at the carbon post–headframe screw interface (Fig. 12), causing the region of the post surrounding the headframe screw to heat, there is slightly less heating at the screw–patient head interface (Fig. 11), which again is consistent with electromagnetic induction heating. The carbon post–screw interface has a significantly higher impedance compared with the alumina post–screw interface and, thus, dissipates a larger amount of the induced current here, resulting in a reduced dissipation at the patient head–screw interface.

Replacing the uninsulated posts with the insulated posts prevented all but negligible heating of the melon headframe composite (Fig. 13), which is consistent with Faraday's law. The insulating nuts greatly increase the resistance of the loop. If, for example, the resistance of the loop is doubled, then the induced voltage, which is a function only of the cross-sectional area of the loop, is still the same, resulting in the current being halved. Resistive heating $P = i^2R$,

so that while the resistance is doubled, the induced current squared is quartered; therefore, the heating is halved. Thus increasing the resistance in any given loop reduces the heating when the mechanism is Faraday's law (e.g., electromagnetic induction). The manufacturer's recommended method works because the heating mechanism is electromagnetic induction. It is important to note that all four posts should be insulated, because as shown in Fig. 9, multiple loops contribute to the heating at any given screw tip. This same antiheating technique is effective for any headframe post material, and because carbon posts may offer some advantages in CT scans, it would be possible to use these posts with minimal heating by using the same insulated nut setup that is currently used with the alumina posts.

The manufacturer's recommended heating prevention method, however, works only to prevent heating by electromagnetic induction and would not prevent antenna-effect heating. An entirely different method would be required to prevent heating by the antenna effect. Fortunately, the GK headframe geometry is not a problem at 1.5 T or 3 T field strengths, because the dimensions are too small to heat by this method. However, if the static field operated at 7–10 T, the implant dimensions required for the antenna effect would be decreased to ~ 30–50 cm in air, and as small as just a few cm in the human body, depending on the type of tissue or organ where the implant is located, with the amount of heating dependent on the implant's depth below the surface and its angle with respect to the applied EM wave. This effect may be a major concern for patients with small implants in the human body, such as stents or aneurysm clips, that could pose a severe burn hazard at very high field strengths. Thus, with current MRI scanners operating at fields up to 7 T, the antenna effect may become the dominant heating hazard in the near future.

One of the key implications of this study is that therapists and other health professionals who image GK patients with headframes in MRI scanners and have not yet obtained insulated posts need to be aware of new safety regulations (such as the requirement to use only insulated posts for MRI scans of GK patients with headframes). It may be useful for GK health professionals to obtain additional training to understand how RF interacts with and potentially heats the human body through resistive heating in loops. It should be understood how current loops could potentially form through complex combinations of parts of a patient, a patient monitoring device, or instrument wiring via capacitive coupling, especially for higher field MRI units. The more complex heating mechanism of the antenna effect should also be understood by GK health professionals so that they are aware that thermal injuries can occur by mechanisms other than EM induction. Tables of conductivities and permittivities of different organs and tissues within the human body should be made readily available, along with dimensions of conducting implants that lead to antenna-effect heating in various tissues in different field strength MRI scanner.

V. CONCLUSIONS

This study shows that heating caused by the RF field of a 3T MRI scanner due to electromagnetic induction, as described by Faraday's law, occurs at the GK headframe screws when melon phantoms are mounted in the headframe during stereotactic MR imaging. Titanium screws combined with the uninsulated alumina posts result in maximum heating at the screw tips. This heating can be greatly reduced to negligible levels by the use of insulating nuts (the manufacturer's recommended procedure) that electronically separate the metallic screws from the posts. This method would, in principle, work for any conducting headframe post material (e.g., steel and carbon fiber).

There is increased risk of thermal injury at field strengths higher than 3T. The antenna effect was ruled out as the cause of headframe screw heating. However, above 3T it poses an increased risk of internal heating for GK and other patients with metallic implants having lengths suitable for standing wave formation (such as pacemaker wires), because resonant length decreases with increasing field strength and RF frequency. Thus, injury may be possible with

even small-dimension implants, such as aneurysm clips and stents. Electromagnetic induction, the principal heating mechanism identified for GK patients with attached headframes, also poses an increased risk because higher RF frequencies at field strengths above 3T may create unintended current paths through unintended capacitances. Thus, at sufficiently high magnetic fields beyond 3T, the electrically insulating nuts may no longer protect against induced heating. Their effective protection will need to be validated before use for GK patients with headframes undergoing stereotactic very high-field (e.g., 4T, 7T, and higher) MR imaging.

ACKNOWLEDGMENTS

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Designation: F2182 – 11a

Standard Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants During Magnetic Resonance Imaging[1]

This standard is issued under the fixed designation F2182; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This test method covers measurement of radio frequency (RF) induced heating on or near a passive medical implant and its surroundings during magnetic resonance imaging (MRI).

1.2 This test method is one required to determine if the presence of a passive implant may cause injury to the patient with the implant during an MR procedure. Other safety issues that should be addressed include magnetically induced displacement force and torque, as well as proper device function while in various configurations in the MR environment.

1.3 The amount of RF-induced temperature rise for a given specific absorption rate (SAR) will depend on the RF frequency, which is dependent on the static magnetic field strength of the MR system. While the focus in this test method is on 1.5 Tesla (T) or 3 Tesla cylindrical bore MR systems, the RF-induced temperature rise for an implant in MR systems of other static magnetic field strengths or magnet designs can be evaluated by suitable modification of the method described herein.

1.4 This test method assumes that testing is done on devices that will be entirely inside the body. For other implantation conditions (for example, external fixation devices, percutaneous needles, catheters or tethered devices such as ablation probes), modifications of this test method are necessary.

1.5 This test method applies to whole body magnetic resonance equipment, as defined in section 2.2.103 of the IEC Standard 60601-2-33, Ed. 2.0, with a whole body RF transmit coil as defined in section 2.2.100. The RF coil is assumed to have quadrature excitation.

1.6 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

1.7 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

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[redacted]

[1] This test method is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.15 on Material Test Methods.

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[2] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

[3] Available from the International Electrotechnical Commission (IEC), 3 rue de Varembe, Case postale 131, CH-1211 Geneva 20, Switzerland.

[4] Available from National Electrical Manufacturers Association (NEMA), 1300 N. 17th St., Suite 1752, Rosslyn, VA 22209, http://www.nema.org.

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Designation: F2119 – 07 (Reapproved 2013)

Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants[1]

This standard is issued under the fixed designation F2119; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This test method characterizes the distortion and signal loss artifacts produced in a magnetic resonance (MR) image by a passive implant (implant that functions without the supply of electrical or external power). Anything not established to be MR-Safe or MR-Conditional is excluded.

1.2 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

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5. Significance and Use

5.1 This test method provides a quantified measure of the image artifact produced under a standard set of scanning conditions.

5.2 This test method applies only to passive implants that have been established to be MR-Safe or MR-Conditional.

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Summary, conclusions and recommendations: adverse temperature levels in the human body

L. S. GOLDSTEIN†*, M. W. DEWHIRST‡, M. REPACHOLI† and L. KHEIFETS†

† Radiation Studies Program, World Health Organization, 20, Avenue Appia, CH-1211, Geneva 27, Switzerland
‡ Department of Radiation Oncology, Duke University School of Medicine, Durham, NC, USA

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In the spring of 2002, The World Health Organization workshop 'Adverse Temperature Levels in the Human Body' brought together scientists with expertise in biological effects of hyperthermia to review the data and determine the evidence that could be used to evaluate potential adverse effects from human exposures to radiofrequency (RF) electromagnetic radiation in the range of 10–300 GHz. Standards for RF exposure in this frequency range are based currently on thermal effects. Information was reviewed on the ability of hyperthermia, either to the whole body or to part of the body to affect physiology, particularly the heart and circulatory system, to induce other thermoregulatory responses such as sweating, to affect the performance of simple and complex mental tasks, to induce various heat-related disorders such as heat stroke and to damage body tissue. Risks to a variety of organs were considered. In addition, thresholds for effects on developing embryos and foetuses and possible carcinogenic effects were also examined. These findings were discussed in the context of known cellular and biochemical responses of cells and tissues to hyperthermia. The experts judged the relevance of each study for informing decision-makers on the scientific basis for establishing safe exposure levels. The consensus was that standards should consider both temperature and time of exposure, whenever possible.

Key words: Hyperthermia, normal tissue, carcinogenesis, embryo, threshold risk.

* To whom correspondence should be addressed. e-mail: goldsteinl@who.int

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Designation: F2503 – 13

Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment[1]

This standard is issued under the fixed designation F2503; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This international standard applies to the practice of marking of items that might be used in the magnetic resonance (MR) environment.

1.2 The purpose of this practice is to mark items that might be brought into the MR environment and to recommend information that should be included in the marking.

1.3 The standard specifies the permanent marking of items, which are used in an MR environment, by means of terms and icons.

1.4 MR image artifacts are not considered to be a performance issue and so are not addressed in this international standard practice (see X1.5).

1.5 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

1.6 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

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[1] This practice is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.15 on Material Test Methods.

Current edition approved June 1, 2013. Published July 2013. Originally approved in 2005. Last previous edition approved in 2008 as F2503–08. DOI: 10.1520/F2503-13.

[2] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

[3] Available from International Electrotechnical Commission (IEC), 3, rue de Varembé, P.O. Box 131, CH-1211 Geneva 20, Switzerland, http://www.iec.ch.

[4] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, http://www.ansi.org.

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NOTE 3—An item composed entirely of electrically nonconductive, nonmetallic and nonmagnetic materials may be determined to be MR Safe by providing a scientifically based rationale rather than test data. Examples of MR Safe items are a cotton blanket or a silicone catheter.

4. Significance and Use

4.1 Interactions of medical devices and other items with the MR environment has resulted in serious injuries and death of patients and other individuals. Additionally, hazards stemming from equipment malfunction are of concern. Section 4.2 lists possible direct and indirect causes of hazards in the MR environment.

4.2 Potential direct and indirect causes of hazards:

4.2.1 Direct causes:

4.2.1.1 mechanical causes, including magnetically induced displacement force, torque, and vibration

4.2.1.2 electromagnetic causes, including induction (heating, stimulation) and discharge (spark gap)

4.2.1.3 acoustic causes

4.2.2 Indirect causes:

4.2.2.1 malfunction of items, for example of vital components such as valves, monitors and pumps

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Guidance for Industry and FDA Staff

Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment

Document issued on: August 21, 2008

For questions regarding this document, contact Terry O. Woods, Ph.D. at 301-796-2503 or by email at terry.woods@fda.hhs.gov

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Division of Solid and Fluid Mechanics
Office of Science & Engineering Laboratories

Contains Nonbinding Recommendations

Preface

Public Comment

Written comments and suggestions may be submitted at any time for Agency consideration to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852.

When submitting comments, please refer to the exact title of this guidance document. Comments may not be acted upon by the Agency until the document is next revised or updated.

Additional Copies

Additional copies are available from the Internet at: http://www.fda.gov/cdrh/osel/guidance/1685.pdf. You may also send an e-mail request to dsmica@fda.hhs.gov to receive an electronic copy of the guidance or send a fax request to 240-276-3151 to receive a hard copy. Please use the document number (1685) to identify the guidance you are requesting.

Contains Nonbinding Recommendations

Table of Contents

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Guidance for Industry and FDA Staff

Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

1. Introduction

This guidance addresses testing and labeling of passive implants for safety and compatibility in the magnetic resonance (MR) environment. In preparing a premarket approval application (PMA), Investigational Device Exemption (IDE), and premarket notification (510(k)) submission, this guidance document applies to MR devices that serve their function without the supply of electronic power. Active implants or devices that are not implants do not fall within the scope of this guidance. The information in this guidance supplements the Agency's related publications on PMA's, IDE's, and 510(k)s and is not intended to describe or substitute the information otherwise required in the following premarket submissions:

- **Premarket Approval Application (PMA) Information**

For general information about PMA applications, refer to 21 CFR 814 or "**Application Methods**," at http://www.fda.gov/cdrh/devadvice/pma/app_methods.html.

- **Investigational Device Exemption (IDE) Information**

For general IDE information, refer to 21 CFR Part 812 or to the "**Introduction IDE Overview**," at http://www.fda.gov/cdrh/devadvice/ide/index.shtml.

- **Premarket Notification (510(k)) Information**

For general information on 510(k), refer to 21 CFR 807.87, the guidance entitled "**Format for Traditional and Abbreviated 510(k)s**" and "**Premarket Notification 510(k)**" in the (Center for Devices and Radiological Health) **CDRH Device Advice** at http://www.fda.gov/cdrh/devadvice/314.html.

A manufacturer who intends to market a passive implant must conform to the general controls of the Federal Food, Drug, and Cosmetic Act (the act).

The Least Burdensome Approach

We believe we should consider the least burdensome approach in all areas of medical device regulation. This guidance reflects our careful review of the relevant scientific and legal requirements and what we believe is the least burdensome way for you to comply with those requirements. However, if you believe that an alternative approach would be less burdensome, please contact us so we can consider your point of view. You may send your written comments to the contact person listed in the preface to this guidance or to the CDRH Ombudsman. Comprehensive information on CDRH's Ombudsman, including ways to contact him, can be found on the Internet at http://www.fda.gov/cdrh/ombudsman/.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

2. MR Testing

The main issues affecting the safety and compatibility of passive implants in the MR environment concern magnetically induced displacement force and torque, radio frequency (RF) heating, and image artifacts. The MR static field induces displacement forces and torques on magnetic materials. Patients have been killed by the projectile effect on devices and by the rotations produced by magnetically induced force and torque.[1] RF heating in the body is created by currents induced by the RF excitation pulses applied during MR scanning. Patients have been severely burned as a result during an MR scan.[2] The presence of an implant may produce an image artifact that may appear as a void region or as a geometric distortion of the true image. If the image artifact is near the area of interest, the artifact may make the MR scan uninformative or may lead to an inaccurate clinical diagnosis, potentially resulting in inappropriate medical action.

We recommend that you provide the nonclinical testing described below in your PMA, IDE or 510(k) to establish the safety and compatibility of your passive implant in the MR environment. Testing should encompass the range of sizes of the device you intend to market. If you do not test all sizes of the device you intend to market, we recommend you test a size or combination of sizes that represent the worst-case scenario for each test.

We recommend you explain the rationale for determining why the size(s) you selected represent the worst-case scenario for each test.

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[1] Woods, T.O. “MRI Safety” in Wiley Encyclopedia of Biomedical Engineering (Metin Akay, ed.) Hoboken: John Wiley & Sons, Inc., 2006, pp. 2360-2371.
[2] Ibid.

We suggest you present data in a clear tabular or graphical form. We also recommend you describe all testing protocols. Each protocol description should include:

- test objective
- equipment used
- acceptance criteria
- rationale for test conditions
- rationale for the acceptance criteria
- number of devices tested
- description of devices tested, including device size
- description of any differences between test sample and final product, and justification for why differences would not impact the applicability of the test to the final product
- results (summarized and raw form).

Terminology

Terminology for defining the safety of items in the MR environment is provided in ASTM F2503 Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment. We recognize implementing new terminology may be challenging, but FDA believes this new terminology will help reduce the possibility of injuries involving passive implants related to MRI (Magnetic Resonance Imaging). We recommend using the terminology MR Safe, MR Conditional, and MR Unsafe, defined in ASTM F2503. If you label your device as "MR Safe," your submission should include a scientific rationale or the testing described below. If you label your device as "MR Conditional," your submission should include the testing described below. If you label your device as "MR Unsafe," your submission should include a scientific rationale or the testing described below.

MR Safe based on scientific rationale

A scientifically based rationale rather than test data may be sufficient to support identifying an implant as "MR Safe," for example, a nonconducting or a nonmagnetic item, such as a plastic Petri dish, poses no known hazards in all MR environments.

If you intend to use a scientific rationale to support identifying your device as "MR Safe," we recommend that you provide a scientific rationale that addresses the following issues.

- magnetically induced displacement force
- magnetically induced torque
- heating of your device by RF (radio frequency) fields.

MR Unsafe based on scientific rationale

A scientifically based rationale rather than test data, may be sufficient to support identifying an item as "MR Unsafe."

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If you intend to use a scientific rationale to support identifying your device as "MR Unsafe," we recommend that you provide a scientific rationale to address:

- magnetically induced displacement force
- magnetically induced torque
- heating of your device by RF (radio frequency) fields.

MR Conditional, MR Safe, or MR Unsafe based on experimental data

If you identify your device as "MR Conditional," we recommend you provide experimental data as described below. You may also choose to provide experimental data to support identifying your device as "MR Safe" or "MR Unsafe." In each case, we recommend you follow the methods described in the standards below or equivalent methods.

- Magnetically Induced Displacement Force

  ASTM F2052, Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment

- Magnetically Induced Torque

  ASTM F2213, Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment

- Heating by RF Fields

  ASTM F2182, Standard Test Method for Measurement of Radio Frequency Induced Heating Near Passive Implants During Magnetic Resonance Imaging

- Image Artifact

  ASTM F2119, Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants

Although commercial 1.5T MR systems are currently the most common, 3T MR systems are becoming more common. A medical device that is MR Safe or MR Conditional in a 1.5T scanner may not be MR Safe or MR Conditional in an MR system with a higher or lower field strength. The amount of RF heating can vary depending on the system geometry, MR system and scan conditions, and the conductive length of the device. The critical length for a specific device during a particular MR scan cannot be calculated precisely, so we recommend you evaluate a range of lengths and conditions to determine the worst case conditions for RF induced heating. To achieve worst-case heating conditions in the phantom, you should pay attention to the local electric and magnetic field distribution near the implant inside the phantom. These fields need to be similar to the local electric and magnetic field distribution near the implant inside the patient so the heating of the implant in the phantom is comparable to the heating inside the patient. Anatomical positioning of the implant in the phantom does not reliably predict the implant heating in the patient. Therefore, we recommend you describe the field conditions and system geometry under which you tested your device and demonstrate that your test conditions are comparable to worst-case clinical conditions. Accurate assessment of the whole body averaged specific absorption rate (WB-SAR) used in your testing is critical to determining whether your testing represents reasonable worst-case heating conditions. Therefore, we recommend that you base WB-SAR assessments upon calorimetry measurements

rather than relying on the MR scanner display, which may not have adequate accuracy. See also **4. Labeling for the MR Environment**.

3. Labeling for the MR Environment

General labeling requirements for medical devices are described in 21 CFR Part 801. See CDRH **Device Advice** (http://www.fda.gov/cdrh/devadvice/33.html) for additional information. In accordance with 21 CFR 814.20(b)(10), you must submit all proposed labeling in a PMA. A 510(k) must include labeling in sufficient detail to satisfy the requirements of 21 CFR 807.87(e). An IDE must include labeling to satisfy the requirements of 21 CFR 812.5. The following suggestions may assist you in preparing labeling that satisfies the requirements of 21 CFR Part 801[3].

MR Labeling

We recommend you consider using the MR terminology in ASTM F2503, Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment. See **Section 3. MR Testing** for information describing the process to determine the appropriate MR safety term for your device.

MR Safe

The following statement may be used in your labeling for a MR Safe device:

> The (*insert device name)* is MR Safe.

MR Unsafe

The following statement may be used in your labeling for an MR Unsafe device:

The *(insert device name)* is MR Unsafe.

Labeling for an MR Unsafe implant should recommend that patients register their implant information with the MedicAlert Foundation (www.medicalert.org) or equivalent organization.

[3] Although final labeling is not required for 510(k) clearance, labeling is reviewed in a 510(k) and the final labeling must comply with the requirements of 21 CFR Part 801 before a medical device is introduced into interstate commerce. In addition, final labeling for prescription medical devices must comply with 21 CFR 801.109. Labeling recommendations in this guidance are consistent with the requirements of Part 801.

MR Conditional

Labeling for MR Conditional devices should indicate the device was tested under non-clinical conditions and list the conditions under which the device can be safely scanned, for example:

Non-clinical testing has demonstrated the *(insert device name)* is MR Conditional. It can be scanned safely under the following conditions:

- static magnetic field of ___ Tesla
- spatial gradient field of ___ Gauss/cm
- maximum whole body averaged specific absorption rate (SAR) of __W/kg for __ minutes of scanning.

In non-clinical testing, the *(insert device name)* produced a temperature rise of less than __°C at a maximum whole body averaged specific absorption rate (SAR) of ___ W/kg, as assessed by calorimetry for ___ minutes of MR scanning in a *(field strength _____)* (*model _____) (manufacturer _____) (software version _____)* MR scanner.

Image Artifact – General

We also recommend your labeling indicate the amount of image artifact and that you acquire MR images using standard sequences (e.g., as described in ASTM F2119) or an equivalent method. We recommend your labeling indicate the extent of the artifact for one or more of the sequences used in your testing. The labeling should also include information about the shape and extent of the artifact. For devices with a lumen, the labeling should indicate whether the lumen is obscured by the artifact. A dimensioned figure showing the implant in its typical implant site and the extent of the artifact in at least one plane may be included. It may be helpful to provide a separate dimensioned drawing of the implant and a figure showing the typical implant site.

Image Artifact – Special Examples

Devices with Slight (1-2mm) Artifact

The following statement may be used for a device with an image artifact that extends only slightly (1-2 mm) beyond the device:

> MR image quality may be compromised if the area of interest is in the same area or relatively close to the position of the device. Therefore, it may be necessary to optimize MR imaging parameters for the presence of this implant.

Devices with a Lumen

For devices with a lumen, we recommend you specify whether the lumen is obscured by the artifact, for example:

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The image artifact extends approximately __ mm from the device, both inside and outside the device lumen when scanned in nonclinical testing using the sequence: _____ in a (Field Strength) (Model)(Manufacturer)(software version) MR system with _____ coil.

We also recommend that the device labeling for an MR Conditional implant recommend that patients register the conditions under which the implant can be scanned safely with the MedicAlert Foundation (www.medicalert.org) or equivalent organization.

(b)(4) Device Engineering Drawing

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Integra®

Disposable Head Ring Screws (DHRS) Instructions for Use

USA (800) 997-4868 FAX (888) 980-7742
www.integralife.com

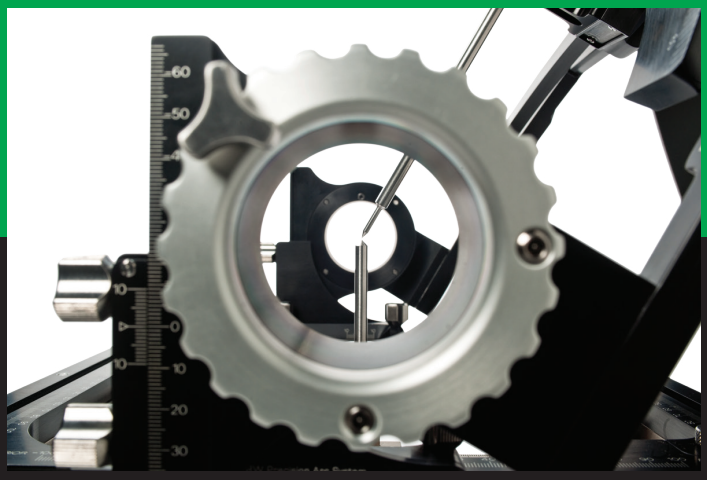
Manufacturer:
Integra LifeSciences Corporation
4900 Charlemar Drive, Building A
Cincinnati, OH 45227 ▪ USA

CAUTION
▪ U.S. Federal law restricts this device to sale by, or on the order of, a physician..

Integra®

Disposable Head Ring Screws (DHRS)

Instructions for Use



INTEGRA®

Single Use Precautions

Single use devices are used with the CRW stereotactic system. The following precautions should be taken:

For single patient use only. The Disposable Head Ring Screws, Long and Short (DHRSS5, DHRSL5) are designed as single-use, disposable products and should not be re-sterilized or reused.

Re-sterilization and reuse may result in dullness of the screw, leading to potential head ring movement, and cross-contamination. Any Disposable Head Ring Screw, once used, should be discarded according to hospital policy.

Using the CRW® System in a Magnetic Resonance Imaging Environment

MR Conditional

Non-clinical testing has demonstrated that the DHRS, UCHRA, and LL01 devices, when assembled, are MR Conditional. This construct can be scanned safely under the following conditions::

- Static magnetic field of 1.5-Tesla (1.5 T) or 3.0-Tesla (3.0 T)
- Spatial gradient field of up to:
  - 11,440 G/cm (114.40 T/m) for 1.5 T systems
  - 5,720 G/cm (57.20 T/m) for 3.0 T systems
- Maximum whole body averaged specific absorption rate (SAR) of:
  - 2.0 W/kg for 15 minutes of scanning in Normal Operating Mode at 1.5 T
  - 2.0 W/kg for 15 minutes of scanning in Normal Operating Mode at 3.0 T

1.5 T RF heating

In non-clinical testing with body coil excitation, components on the DHRS, UCHRA, and LL01 devices that may be in contact with a patient when assembled produced a temperature rise of 2.4 °C or less at a maximum whole body averaged specific absorption rate (SAR) of 2.0 W/kg, as assessed for 15 minutes of scanning in a 1.5 T Siemens Espree (MRC30732) MR scanner with SYNGO MR B19 software.

3.0 T RF heating

In non-clinical testing with body coil excitation, components on the DHRS, UCHRA, and LL01 devices that may be in contact with a patient when assembled produced a temperature rise of 1.1 °C or less at a maximum whole body averaged specific absorption rate (SAR) of 2.0 W/kg, as assessed for 15 minutes of scanning in a 3.0 T Siemens Trio (MRC20587) MR scanner with SYNGO MR A35 4VA30A software.

Caution: The RF heating behavior does not scale with static field strength. Devices which do not exhibit detectable heating at one field strength may exhibit high values of localized heating at another field strength.

MR Artifact

MR image quality may be compromised if the area of interest is in the same area or relatively close to the position of the device. Therefore, it may be necessary to optimize MR imaging parameters for the presence of this implant. In testing using a 1.5 T and 3.0 T system with spin-echo and gradient-echo sequences, the shape of the image artifact follows the approximate contour of the device and extends radially less than 1 mm from the device.

Disposable Head Ring Screws (MR/CT Compatible)	DHRSL5 (48 mm / box of long screws / 5 packs, 2 screws per pack) DHRSS5 (34 mm / box of short screws /5 packs, 2 screws per pack)

Integra Radionics Disposable Head Ring Screws are designed to be used with the UCHR Universal Compact Head Ring and the HRAIM (Head Ring Intubation Assembly) and are components of the CRW® Precision and CRWASL Stereotactic Systems. For complete instructions, warnings and precautions, consult the appropriate Operator's Manual.

Instructions for Use

1. Clean and anesthetize the skull pin sites.
2. Allow the local anesthetic to take effect.

Caution: Avoid the temporalis muscle.

Note Integra recommends the use of an antibacterial ointment on the tips of the screws to help avoid infection.

3. Using the head ring wrench, insert and tighten two diagonally-opposed head ring screws.

Caution: When installing the head ring screws:

- **Only use Integra disposable head ring screws.**
- **Select the appropriate head ring screw length so that the screws protrude at least 13 mm from the outside surface of the head ring posts.**
- **Use all four (4) head ring screws to attach the head ring.**

INTEGRA®

Integra®
Luminant® MR/CT Localizer

Instructions for Use

CE

Rx ONLY

ENGLISH

Description

The Integra® Luminant® localizer features an open and lightweight design, and is compatible in both MR and CT imaging applications.

Designed as a simple attachment for the Integra® Universal Compact Head Ring Assembly (UCHRA) during standard MR or CT imaging, the Luminant localizer can be used with a variety of Integra software products.

Components

Part Number	Description
LL01	Localizer with storage case
LL02	Storage case only
LL03INC	One factory service, inspection and calibration

Compatibility

The Luminant MR/CT localizer is compatible with the following Integra software products:

- XKnife® RT ver. 2.1.3 or higher
- NeuroSight® Arc 1.0 or later
- StereoCalc™ 1.2
- OmniSight®™ ver. 1.1 or higher

Symbols

	Consult instructions for use
	Use by
	Fragile

	Temperature limits
	Catalog number
	Serial number
	Manufacturer
	Authorized representative in the European community.
	Device is compliant with the European Communities Council Directive 93/42/EEC, Medical Device Directive.
	Federal (USA) law restricts this device to sale by or on the order of a physician.
	MR Conditional Components

Assembly

1. Remove the Luminant localizer posterior panel using the two captured thumbscrews (this is an optional step that may facilitate localizer attachment to UCHRA).
2. Position the Luminant localizer so that the anterior panel is above the UCHRA intubation hoop (without the Arc Adapter installed).
3. Secure the Luminant localizer to the UCHRA with the four attachment screws.
4. If the posterior panel was removed, reattach it by fitting the bottom of the panel over the pins on the base of the localizer. Secure the panel by tightening the captured thumbscrews into the correspond-

ing holes on the localizer frame. If the posterior panel is not replaced, only axial and coronal scans may be used.

Note Locating pins ensure that the Luminant localizer and UCHRA fit together in one orientation only—all four screws will seat fully with proper alignment. Do not attempt to assemble these parts in another orientation.

Note Finger-tighten all localizer thumbscrews; do not use tools to tighten them.

Note If the crossbar is being used, do not force the Luminant over the crossbar as there is the potential for the crossbar to interfere with the fiducial rod. The Luminant should fit over the crossbar and sit flush on the UCHRA prior to tightening the thumbscrew. Observe the relationship of the Luminant to the crossbar as the screws are tightened and verify that the fiducial rod does not contact the crossbar.

Note The crossbar design update has been made to accommodate a wider range of patient head sizes when using the UCHRA and Luminant together. Please contact technical support for additional information if your crossbar has only the engraved number 214132 without a letter designation following the number.

Note It is recommended that the Luminant MR/CT Localizer Frame be attached and secured to the Universal Compact Head Ring (UCHRA) before placing the devices on the patient.

Caution DO NOT submit the Luminant localizer to any impact, as severe jarring could cause breakage of the localizer frame and/or its fiducial rods. Return the localizer to Integra for evaluation if it is subjected to an impact.

Data Collection from the MR or CT Scan

The Luminant localizer and UCHRA are directly compatible with MR and CT imaging; no change in equipment is necessary when changing imaging modalities.

The exclusive use of MR images for stereotaxy is not recommended. MR imaging has an inherent degree of distortion that may be intrinsic to the scanner and to the types of materials within the image volume.

Note An Integra® Geometric Phantom can be purchased to measure and periodically confirm the accuracy of your scanners. Contact Integra to order part # GEOSYS and the appropriate adapter plate for your head ring.

Note The use of Integra® ImageFusion™ software can improve the accuracy of MR scans. Fusing CT and MR image sets combines the advantages of CT spatial accuracy with the superior tissue definition of MR.

Note Set the localizer type in the Integra software to either UCLF or Luminant. Both the UCLF and Luminant have the same rod locations.

MR Scanning

Non-clinical testing has demonstrated that the Disposable Head ring Screws (DHRS), Universal Compact head Ring Assembly (UCHRA), and Luminant™ MR/CT Localizer (LL01) devices, when assembled, are MR Conditional. This construct can be scanned safely under the following conditions:

- Static magnetic field of 1.5-Tesla (1.5 T) or 3.0-Tesla (3.0 T)
- Spatial gradient field of up to:
  - 11,440 G/cm (114.40 T/m) for 1.5 T systems
  - 5,720 G/cm (57.20 T/m) for 3.0 T systems
- Do not exceed a MR System reported, whole body averaged specific absorption rate (SAR) of 2.0 W/kg at 1.5 T and 3 T. Normal Operating Mode only.

1.5 T RF heating

In non-clinical testing with body coil excitation, components on the DHRS, UCHRA, and LL01 devices that may be in contact with a patient when assembled produced a temperature rise of 2.4 ºC or less at a maximum whole body averaged specific absorption rate (SAR) of 2.0 W/kg, as assessed for 15 minutes of scanning in a 1.5 T Siemens Espree (MRC30732) MR scanner with SYNGO MR B19 software.

3.0 T RF heating

In non-clinical testing with body coil excitation, components on the DHRS, UCHRA, and LL01 devices that may be in contact with a patient

when assembled produced a temperature rise of 1.1 ºC or less at a maximum whole body averaged specific absorption rate (SAR) of 2.0 W/kg, as assessed for 15 minutes of scanning in a 3.0 T Siemens Trio (MRC20587) MR scanner with SYNGO MR A35 4VA30A software.

Caution The RF heating behavior does not scale with static field strength. Devices which do not exhibit detectable heating at one field strength may exhibit high values of localized heating at another field strength.

MR Artifact

MR image quality may be compromised if the area of interest is in the same area or relatively close to the position of the device. Therefore, it may be necessary to optimize MR imaging parameters for the presence of this implant. In testing using a 1.5 T and 3.0 T system with spin-echo and gradient-echo sequences, the shape of the image artifact follows the approximate contour of the device and extends radially less than 1 mm from the device.

Once the Luminant localizer is correctly assembled to the UCHRA, proceed with scanning.

Note Make sure that the entire localizer frame is positioned within the confines of the scanner head coil.

Note While exact orientation is not necessary, use a towel or head rest beneath the superior part of the localizer to align it so that the UCHRA is perpendicular to the central axis of the scanner head coil.

Note The UCHRA intubation hoop must be in the down position to fit into the MR scanner head coil.

Caution Always keep patient movement to a minimum during the MR scan.

CT Scanning

Once the Luminant localizer is correctly assembled to the UCHRA, proceed with scanning.

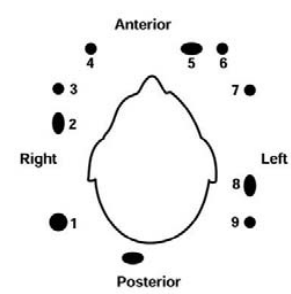
An Integra CT clamping plate attaches the UCHRA assembly to the CT couch and aligns the Luminant localizer/UCHRA assembly with the scanner.

Caution Always keep patient movement to a minimum during the CT scan.

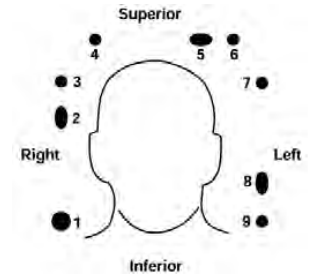
Note To optimize automatic localization when selecting rods on CT images, Rod Threshold and Window Level settings should be adjusted. Rod thresholds between 1200 and 1500 are normally sufficient to allow selection of the rod centers. Window Level settings should be adjusted so that the rods appear clearly as rings, distinct from the other localizer components.

Rod Orientations

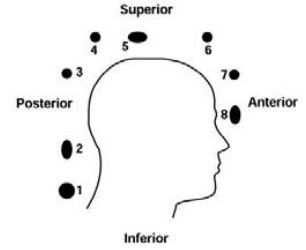
Confirm correct localizer placement by verifying accurate rod orientations while the patient is scanned.



Axial



Coronal



Sagittal

Caution The posterior rod in axial scans is NOT used for axial scan localization; it is only used for sagittal scan localizations.

Manual Calculations

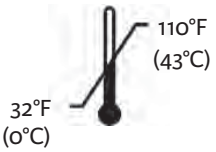
Refer to the CRW® stereotactic system User's Manual for instructions to manually calculate the CRW system target coordinates.

Cleaning

Grease or other dirt may accumulate on the frame in the course of normal use. In such cases, wipe the localizer frame with distilled water only, and dry it promptly.

Storage and Shipping

Always use the supplied case for proper localizer storage and shipping. In addition, the case must be placed into the original overshipper and shipped via next day service to avoid damage to the localizer.



Allowable temperature exposure range: 32°F to 110°F (0°C to 43°C).

Service

Caution The Luminant localizer consists of no user-serviceable parts. Return the localizer to Integra for service.

Caution In the event a localizer tube is damaged, care must be taken to avoid any effects of broken glass. The non-flowing gel component of the localizer tube does not present significant risk at the quantities and concentrations provided. As with any technical product, it is advisable to avoid repeated and prolonged exposure to materials not specifically intended for use on human skin.

First Aid Measures in Case of Contact with Gel

- Eye
  Flush eye with plenty of water immediately.
- Skin
  Wash with soap and flowing water.
- Ingestion
  Wash mouth with water.

Contact medical personnel if adverse effects appear.

Disposal

In most cases where a rod is broken, the gel will remain in the broken tube. Clean up loose gel with paper towels. Gel can be discarded in local sanitary sewer systems. Disposal should be by carefully placing the broken glass tube in a trash container.

Maintenance

The Luminant localizer's rods require regular maintenance by Integra service personnel. An expiration date may be found on the identification plate on the side of the localizer—do not use the localizer after this date. To maintain and extend your localizer warranty, contact Integra to have

periodic maintenance and calibration performed on the localizer prior to the expiration date.

INTEGRA®

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Integra LifeSciences Corporation
4900 Charlemar Drive, Building A
Cincinnati, OH 45227
USA (800) 997-4868
FAX (888) 980-7742
www.integralife.com

EC REP

Integra LifeSciences Services (France) SAS
Immeuble Sequoia 2
97 allée Alexandre Borodine
Parc Technologique de la Porte des Alpes
69800 Saint Priest – France
Telephone: 33 (0) 4 37 47 59 10
Fax: 33 (0) 4 37 47 59 29

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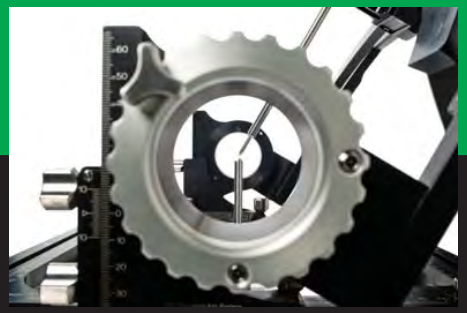
Integra®

CRW® Universal Compact

Head Ring Assembly (UCHRA)

OPERATOR'S MANUAL



United States, Canada, Asia, Pacific, Latin America
USA 800-997-4868 ▪ 888-980-7742 fax
Outside USA 609-936-5400 ▪ 609-750-4259 fax
integralife.com

Europe, Middle-East, Africa
International: +33 (0)4 37 47 59 50 ▪ +33 (0)4 37 47 59 25 fax
Benelux: +32 (0)2 257 4130 ▪ +32 (0)2 253 2466 fax
France: +33 (0)4 37 47 59 10 ▪ +33 (0)4 37 47 59 29 fax
Germany: +49 (0) 2102 5535 6200 ▪ +49 (0)2 102 5536 636 fax
Switzerland: +41 (0)22 721 23 00 ▪ +41 (0)22 721 23 99 fax
United Kingdom: +44 (0)1 264 345 780 ▪ +44 (0)1 264 363 782 fax
integralife.eu

CE 0086

EC REP Integra LifeSciences Services (France) SAS
Immeuble Sequoia 2
97 allée Alexandre Borodine
Parc Technologique de la Porte des Alpes
69800 Saint Priest – France
Telephone: 33 (0) 4 37 47 59 10 ▪ Fax: 33 (0) 4 37 47 59 29

Manufacturer:
Integra LifeSciences Corporation
4900 Charlemar Drive, Building A
Cincinnati, OH 45227
USA (800) 997-4868 FAX (888) 980-7742
www.integralife.com

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INTEGRA®

Notices

Warranty

Integra Lifesciences, Inc. ("Integra") warrants to the original purchaser only that each new Integra product is free from manufacturing defects in material and workmanship under normal use and service for a period of one year from the date of delivery by Integra to the first purchaser, but in no event beyond the expiration date stated on any product labeling.

- Surgical instruments are guaranteed to be free from defects in material and workmanship when maintained and cleaned properly and used normally for their intended purpose.
- Any covered product that is placed by Integra under a lease, rental or installment purchase agreement and that requires repair service during the term of such placement agreement shall be repaired in accordance with the terms of such agreement.

If any covered defect occurs during the warranty period or term of such placement agreement, the purchaser should communicate directly with the Integra home office. If purchaser seeks to invoke the terms of this warranty, the product must be returned to Integra at its home office. The defective product should be returned promptly, properly packaged and postage prepaid. Loss or damage in return shipment to Integra shall be at Customer's risk. Integra' sole responsibility under this warranty shall be repair or replacement, at the sole discretion and expense of Integra, subject to the terms of this warranty and applicable agreements.

IN NO EVENT SHALL INTEGRA BE LIABLE FOR ANY INCIDENTAL, INDIRECT, CONSEQUENTIAL OR PUNITIVE DAMAGES IN CONNECTION WITH THE ACQUISITION OR USE OF ANY INTEGRA PRODUCT. Further, this warranty shall not apply to, and Integra shall not be responsible for, any loss arising in connection with the purchase or use of any Integra product that has been repaired by anyone other than an authorized Integra service representative or altered in any way so as, in Integra' judgment, to affect its stability or reliability, or which has been subject to misuse, negligence or accident, or which has been used otherwise than in accordance with the instructions furnished by INTEGRA. THIS LIMITED WARRANTY IS EXCLUSIVE AND IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, AND OF ALL OTHER OBLIGATIONS OR LIABILITIES ON THE PART OF INTEGRA, AND INTEGRA NEITHER ASSUMES NOR AUTHORIZES ANY REPRESENTATIVE OR OTHER PERSON TO ASSUME FOR IT ANY OTHER LIABILITY IN CONNECTION WITH INTEGRA PRODUCTS.

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Definitions of Alerts Used in this Manual

Warning: An operation or maintenance procedure, practice, condition, statement, etc. which, if not strictly adhered to, could result in injury, long term health hazard, or death of a patient or personnel.

Caution: ***An operation or maintenance procedure, practice, condition, statement, etc. which, if not strictly adhered to, could result in damage to or destruction of part or all of the device, or could result in displaying erroneous information.***

Note: An important point of interest or instruction which may simplify a procedure or prevent unnecessary labor.

Table of Contents

Chapter 1 About the Universal Compact Head Ring

About this User's Manual

This manual supports the Universal Compact Headring (UCHR) and Universal Compact Headring Assembly (UCHRA) and is not intended to be a clinical medical document. This publication details the mechanical/functional features of the system and describes how to properly assemble, use, sterilize and maintain the equipment in the system. Read and become familiar with these instructions before using the system in surgery.

About UCHRA System Compatibility

The UCHR is designed to be used in conjunction with the Integra CRW® Precision Stereotactic System, the CRWASL Stereotactic System, and the XKnife Radiosurgery System. The UCHRA is configured to be CT and MRI compatible.

Indications for Using the UCHRA

Standard Stereotactic Procedures

The CRW System is a stereotactic system to be used for neurosurgical procedures that require precise target localization, such as craniotomies, biopsies, and functional Stereotaxy

Note: Localization is performed using CT or MR imaging.

Contraindications for Using the UCHRA

- The head ring is contraindicated for infants whose coronal sutures have not yet closed.
- The CRW system is contraindicated for patients with Creutzfeldt–Jakob disease.

Single Use Precautions

Single use devices are used with the CRW stereotactic system. The following precautions should be taken:

For single patient use only. The Disposable Head Ring Screws, Long and Short (DHRSS5, DHRSL5) are designed as single-use, disposable products and should not be re-sterilized or reused.

Re-sterilization and reuse may result in dullness of the screw, leading to potential head ring movement, and cross contamination. Any Disposable Head Ring Screw, once used, should be discarded according to hospital policy.

For single patient use only. The Apuzzo Stereotactic Drapes (ASD1 and ASD1B) are designed as single-use, disposable products and should not be re-sterilized or reused.

Reuse of this device may result in cross contamination or compromised sterility of the drape and sterile field. Any drape, once used, should be discarded according to hospital policy.

To ensure proper accuracy and function of the CRW system, do not subject any of the CRW system's parts or accessories to any forces that may affect its use or calibration.

Always inspect the UCHR prior to use. If any of the parts or accessories are damaged in a way that may potentially affect the system's accuracy or function, please return the system to Integra for service (see page 77 for packaging instructions).

Using the CRW® System with Electrosurgical Devices

If the UCHR is to be used with a ground–referenced electrosurgical device (monopolar or bipolar electrode), the headring should not contact the patient. Maintain a gap (at least ¼ inch) between the head ring and the patient's body.

- Follow safety procedures consistent with the use of anesthetizing gases when using the UCHR with electrosurgical equipment.
- Review the system and its accessories prior to surgery to ensure that all items are available and functional.

Chapter 2 Using the CRW® System in a Magnetic Resonance Imaging Environment

MR Conditional Components

MR Conditional

Non-clinical testing has demonstrated that the Disposable Head Ring Screws (DHRS), Universal Compact head Ring Assembly (UCHRA), and Luminant® MR/CT Localizer (LL01) devices, when assembled, are MR Conditional. This construct can be scanned safely under the following conditions:

- Static magnetic field of 1.5-Tesla (1.5 T) or 3.0-Tesla (3.0 T)
- Spatial gradient field of up to:
  - 11,440 G/cm (114.40 T/m) for 1.5 T systems
  - 5,720 G/cm (57.20 T/m) for 3.0 T systems
- Maximum whole body averaged specific absorption rate (SAR) of:
  - 2.0 W/kg for 15 minutes of scanning in Normal Operating Mode at 1.5 T
  - 2.0 W/kg for 15 minutes of scanning in Normal Operating Mode at 3.0 T

1.5 T RF heating

In non-clinical testing with body coil excitation, components on the DHRS, UCHRA, and LL01 devices that may be in contact with a patient when assembled produced a temperature rise of 2.4ºC or less at a maximum whole body averaged specific absorption rate (SAR) of 2.0 W/kg, as assessed for 15 minutes of scanning in a 1.5 T Siemens Espree (MRC30732) MR scanner with SYNGO MR B19 software.

3.0 T RF heating

In non-clinical testing with body coil excitation, components on the DHRS, UCHRA, and LL01 devices that may be in contact with a patient when assembled produced a temperature rise of 1.1ºC or less at a maximum whole body averaged specific absorption rate (SAR) of 2.0 W/kg, as assessed for 15 minutes of scanning in a 3.0 T Siemens Trio (MRC20587) MR scanner with SYNGO MR A35 4VA30A software

Caution: The RF heating behavior does not scale with static field strength. Devices which do not exhibit detectable heating at one field strength may exhibit high values of localized heating at another field strength.

MR Artifact

MR image quality may be compromised if the area of interest is in the same area or relatively close to the position of the device. Therefore, it may be necessary to optimize MR imaging parameters for the presence of this implant. In testing using a 1.5 T and 3.0 T system with spin-echo and gradient-echo sequences, the shape of the image artifact follows the approximate contour of the device and extends radially less than 1 mm from the device.

MR Unsafe Components

The following components of the CRW® System are MR Unsafe:

Cat. No.	Device Description	Metallic Materials
UCHREBA	Ear Bar Assembly	6061-T6 Aluminum
HRW	Head Ring Wrench	303, 416 Stainless Steel
TAP	Cleaning Tap	High Speed Tool Steel

Chapter 3 Assembling the Universal Compact Head ring Assembly

List of UCHR Components and Accessories

Head Rings and Accessories		
UCHRA (Universal Compact Head Ring Assembly)	UCHRA	
UCHRAP (Adapter Plate)	UCHRAP	
UCHRA Storage and Sterilization Case	UCHRCASE	

Head Rings and Accessories		
UCHRHK (UCHRA Hardware Kit)	UCHRHK	**UCHRHK** This kit includes: (4) Adapter plate attachment screws (2) Intubation hoop attachment screws (4) Head post attachment screws (2) Ear bar assembly attachment screws (2) Ear bar assembly nylon thumb screws
UCHRP (Composite Post & Cross Bar Kit)	UCHRP	
UCHREBA (Head Ring Ear Bar Kit) UCHREB (Individual Ear Bars for UCHREBA)	UCHREBA UCHREB	
HRW (Head Ring Wrench)	HRW	

Head Rings and Accessories		
TAP (Cleaning Tap for HRP and UCHRP)	TAP	
HRKTP (Head Ring Positioner)	HRKTP	
CSS (Conical T-Bolt Screws)	CSS	

Imaging Localizers		
BRWLF (CT Localizer Frame)	BRWLF	
LL01 (Luminant® (MR/CT Localizer))	LL01	

Sterile Devices (Single Use Only)		
Apuzzo Stereotactic Drape	ASD1 (sterile drape) ASD1B (10 sterile drapes)	
Disposable Head Ring Screws (MR/CT Compatible)	DHRSL5 (48 mm / box of long screws / 5 packs, 2 screws per pack) DHRSS5 (34 mm / box of short screws /5 packs, 2 screws per pack)	

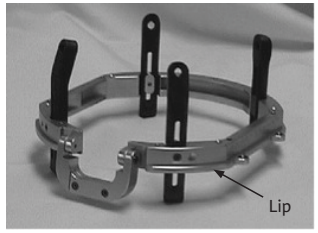
Assembling the Universal Compact Head Ring (UCHR)

1. Attach the 4 head ring posts onto the head ring. Use the head ring wrench to tighten the head post attachment screws.

Note The anterior head ring posts are longer than the posterior posts, and are angled rather than straight.

Caution: Assemble the head ring posts onto the head ring prior to installing the head ring screws. Failure to do so could potentially place increased stress on the head ring post assembly.

2. See the picture to the right for a sample of a properly assembled head ring.



Note The "lip" that goes around the head ring should be on the bottom.

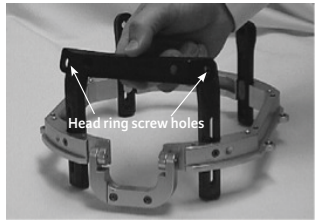
Note To prevent breaking the head post attachment screws, ensure that the post screws are tightened so that the post is flush with the head ring before tightening the disposable head ring screws.

Attaching the Head Ring Screw Cross Bar (Optional)

Note If you are not using the optional head ring screw cross bar, proceed to "Installing the Ear Bars (Optional)" on page 21).

Caution: To avoid placement of the head ring screws into the temporalis muscle, use head ring cross bar.

1. Align the cross bar holes with the head ring screw holes of the anterior head ring posts.

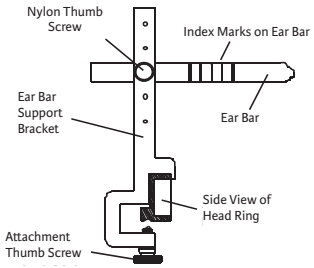


2. Attach the cross bar with the cross bar attachment screws to the anterior head ring posts.

Installing the Ear Bars (Optional)

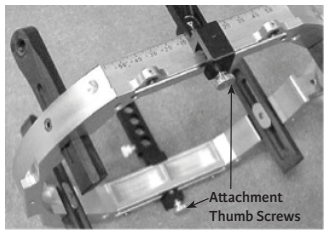
Assembling the Ear Bar

1. Loosen the nylon thumb screw on the ear bar support bracket to place the ear bar in the bracket.



2. Fit the support brackets on opposite sides of the head ring, then finger tighten the attachment thumb screws.

Note The scales on the sides of the head ring are for reference only and allow for alignment of the head ring to the patient.



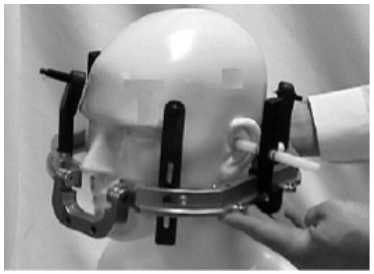
Placing the Head Ring Assembly on the Patient

Note Placing the head ring assembly is easier if multiple people perform the procedure.

1. The first person should hold the head ring in the desired position over the patient's head.
2. The second person may arrange the ear bars so that the rounded end of each bar rests comfortably in the patient's outer ear.

Note Use the index marks on each ear bar to help center the assembly.

Note Fit the head ring to the patient's skull while the patient is in a sitting position.



Caution: To reduce patient discomfort, do not allow the weight of the head ring assembly to rest on the ear bars.

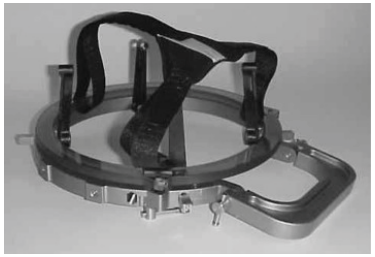
Caution: Use of the Velcro strap (GTCSVS) helps position the head ring assembly and take the weight off the ear bars. For more information on this strap, see page 26.

3. Finger-tighten nylon thumb screw on each support bracket to secure the ear bars.

Place the HRKTP head ring positioner onto the head ring (Optional)

Note Using the head ring positioner helps support the weight of the head ring assembly during placement on the patient.

Head Ring Positioner (HRKTP



1. Place the head ring over the patient's head.

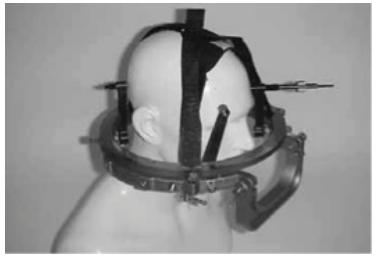
Note The head ring can be placed in any rotational orientation on the patient's head; targeting is not affected. It should be placed on the patient's head inferior to the target in order for the localization frame to encapsulate the target.

Caution: Avoid the temporalis muscle.

1. Clean and anesthetize the skull pin sites.
2. Allow the local anesthetic to take effect.

Note Integra recommends the use of an antibacterial ointment on the tips of the screws to help avoid infection.

3. Using the head ring wrench, insert and tighten two diagonally-opposed head ring screws.

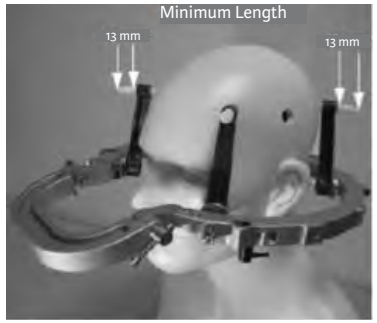


Caution: When installing the head ring screws:

- **Only use Integra disposable head ring screws.**
- **Select the appropriate head ring screw length so that the screws protrude at least 13 mm from the outside surface of the head ring posts.**
- **Use all four (4) head ring screws to attach the head ring.**

4. After securing the first pair of head ring screws, install the second pair.

Note Hand-tighten all screws with the head ring wrench.



Caution: Oversrtightening the head ring screws can cause premature failure of the head ring posts and/or head ring screws.

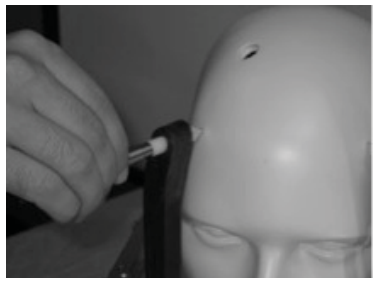
Installing the Head Ring Screws

Caution: When installing the head ring screws:

- **Only use Integra disposable head ring screws.**
- **Select the appropriate head screw length so that the screws protrude at least 13 mm from the outside surface of the head ring posts.**
- **Use all four (4) head ring screws to attach the head ring.**

1. Cleanse the patient's scalp and apply local anesthesia through the head ring post openings (or cross bar openings, if applicable).
2. Allow the local anesthetic to take effect.
3. Use the head ring wrench to drive the head ring screws into the patient's skull.

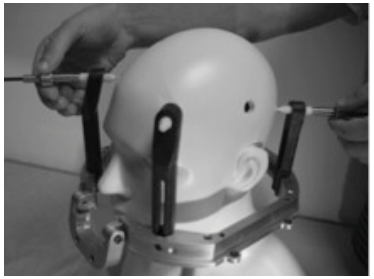
Note Integra recommends the use of an antibacterial ointment on the tips of the screws to help avoid infection.



4. Insert and tighten two diagonally-opposed head ring screws at a time.

Note Using the head ring wrench, hand-tighten each screw equally and alternately.

5. After securing the first pair of screws, install the second pair.
6. Be sure that the head ring assembly is securely in place, then remove the two ear bars from the support brackets.
7. Loosen the thumb screws and remove the ear bar support brackets from the head ring assembly.
8. Remove the head ring positioner (HRKTP) and/or Velcro strap if used.



Caution: Overtightening of the head ring screws can cause premature failure of the head ring posts and/or the head ring screws.

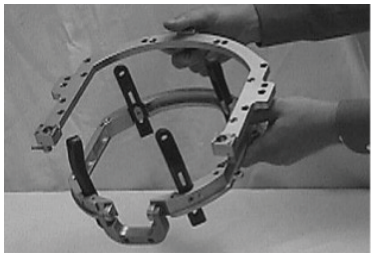
The head ring is now ready for Luminant® localizer attachment. If attaching the BRWLF to the head ring, proceed to the next page for further assembly instructions.

Attaching the Arc Adapter Plate to the UCHRA

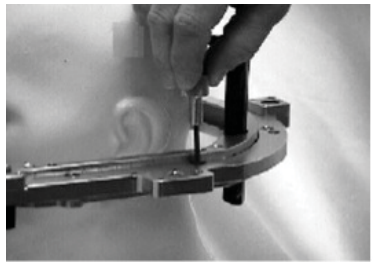
Note You must attach the arc adapter plate to the head ring before you can place the BRWLF on the head ring.

1. Position the arc adapter plate so that the open end faces the head ring assembly anterior.

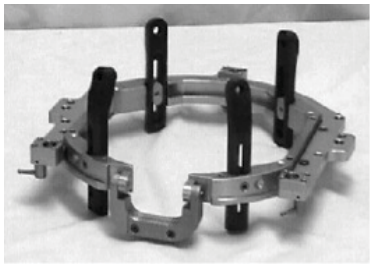
Note The arc adapter is used to attach the BRWLF to the head ring for CT scanning, and also attach the CRW system to the head ring.



2. Use the head ring wrench to tighten the attachment screws, securing the arc adapter plate to the head ring assembly.



3. The UCHRA with the arc adapter plate in place.



Assembling the Localizer Frames

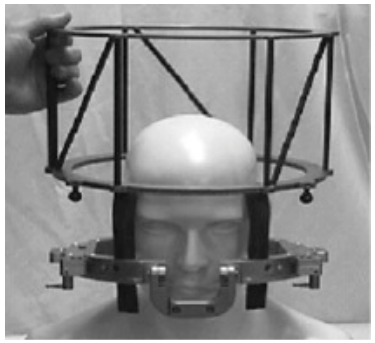
The CRW supports the BRWLF and Luminant® localizer frames.

Assembling the BRWLF on the UCHRA

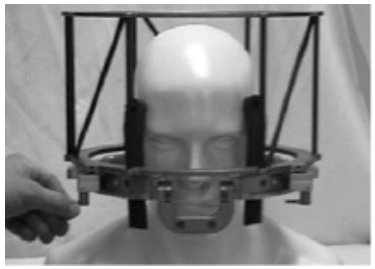
The BRW localizer frame is CT imaging-compatible only. The BRW localizer frame is not indicated for use with MR imaging.

Note To ensure proper attachment of the localizer to the head ring, inspect the balls on the bottom of the localizer prior to assembly to verify that they are not damaged or loose.

1. Place the BRW localizer frame (BRWLF) onto the UCHRA (with the arc adapter installed):
   - The BRWLF on the UCHRA is shown:



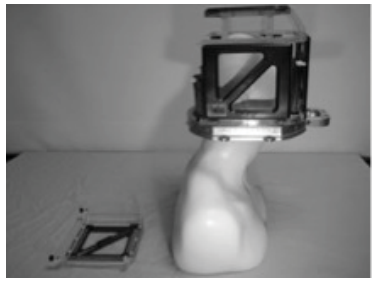
2. Lock the cams to fasten the localizer frame to the Adapter Plate of the UCHRA.



Assembling the Luminant® on the UCHRA

Note For MR setup, do not attach the arc adapter to the UCHRA.

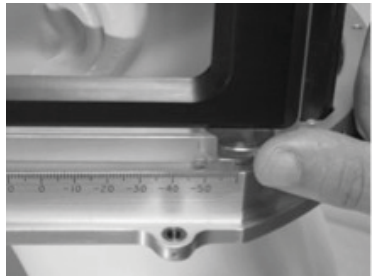
1. Remove the Luminant® localizer posterior panel and position the localizer so that the anterior panel is above the intubation hoop on the head ring assembly (without the arc adapter installed).



Note The UCHRA intubation hoop must be in the down position to fit into the MR scanner head coil - the illustration at the right displays the hoop in the Up position. Use the head wring wrench (HRW) to loosen/tighten the intubation hoop for positioning.

2. Secure the Luminant localizer by thumb-tightening the four attachment screws into the four threaded holes on the top of the head ring.

Note The Luminant localizer and UCHRA fit together in one orientation only --all four screws will align properly. Do not attempt to assemble these parts in another orientation.

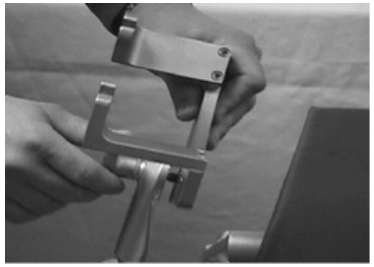


Attaching the Universal Compact Head Ring (UCHRA) to the Operating Table

This procedure requires the MAYFIELD® Adapter or flat MAYFIELD® Adapter and the CSS bolts.

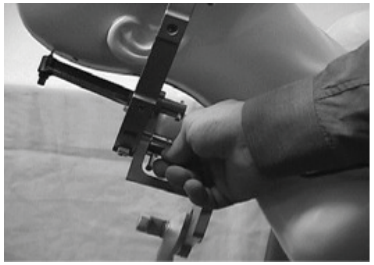
Note The following procedure outlines the use of the MAYFIELD Adapter; the same steps should be followed when using the flat MAYFIELD Adapter.

1. Clamp the MAYFIELD Adapter to the operating table as shown.



2. Attach the UCHRA to the MAYFIELD Adapter using the short T-Bolts.

Note Place the CSS T-bolts onto the head ring and guide the patient onto the head ring and guide the patient onto the CRWMA MAYFIELD Adapter to prevent the binding of the MAYFIELD Adapter to the MAYFIELD Swivel or Tri-Star Swivel Adapter.



Chapter 4 Cleaning, Sterilizing and Maintaining the Universal Compact Head Ring

Cleaning the Universal Compact Head Ring

Note The use of Betadine® and other related fluids containing iodine may stain the surface of the stereotactic system. To minimize discoloration, wipe off any traces of Betadine® and similar solutions as soon as a possible during or following the surgery.

Use the following guidelines when cleaning the Universal Compact Head Ring (UCHR) components (head ring, posts, and screws):

Caution: Do not use saline, as it will attack the metal surface. Do not use corrosive agents, such as Clorox® or Cidex®. Do not use alcohol or hydrogen peroxide on any black composite materials.

- After each procedure, clean components with de-ionized distilled water to remove any residue of Betadine®, blood, CSF or other debris.
- Thoroughly dry and wrap components for sterilization.
- Remove any liquids from components as soon as possible after surgery to prevent corrosion or tarnishing of the surfaces.
- The cleaning tap (TAP) may be used to remove debris from inside the head ring post threads. Insert fully and remove the tap to cleanse the thread.

Packing the UCHR Components

Pack the UCHR components into the sterilization trays after cleaning and before sterilization.

Sterilizing the UCHR Components

Whenever virus–contact with the instrumentation is possible, proper sterilizing measures must be followed. It is the responsibility of hospital personnel to review sterilization procedures for susceptible components and to implement procedures addressing such hazards.

Caution: Do not sterilize the localizer frame. Sterilization may damage the component and render it inoperable.

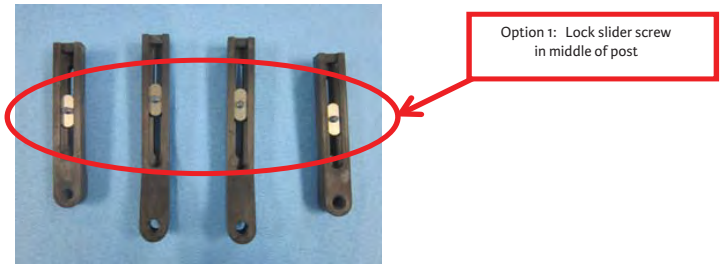
Parameters for Sterilizing the UCHR Components

The following tables provide recommended sterilization parameters for the UCHR components. Due to variations in sterilization chambers and load configurations, it is the responsibility of the facility to determine a sterilization protocol that ensures sterility of the device.

EtO(100% EtO)	
Parameters:	Cycle 1
Concentration:	883 mg/L
Temperature:	131°F / 55°C
Exposure Time:	>= 60 minutes
Humidity:	>= 50% RH

Steam AutoClave (Pre-Vacuum)			
Parameters:	Option 1	Option 2	Option 3
Temperature:	270°F / 132°C	275°F / 135°C	273°F / 134°C
Exposure Time:	4 minutes	3 minutes	18 minutes
Dry Time:	20 minutes	16 minutes	20 minutes

Sterrad®		
Parameters:	Option 1	Option 2
System:	100S	100NX
Position of Slider Screw on Composite Post (UCHRP):	Lock into center of slot prior to sterilization (see picture below)	Any position
Containment	Single self-seal sterilization pouch	Single self-seal sterilization pouch
Cycle:	Standard	Standard



Summary of UCHR Sterilization Procedures

Component	Description	EtO	Steam Autoclave	Sterrad®
UCHR	Universal Compact Head Ring	Yes	Yes	No
UCHRPA, UCHRPP	Composite Head Ring Posts, Cross Bar & attached screws	Yes	No	Yes
HRW	Head Ring Wrench	Yes	Yes	No
UCHRAP	UCHR Adapter Plate	Yes	Yes	No
UCHREBA	Ear Bar Assembly Kit	Yes	Yes	No
UCHREB	Ear Bar	Yes	Yes	No

INTEGRA

Manufacturer: Integra LifeSciences Corporation
4900 Charlemar Drive, Building A,
Cincinnati, OH 45227
USA (800)997-4868 Fax (888)980-7742
www.integralife.com

REF HRW
Catalog Number

LOT XXXXXXXXXXXX
Lot Number

Head Ring Wrench
Cle pour Serre-tete
Chiave per Anello Craniale
Kopfring-Schraubenschlusse
Llave para aro p/Cabeza
Sleutel voor Hoofdring

QTY: (1X)

Rx ONLY

Consult Instructions for Use

YYYY-MM-DD
Date of Manufacture

NON STERILE

CE 0086

Product complies with the requirements of directive 93/42/EEC

MR

+M248HRW1P

+$$8017LLLLLLLLLLLLLP3

Made in USA

14770001 Rev. J

INTEGRA

Manufacturer: Integra LifeSciences Corporation
4900 Charlemar Drive, Building A,
Cincinnati, OH 45227
USA (800)997-4868 Fax (888)980-7742
www.integralife.com

REF TAP
Catalog Number

LOT XXXXXXXXXXXXX
Lot Number

Tap for Head Ring Posts
Canelle de la broche
Presa per colonna craniale
Kopfatift-Gewindeboher
Perforador de soporte picabeza
Dutch Translation

QTY: (1X)

Rx ONLY

CE 0086
Product complies with the requirements of directive 93/42/EEC

Consult Instructions for Use

MR

YYYY-MM-DD
Date of Manufacture

NON STERILE

+M248TAP1D

+$$8017LLLLLLLLLLLLDY

Made in USA

14970003 Rev. G

INTEGRA

Manufacturer: Integra LifeSciences Corporation
4900 Charlemar Drive, Building A
Cincinnati, OH 45227
USA (800)997-4868 Fax (888)890-7742
www.integralife.com

REF UCHRA
Catalog Number

SN XXXXXXXXXXXX
Serial Number

UCHR Assembly

(1)Sterilization case; (1) CRW User's manual; (1)Tap • ; (2) Wrenches• ; (1) Cross bar▲ ;(2) Cross bar locking screws▲ ;(2) Anterior head posts ▲ ;(2) Posterior head posts ▲ ; (1) Head ring ▲ ; (1) Adapter ring ▲ ; (2) Ear bar assemblies• ; (4) Post screws ▲

Ensemble UCHR (Arceau de tête compact universel)

(1) Boîtier de stérilisation; (1) Manuel d'utilisation CRW; (1) Taraud •; (2) Clés •; (1) Barre transversale ▲ ; (2) Vis à verrouillage de la barre transversale ▲ ; (2) Tenons de tête antérieurs ▲ ; (2) Tenons de tête postérieurs ▲ ; (1) Arceau de tête ▲ ; (1) Arceau adaptateur ▲ ; (2) Ensembles de barre d'oreille •; (4) Vis de tenon ▲

Ensamblaje ACCU

(1) Caja de esterilización; (1) Manual del usuario de CRW; (1) Conformador de rosca • ; (2) Llaves •; (1) Barra cruzada ▲ ; (2)Tornillos de bloqueo de la barra cruzada ▲ ; (2) postes anteriores de la cabeza ▲ ; (2) Postes posteriores de la cabeza ▲ ; (1) Anillo de la cabeza ▲ ; (1) Anillo adaptador ▲ ; (2) Montajes de las barras de las orejas •; (4) Tornillos de los postes ▲

UCHR-Baugruppe (Universal-Kompaktkopfring)

(1) Sterilisationskassette; (1) CRW-benutzerhandbuch; (1) Gewindebohrer • ; (2) Schlüssel •; (1) Querstange ▲ ; (2) Feststellschrauben für quesrstange ▲ ; (2) Anteriore kopfstangen ▲ ; (2) Posteriore kopfstangen ▲ ; (1) Kopfring ▲ ; (1) Adapterring ▲ ; (2) Ohrstangenanordnungen •; (4) Schrauben für stangen ▲

Gruppo UCHRA (anello universale compatto per testa)

(1) Cassetta di sterilizzazione; (1) Manuale d'uso del sistema CRW; (1) Maschio • ; (2) Chiavi •; (1) Barra transversale ▲ ; (2) Viti di bloccaggio barra transversale ▲ ; (2) Aste anteriori testa ▲ ; (2) Aste posteriori testa ▲ ; (1) Anello testa ▲ ;(1) Anello adattatore ▲ ; (2) Gruppi barra auricolare •; (4) Viti per aste ▲

UCHR-samenstel

(1) Sterilisatiedoos; (1)Gebruikershandleiding CRW; (1) Tap • ; (2) Moersleutels •; (1) Dwarsstang ▲ ; (2)Borgschroeven voor dwarsstang ▲ ; (2) Anterieure hoofdstijlen ▲ ; (2)Posterieure hoofdstijlen ▲ ; (1) Hoofdring ▲ ; (1)Adapterring ▲ ; (2) Oorstang samenstellen•; (4) Stijlschroeven ▲

QTY: (1X)

Rx ONLY

+M248UCHRA12

+$$8017LLLLLLLLLLLL2N

Consult Instructions For Use

YYYY-MM-DD
Date of Manufacture

NON STERILE

• Component

MR

▲ Component

MR

CE 0086

Product complies with the requirements of directive 93/42/EEC

Made in USA 3787 0001 Rev. N

INTEGRA

Manufacturer: Integra LifeSciences Corporation
4900 Charlemar Drive, Building A,
Cincinnat', OH 45227
USA (800)997-4868 Fax (888)980-7742
www.integralife.com

REF UCHRAP
Catalog Number

LOT XXXXXXXXXXXXX
Lot Number

UCHR ARC Adapter Plate
Plaque d'adaptateur ARC
Paistra adaltmento ARC
ARC Adapter-Platie
Planoha adapladora p/ARC
Dutch Translation

QTY: (1X)

Rx ONLY

CE 0086

YYYY-MM-DD
Date of Manufacture

NON STERILE

Consult Instructions For Use

Product complies with the requirements of directive 93/42/EEC

MR

MR Conditional

+M248UCHRAP1R

+$$8017LLLLLLLLLLLLLR5

Made in USA

37870005 Rev. G

INTEGRA

Manufacturer: Integra LifeSciences Corporation
4900 Charlemar Drive, Building A,
Cincinnati, OH 45227
USA (800)997-4868 Fax (888)980-7742
www.integralife.com

REF UCHRCBS
Catalog Number

LOT XXXXXXXXXXXX
Lot Number

UCHR Cross Bar Screw, (1)

Vlis de Barre Transversale UCHR (1)

Viti Barre Transversale UCHR, (1)

UCHR Quersstangenschrauben, (1)

Tornillos para Barre Transversal UCHR, (1)

UCHR Cross Bar Screw, (1)

QTY: (1X)

Rx ONLY

DO NOT AUTOCLAVE

Consult Instructions for Use

YYYY-MM-DD
Date of Manufacture

NON STERILE

CE 0086

Product complies with the requirements of directive 93/42/EEC

MR
MR Conditional

+M248UCHRCBS10

+$$8017LLLLLLLLLLLLoL

Made in USA
37870008 Rev. J

INTEGRA

Manufacturer: Integra LifeSciences Corporation
4900 Charlemar Drive, Building A,
Cincinnati, OH 45227
USA (800)997-4868 Fax (888)980-7742
www.integralife.com

REF UCHRHK
Catalog Number

LOT XXXXXXXXXXXXX
Lot Number

Hardware Kit for UCHR

(4) Adapter Plate Attachment Screws •;(2) Intubation Hoop Attachment Screws▲;
(4) Head Post Attachment Screws •;(2) Ear Bar Assmebly Nylon Thumb Screws •

Trousse d'équipement UCHR

Kit Accessori UCHR

Material -Satz UCHR

Kit de Ferretería, UCHR

Hardwareset voor UCHR

QTY: (1X)

Rx ONLY

CE 0086

Product complies with the requirements of directive 93/42/EEC

Consult Instructions for Use

NON STERILE

YYYY-MM-DD
Date of Manufacture

+M248UCHRHK1T

+$$8017LLLLLLLLLLLT7

▲ Component

MR
MR Conditional

• Component

MR

Made in USA 37870011 Rev. J

INTEGRA

Manufacturer: Integra LifeSciences Corporation
4900 Charlemar Drive, Building A,
Cincinnati, OH 45227
USA (800)997-4868 Fax (888)980-7742
www.integralife.com

REF UCHR-EBA
Catalog Number

LOT XXXXXXXXXXXXX
Lot Number

UCHR Ear Bar Assembly

Assemblage Barre Auriculaire UCHR

Gruppo Barre Orecchie UCHR

UCHR Ohrenstangen-Baugruppe

Conjunto de Barre para la Oreja, UCHR

UCHR oorstaafconstructie

QTY: (1X)

Do Not Autoclave

YYYY-MM-DD
Date of Manufacture

Rx ONLY

NON STERILE

CE 0086
Product complies with the requirements of directive 93/42/EEC

Consult Instructions for Use

MR

+M248UCHREBA1K

+$$8017LLLLLLLLLLLL

Made in USA

38370001 Rev. J

LUMINANT
MR/CT Localizer

MR
MR Conditional

INTEGRA

INTEGRA

Manufacturer:
Integra LifeSciences Corporation
4900 Charlemar Drive, Building A
Cincinnati, OH 45227
USA 1(866)942-869 Fax 1(877) 558-6227
www.integralife.com

REF DHRSL5 LOT XXXXXXXXX
Catalog Number Lot Number

+$$01MMYYLLLLLLLLLH

Long, Disposable, HRS

Disposable Head Ring Screw, Long

Einmal-Kopfringschraube, Lang

Hovedringsskrue til engangsbrug, Lang

Engangsskruv till skallstativ, Lang

Parafuso anelar descartável, Comprido

Engangs hoderingskrue, Lang

Hoofdringschroef voor eenmalig gebruik, Lang

Vite con testa ad anello monouso, Linga

Vis à oeilleton jetable, Longue

Tornillo desechable para la cabeza, Largo

CE 0086

Rx ONLY QTY: (5X2)

YYYY-MM-DD
Date of Manufacture

YYYY-MM-DD
Use By

MR
MR Conditional

+M248DHRSL51H

70DHRSL5
Rev. J

INTEGRA

Manufacturer:
Integra LifeSciences Corporation
4900 Charlemar Drive, Building A
Cincinnati, OH 45227
USA 1 (866)942-8698 Fax 1 (877) 558-6227
www.integralife.com

REF DHRSS5 LOT XXXXXXXXX
Catalog Number Lot Number

Short, Disposable, HRS

Disposable Head Ring Screw, Short

Einmal-Kopfringschraube, Kurz

Hovedringsskrue til engangsbrug, Kort

Engangsskruv till skallstativ, Kort

Parafuso anelar descartável, Curto

Engangs hoderingskrue, Kort

Hoofdringschroef voor eenmalig gebruik, Kort

Vite con testa ad anello monouso, Corta

Vis à oeilleton jetable, Courte

Tornillo desechable para la cabeza, Corto

+$$801MMYYLLLLLLLLO1

CE 0086 Rx ONLY QTY: (5X2)

YYYY-MM-DD
Date of Manufacture

YYYY-MM-DD
Use By

MR
MR Conditional

+M248DHRSS51O

70DHRSS5
Rev. J

INTEGRA

Manufacturer: Integra LifeSciences Corporation
4900 Charlemar Drive, Building A,
Cincinnati, OH 45227
USA (800) 997-4868 Fax (888) 980-7742
www.integralife.com

REF LL01
Catalog Number

SN XXXXXXXXXXXXX
Serial Number

Luminant® Localizer
Localisateur Luminant®
Localizador Luminant®
Luminant® -Lokalisator
Localizzatore Luminant®
Luminant® lokalisator

QTY: (1X)

Rx ONLY

Consult Instructions For Use

CE 0086
Product complies with the requirements of directive 93/42/EEC

YYYY-MM-DD
Use By

YYYY-MM-DD
Date of Manufacture

NON STERILE

Do Not Autoclave

Temperature Limitation

Fragile, Handle with Care

MR
MR Conditional

+M248LL011Z

+$$801MMYYLLLLLLLLLLZY

Made in USA

70LL01 Rev. G

INTEGRA

Manufacturer: Integra LifeSciences Corporation
4900 Charlemar Drive, Building A,
Cincinnati, OH 45227
USA (800) 997-4868 Fax (888) 980-7742
www.integralife.com

REF UCHRCB1
Catalog Number

LOT XXXXXXXXXXXXX
Lot Number

UCHR Cross Bar and Screws

(1) UCHR Cross Bar, (2) UCHR Cross Bar Screws

Crossbar, Vis de barre transversale UCHR

(1) Crossbar UCHR, (2) Vis de barre transversale UCHR

UCHR Befestigungssch r. Querstange, Quersangenschrauben

(1) UCHR Befestigungeschrauben f. Querstange, (2) UCRA Quersatangenschrauben

Barra trsversale, Viel barra tresversale UCHR

(1) Barra trasversale UCHR, (2) Viel barra tresversale UCHR

Barra transversal,Tornillos para transversal, UCHR

(1) Barra trasversal UCHR, (2) Tornillos para barra transversal UCHR

Dutch Translation

QTY: (1X)

DO NOT AUTOCLAVE

YYYY-MM-DD
Date of Manufacture

Rx ONLY

Consult Instructions For Use

NON STERILE

CE 0086

Product complies with the requirements of directive 93/42/EEC

MR
MR Conditional

+M248UCHRCB11K

+$$8017000000XXXXXXKC

Made in USA

70UCHRCB1 Rev. F

INTEGRA

Manufacturer: Integra LifeSciences Corporation
4900 Charlemar Drive, Building A,
Cincinnati, OH 45227
USA (800)997-4868 Fax (888)980-7742
www.integralife.com

REF UCHREB
Catalog Number

LOT XXXXXXXXXXXX
Lot Number

UCHR Ear Bar
Barre auriculaire UCHR
Barra orecchie UCHR
UCHR Ohrenstangen
Barra para lo oreja, UCHR
Oorstaafje voor UCHR

QTY: (1X)

Rx ONLY

Consult Instructions For Use

YYYY-MM-DD
Date of Manufacture

MR

NON STERILE

CE 0086

Product complies with the requirements of directive 93/42/EEC

Do Not Autoclave

+M248UCHREB1H

*+$$8017LLLLLLLLLLLLLH *

Made in USA

70UCHREB Rev. D

INTEGRA

Manufacturer: Integra LifeSciences Corporation
4900 Charlemar Drive, Building A,
Cincinnati, OH 45227
USA (800) 997-4868 Fax (888) 980-7742
www.integralife.com

REF UCHRP
Catalog Number

LOT XXXXXXXXXXXXX
Lot Number

UCHR Post and Cross Bar Kit

(2) UCHR Anterior Head Posts,, (2) UCHR Posterior Head Posts, (1) UCHR Cross Bar, (2) UCHR Cross Bar Screws

Jau de Pièces UCHR Broche Crossbar

(2) Broche UCHR,anterieure, (2) Broche UCHR, posterieure, (1) Crossbar UCHR, (2) Vis de barre transversale UCHR

UCHR Kopfetift Befestigungssch f. Querstange Kit

(2) UCHR Kopfstift, anteroar, (2) UCHR Kopftift, posterior, (1) UCHR Befestigungeschrauben f. Querstange, (2) UCRA Quersatangenschrauben

Kit Colonna testa Barre trasversale, UCHR

(2) Colonra testa, anteriore, (2) Colonna testa, posteriore, UCHR, (1) Barra trasversale UCHR, (2) Viel barra tresversale UCHR

Kit de Soporte para la cabeza Barra transversal, UCHR

(2) Soporte anterior para la cabeza, UCHR, (2) Soporte poserior para la cabeza, UCHR, (1) Barra trasversal UCHR, (2) Tornillos para barra transversal UCHR

Dutch Translation

QTY: (1X)

DO NOT AUTOCLAVE

YYYY-MM-DD
Date of Manufacture

Rx ONLY

Consult Instructions For Use

NON STERILE

CE 0086
Product complies with the requirements of directive 93/42/EEC

MR
MR Conditional

+M248UCHRP1K

+$$8017000000XXXXXXKC

Made in USA

70UCHRP Rev. E

INTEGRA

Manufacturer: Integra LifeSciences Corporation
4900 Charlemar Drive, Building A,
Cincinnati, OH 45227
USA (800)997-4868 Fax (888)980-7742
www.integralife.com

REF UCHRPA
Catalog Number

LOT XXXXXXXXXXXX
Lot Number

UCHR Post, Anterior
Broche UCHR, Antérieure
Colonna testa Anteriore UCHR
UCHR Kopfstift, Anterior
Soporte Anterior para la Cabeza, UCHR
UCHR-pin Anterieur

QTY: (1X)

Rx ONLY

NON STERILE

CE 0086
Product complies with the requirements of directive 93/42/EEC

Do Not Autoclave

Consult Instructions for Use

YYYY-MM-DD
Date of Manufacture

MR
MR Conditional

+M248UCHRPA1R

+$$8017LLLLLLLLLLLLR5

Made in USA

70UCHRPA Rev. F

INTEGRA

Manufacturer: Integra LifeSciences Corporation
4900 Charlemar Drive, Building A,
Cincinnati, OH 45227
USA (800)997-4868 Fax (888)980-7742
www.integralife.com

REF UCHRPP
Catalog Number

LOT XXXXXXXXXXXX
Lot Number

UCHR Post, Posterior
Broche UCHR, Postérieure
Colonna Testa Posteriore UCHR
UCHR Kopfstift, Posterior
Soporte Posterior Para la Cabeza, UCHR
UCHR-Pin, Anterieur

QTY: (1X)

Do Not Autoclave

YYYY-MM-DD
Date of Manufacture

Rx ONLY

Consult Instructions for Use

NON STERILE

CE 0086

Product complies with the requirements of directive 93/42/EEC

MR
MR Conditional

+M248UCHRPP1%

+$$8017LLLLLLLLLLLL%K

Made in USA

70UCHRPP Rev. F

INTEGRA

Manufacturer: Integra LifeSciences Corporation
4900 Charlemar Drive, Building A,
Cincinnati, OH 45227
USA (800)997-4868 Fax (888)980-7742
www.integralife.com

REF UCHR
Catalog Number

LOT XXXXXXXXXXXX
Lot Number

Universal Compact Head Ring
Anneau Crânien Compact Universel
Anello per Testa Compatto Universale
Universeller Kompaktkopfring
Sujeción Craneal Universal Compacta
Universele Compacte Hoofdring

QTY: (1X)

Rx ONLY

CE 0086
Product complies with the requirements of directive 93/42/EEC

Consult Instructions for Use

YYYY-MM-DD
Date of Manufacture

NON STERILE

MR
MR Conditional

+M248UCHR1Z

+$$8017LLLLLLLLLLLLZD

Made in USA

PKG0000025 Rev. C

☒ Original

☐ Amendment

Product Name: (b)(4) Study

Protocol Number: (b)(4)

Protocol Testing Description: DHRS Shelf-Life Test

(b)(4)

(b)(4)

Approvals:

Department	Name	Signature	Date
(b)(4)			

Revision History:

Rev	Date	Name	Changes
(b)(4)			

☒ Original

☐ Amendment

Product Name: (b)(4) Study

Protocol Number: (b)(4)

Protocol Testing Description: DHRS Shelf-Life Test

Originator(s): N. Cronin

(b)(4)

Approvals:

Department	Name	Signature	Date
(b)(4)			

Revision History:

Rev	Date	Name	Changes
(b)(4)			

☒ Original

☐ Amendment

Product Name: (b)(4) Study

Protocol Number (b)(4)

Protocol Testing Description: DHRS Shelf-Life Test

(b)(4)

(b)(4)

Approvals:

Department	Name	Signature	Date
(b)(4)			

Revision History:

Rev	Date	Name	Changes
(b)(4)			

☒ Original

☐ Amendment

Product Name: (b)(4) Study

Protocol Number (b)(4)

Protocol Testing Description: DHRS Shelf-Life Test

(b)(4)

(b)(4)

Approvals:

Department	Name	Signature	Date
(b)(4)			

Revision History:

Rev	Date	Name	Changes
(b)(4)			

☒ Original

☐ Amendment

Product Name: [redacted] (b) [redacted] Study

Protocol Number: (b)(4)

Protocol Testing Description: DHRS Shelf-Life Test

(b)(4) [redacted]

(b)(4) [redacted]

Approvals:

Department	Name	Signature	Date
(b)(4) [redacted]			

Revision History:

Rev	Date	Name	Changes
(b)(4) [redacted]			

☒ Original

☐ Amendment

Product Name: (b)(4) Study

Protocol Number: (b)(4)

Protocol Testing Description: DHRS Shelf-Life Test

(b)(4)

(b)(4)

Approvals:

Department	Name	Signature	Date
(b)(4)			

Revision History:

Rev	Date	Name	Changes
(b)(4)			

(b)(4) Test Data

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CONFIDENTIAL

(b) (6)

EFFECTIVE ONLY ON DAY OF PRINT

(b)(4)

(b)(4)	STANDARD OPERATING PROCEDURE	DOC #: (b)(4)	REV: E
(b)(4)	INTEGRA BURLINGTON	Page 1 of 1	(b)(4)
SUBJECT:	Account Alias - Material Request Form		

(b)(4)

Requisition ☒ Return to Stock ☐ Scrap ☐

(b)(4)

Material:

Completed by Material Requestor	Completed by Stockroom Associate
(b)(4)	

Approvals (Print, Sign and Date):

(b)(4)

Title Block.Numbe(b)(4) CONFIDENTIAL - Rev:E Title Block.Lifecycle Phase:Effective

INTEGRA
LIMIT UNCERTAINTY

Review and Release to Sterilizer Form

Load #: (b)(4)

Date: (b)(4)

	Case count shipped	Case count returned	BI Lot Number	BI Quantity
(b)(4)				

Quality Assurance Release (b) (6) Date: (b)(4)

Shipped to Sterilize Date: (b)(4)

Received in Post-Steril Date: (b)(4)

INTEGRA LIMIT UNCERTAINTY

Release to Sterilization Accountability Form

DATE: (b)(4) **LOAD:** (b)(4)

PALLET # 1

(b)(4)

Total weight not to exceed 400 lbs.

QA reviews product information, case count, and pallet weight: (b) (4), (b) (6)

QA Sign & Date

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

R55480101

Certificate of Processing

(b)(4)

(b)(4)

(b)(4)

(b)(4)

Integra Pain Management

Work Order (b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

Biological Indicator (BI) Sterility Test Final Report

(b)(4)

INTEGRA LIMIT UNCERTAINTY

Review and Release to Sterilizer Form

Load #: (b)(4)

Date: (b)(4)

	Case count shipped	Case count returned	BI Lot Number	BI Quantity
(b)(4)				

Quality Assurance Release (b) (4), (b) (6) Date: (b)(4)

Shipped to Sterilizer Date:

Received in Post-Sterile Date:

INTEGRA LIMIT UNCERTAINTY

Release to Sterilization Accountability Form

DATE: 5/15/2015 **LOAD:** 15172

PALLET # 1

CATALOG #	Workorder #	Lot Quantity	Number of Cases	Case Weight	Total Weight
3401013	W1504190	190	19	7.4	**140.6**
CUS1264 (TRAPJTD1110-16)	W1503168	100	10	10.9	**108.5**
TOTAL		**290**	**29**		
PALLET WEIGHT TOTAL					**249.1**

Total weight not to exceed 400 lbs.

QA reviews product information, case count, and pallet weight: 5/15/15
QA Sign & Date

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CONFIDENTIAL

(b)(4)

Certificate of Processing

(b)(4)

R55480101

(b)(4)

Customer Name:	Integra Pain Management	Processing Facility:	Salt Lake City	Work Order #	(b)
P.O.#	N/A			Sales Order #	1318459

(b)(4)

ISO 9001 and ISO 13485 Registered

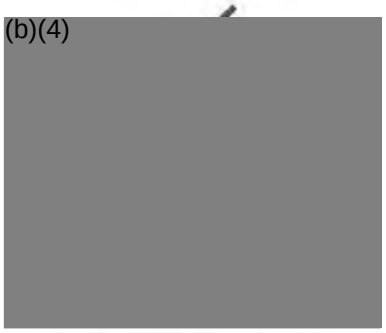
(b)(4)

Integra Pain Management

Work Order (b)(4)

2015-05-18

(b)(4)



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Report Number
(b)(4)

Integra LifeSciences
311 Enterprise Drive
Plainsboro, NJ 08536

(b)(4)

Attn: Nathan Cronin

BUBBLE EMISSION TEST REPORT

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(b)(4)

Report Number
(b)(4)

Integra LifeSciences
311 Enterprise Drive
Plainsboro, NJ 08536

(b)(4)

Attn: Nathan Cronin

SEAL PEEL TEST REPORT

(b)(4)

(b)(4)

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TEST REPORT

VISUAL INSPECTION

SPONSOR: Integra LifeSciences
311 Enterprise Drive
Plainsboro, NJ 08536

CONTACT: Nathan Cronin

REPORT DATE: (b)(4)

REPORT NO: (b)(4)

PURCHASE ORDER NO: (b)(4)

TEST CODE: (b)(4)

TESTING FACILITY: (b)(4)

PACKAGE: DHRS – Disposable Head Ring Screws (b)(4)
EO Processed, Baseline Visual Inspection

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TEST REPORT

VISUAL INSPECTION

SPONSOR: Integra LifeSciences
311 Enterprise Drive
Plainsboro, NJ 08536

CONTACT: Nathan Cronin

REPORT DATE: (b)(4)

REPORT NO: (b)(4)

PURCHASE ORDER NO: (b)(4)

TEST CODE: (b)(4)

TESTING FACILITY: (b)(4)

PACKAGE: DHRS – Disposable Head Ring Screws, Lot # 0318254, EO Processed, Visual Inspection Prior to Simulated Distribution Testing

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TEST REPORT

VISUAL INSPECTION

SPONSOR: Integra LifeSciences
311 Enterprise Drive
Plainsboro, NJ 08536

CONTACT: Nathan Cronin

REPORT DATE: (b)(4)

REPORT NO: (b)(4)

PURCHASE ORDER NO: (b)(4)

TEST CODE: (b)(4)

TESTING FACILITY: (b)(4)

PACKAGE: DHRS – Disposable Head Ring Screws, Lot # 0318254, EO Processed, Visual Inspection prior to 1.0 Year Accelerated Aging

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TEST REPORT

VISUAL INSPECTION

SPONSOR: Integra LifeSciences
311 Enterprise Drive
Plainsboro, NJ 08536

CONTACT: Nathan Cronin

REPORT DATE: (b)(4)

REPORT NO: (b)(4)

PURCHASE ORDER NO: (b)(4)

TEST CODE: (b)(4)

TESTING FACILITY: (b)(4)

PACKAGE: DHRS – Disposable Head Ring Screws, Lot # 0318254, EO Processed, Visual Inspection prior to 2.0 Year Accelerated Aging

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TEST REPORT

VISUAL INSPECTION

SPONSOR: Integra LifeSciences
311 Enterprise Drive
Plainsboro, NJ 08536

CONTACT: Nathan Cronin

REPORT DATE: (b)(4)

REPORT NO: (b)(4)

PURCHASE ORDER NO: (b)(4)

TEST CODE: (b)(4)

TESTING FACILITY: (b)(4)

PACKAGE: DHRS – Disposable Head Ring Screws, Lot # 0318254, EO Processed, Visual Inspection prior to 3.0 Year Accelerated Aging

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APPENDIX B: Data Sheet for (b)(4)

(b)(4)

Screw 1

	Inspection Item	Measurement	Acceptance Criteria	Pass / Fail
(b)(4)				

Screw 2

	Inspection Item	Measurement	Acceptance Criteria	Pass / Fail
(b)(4)				

Screw 3

	Inspection Item	Measurement	Acceptance Criteria	Pass / Fail
(b)(4)				

Screw 4

	Inspection Item	Measurement	Acceptance Criteria	Pass / Fail
(b)(4)				

NOTES:

(b)(4)

INSPECTOR NAME INSPECTOR SIGNATURE DATE

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Report Number
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(b)(4)

Integra LifeSciences
311 Enterprise Drive
Plainsboro, NJ 08536

Attn: Nathan Cronin

SIMULATED DISTRIBUTION TEST REPORT

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This report is confidential. No part may be used for advertising or public announcement without written permission. Results apply only to the sample(s) tested

Report Number
(b)(4)

Integra LifeSciences
311 Enterprise Drive
Plainsboro, NJ 08536

(b)(4)

Attn: Nathan Cronin

SEAL PEEL TEST REPORT

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(b)(4)

Integra LifeSciences
311 Enterprise Drive
Plainsboro, NJ 08536

Attn: Nathan Cronin

BUBBLE EMISSION TEST REPORT

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Report Number (b)(4)

(b)(4)

Integra LifeSciences
311 Enterprise Drive
Plainsboro, NJ 08536

Attn: Nathan Cronin

SEAL PEEL TEST REPORT

(b)(4)

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ACCELERATED AGING REPORT

SPONSOR: Integra LifeSciences
311 Enterprise Drive
Plainsboro, NJ 08536

CONTACT: Nathan Cronin

REPORT DATE: (b)(4)

REPORT NO: (b)(4)

PURCHASE ORDER NO: (b)(4)

TEST CODE: (b)(4)

TESTING FACILITY: (b)(4)

OBJECTIVE: (b)(4)

EQUIPMENT: (b)(4)

SAMPLE: DHRS – Disposable Head Ring Screws, Lot # 0318254, EO Processed, 1.0 Year Accelerated Aging

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Report Number
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(b)(4)

Integra LifeSciences
311 Enterprise Drive
Plainsboro, NJ 08536

Attn: Nathan Cronin

BUBBLE EMISSION TEST REPORT

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(b)(4) [redacted]

(b)(4) [redacted]

Report Number
(b)(4) [redacted]

Integra LifeSciences
311 Enterprise Drive
Plainsboro, NJ 08536

(b)(4) [redacted]

Attn: Nathan Cronin

SEAL PEEL TEST REPORT

(b)(4) [redacted]

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INTEGRA	DHRS Shelf Life Study	(b)(4)

APPENDIX B: Data Sheet for (b)(4)

ITEM:	DHRSL

(b)(4)

Screw 1

	Inspection Item	Measurement	Acceptance Criteria	Pass / Fail

(b)(4)

Screw 2

	Inspection Item	Measurement	Acceptance Criteria	Pass / Fail

(b)(4)

Screw 3

	Inspection Item	Measurement	Acceptance Criteria	Pass / Fail

(b)(4)

Screw 4

	Inspection Item	Measurement	Acceptance Criteria	Pass / Fail

(b)(4)

NOTES:

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ACCELERATED AGING REPORT

SPONSOR: Integra LifeSciences
311 Enterprise Drive
Plainsboro, NJ 08536

CONTACT: Nathan Cronin

REPORT DATE: (b)(4)

REPORT NO: (b)(4)

PURCHASE ORDER NO: (b)(4)

TEST CODE: (b)(4)

TESTING FACILITY: (b)(4)

OBJECTIVE: (b)(4)

EQUIPMENT: (b)(4)

(b)(4)

SAMPLE: DHRS – Disposable Head Ring Screws, Lot # 0318254, EO Processed, 2.0 Year Accelerated Aging

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Report Number
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Integra LifeSciences
311 Enterprise Drive
Plainsboro, NJ 08536

Attn: Nathan Cronin

SEAL PEEL TEST REPORT

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Report Number
(b)(4)

(b)(4)

Integra LifeSciences
311 Enterprise Drive
Plainsboro, NJ 08536

Attn: Nathan Cronin

BUBBLE EMISSION TEST REPORT

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INTEGRA	DHRS Shelf Life Study	(b)(4)

APPENDIX B: Data Sheet for (b)(4)

ITEM:	DHRSL
(b)(4)	

Screw 1

	Inspection Item	Measurement	Acceptance Criteria	Pass / Fail
(b)(4)				

Screw 2

	Inspection Item	Measurement	Acceptance Criteria	Pass / Fail
(b)(4)				

Screw 3

	Inspection Item	Measurement	Acceptance Criteria	Pass / Fail
(b)(4)				

Screw 4

	Inspection Item	Measurement	Acceptance Criteria	Pass / Fail
(b)(4)				

NOTES:

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ACCELERATED AGING REPORT

SPONSOR: Integra LifeSciences
311 Enterprise Drive
Plainsboro, NJ 08536

CONTACT: Nathan Cronin

REPORT DATE: (b)(4)

REPORT NO: (b)(4)

PURCHASE ORDER NO: (b)(4)

TEST CODE: (b)(4)

TESTING FACILITY: (b)(4)

OBJECTIVE: (b)(4)

EQUIPMENT: (b)(4)

SAMPLE: DHRS – Disposable Head Ring Screws, Lot # 0318254, EO Processed, 3.0 Year Accelerated Aging

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Report Number
(b)(4)

(b)(4)

Integra LifeSciences
311 Enterprise Drive
Plainsboro, NJ 08536

Attn: Nathan Cronin

BUBBLE EMISSION TEST REPORT

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Report Number
(b)(4)

(b)(4)

Integra LifeSciences
311 Enterprise Drive
Plainsboro, NJ 08536

Attn: Nathan Cronin

SEAL PEEL TEST REPORT

(b)(4)

(b)(4)

APPENDIX B: Data Sheet for (b)(4)

ITEM:	DHRSL

(b)(4)

Screw 1

	Inspection Item	Measurement	Acceptance Criteria	Pass / Fail
(b)(4)				

Screw 2

	Inspection Item	Measurement	Acceptance Criteria	Pass / Fail
(b)(4)				

Screw 3

	Inspection Item	Measurement	Acceptance Criteria	Pass / Fail
(b)(4)				

Screw 4

	Inspection Item	Measurement	Acceptance Criteria	Pass / Fail
(b)(4)				

NOTES:

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Product Name: DHRS

Report Number: (b)(4)

Report Objective:
To summarize the results of the accelerated aging study conducted on the DHRS

Approvals:

Department	Name	Signature	Date
(b)(4)			

Revision History

Revision	Author	Section/Page	Description of Changes
(b)(4)			

DHRS Shelf-Life Validation: Accelerated Aging REPORT

Product Name: DHRS

Report Number: (b)(4)

Report Objective:
To summarize the results of the accelerated aging study conducted on the DHRS

Approvals:

Department	Name	Signature	Date
(b)(4)			

Revision History

Revision	Author	Section/Page	Description of Changes
(b)(4)			

Product Name: DHRS

Report Number: (b)(4)

Report Objective:
To summarize the results of the accelerated aging study conducted on the DHRS

Approvals:

Department	Name	Signature	Date
(b)(4)			

Revision History

Revision	Author	Section/Page	Description of Changes
(b)(4)			

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(b)(4)

TEST FACILITY

(b)(4)

SPONSOR

Nathan Cronin
Integra LifeSciences
22 Terry Ave
Burlington, MA 01803

STUDY TITLE

Cytotoxicity Study Using the ISO Elution Method

TEST ARTICLE NAME

DHRSL - Disposable Head Ring Screw, Long

TEST ARTICLE IDENTIFICATION

(b)(4)

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TEST FACILITY

(b)(4)

SPONSOR

Nathan Cronin
Integra LifeSciences
22 Terry Ave
Burlington, MA 01803

STUDY TITLE

ISO Intracutaneous Study in Rabbits

TEST ARTICLE NAME

DHRSL - Disposable Head Ring Screw, Long

TEST ARTICLE IDENTIFICATION

(b)(4)

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TEST FACILITY

(b)(4)

SPONSOR

Nathan Cronin
Integra LifeSciences
22 Terry Ave
Burlington, MA 01803

STUDY TITLE

ISO Guinea Pig Maximization Sensitization Test

TEST ARTICLE NAME

DHRSL - Disposable Head Ring Screw, Long

TEST ARTICLE IDENTIFICATION

0265497

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TEST FACILITY

(b)(4)

SPONSOR

Nathan Cronin
Integra LifeSciences
22 Terry Ave
Burlington, MA 01803

STUDY TITLE

ISO Systemic Toxicity Study in Mice

TEST ARTICLE NAME

DHRSL - Disposable Head Ring Screw, Long

TEST ARTICLE IDENTIFICATION

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(b)(4)

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(b)(4)

(b)(4)

TEST FACILITY

(b)(4)

SPONSOR

Nathan Cronin
Integra LifeSciences
22 Terry Ave
Burlington, MA 01803

STUDY TITLE

Cytotoxicity Study Using the ISO Elution Method

TEST ARTICLE NAME

UCHRA Ear Bar - p/n 20212517

TEST ARTICLE IDENTIFICATION

0304742

(b)(4)

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TEST FACILITY

(b)(4)

SPONSOR

Nathan Cronin
Integra LifeSciences
22 Terry Ave
Burlington, MA 01803

STUDY TITLE

ISO Intracutaneous Study in Rabbits

TEST ARTICLE NAME

UCHRA Ear Bar - p/n 20212517

TEST ARTICLE IDENTIFICATION

(b)(4)

(b)(4)

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TEST FACILITY

(b)(4)

SPONSOR

Nathan Cronin
Integra LifeSciences
22 Terry Avenue
Burlington, MA 01803

STUDY TITLE

ISO Guinea Pig Maximization Sensitization Test

TEST ARTICLE NAME

UCHRA Ear Bar - p/n 20212517

TEST ARTICLE IDENTIFICATION

(b)(4)

(b)(4)

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STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☐ Traditional ☐ Special ☒ Abbreviated

STANDARD TITLE [1]

ASTM F2503-13, Standard Practice for Marking Medical Devices and Other Items for Safety in the MR Environment

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#8-349	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment

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

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ASTM F2503-13, Standard Practice for Marking Medical Devices and Other Items for Safety in the MR Environment

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
ASTM F2503-13	Marking Medical Devices and Other Items for Safety in the MRI Environment	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
Met all applicable clauses.

DESCRIPTION
The purpose of this practice is to mark items that might be brought into the MR environment and to recommend information that should be included in the marking.

JUSTIFICATION
Device will be labeled "MR Conditional" or identified items and "MR Unsafe" for identified items

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

* 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.

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Paperwork Reduction Act Statement

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TYPE OF 510(K) SUBMISSION

☐ Traditional ☐ Special ☒ Abbreviated

STANDARD TITLE [1]

ASTM F2052-14 Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices-MR

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#8-381	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: N/A

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

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
ASTM F2052-14 Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices (MR)

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
ASTM F2052-14	Measurement of Magnetically Induced Displacement Force on Medical Device	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
Testing originally performed to -06e1 version of standard, revisions to -14 determined to not affect test results

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

* 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.

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STANDARDS DATA REPORT FOR 510(k)s

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TYPE OF 510(K) SUBMISSION

☐ Traditional ☐ Special ☒ Abbreviated

STANDARD TITLE [1]

ASTM F2119-07 (Reapproved 2013), Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#8-153	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: N/A

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

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
ASTM F2119-07 (Reapproved 2013), Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
ASTM F2119-07	Evaluation of MR Image Artifacts from Passive Implants	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
Met all applicable clauses.

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

* 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.

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TYPE OF 510(K) SUBMISSION

☐ Traditional ☐ Special ☒ Abbreviated

STANDARD TITLE [1]

ASTM F2213-06 (Reapproved 2011), Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#8-128	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐
Title of guidance: N/A		

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

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ASTM F2213-06 (Reapproved 2011), Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
ASTM F2213-06	Magnetically Induced Torque on Medical Devices in the MRI Environment	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
Met all applicable clauses.

DESCRIPTION
The test method covers the measurement of the magnetically induced torque produced by the static magnetic field in the MR environ. on medical devices & the comparison of that torque to the equivalent torque applied by the gravitational force to the implant

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

☐ Traditional ☐ Special ☒ Abbreviated

STANDARD TITLE [1]

ASTM F2182-11a, Standard Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants (MR)

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#8-227	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
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.	☐	☒
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Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: N/A

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

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
ASTM F2182-11a, Standard Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants (MR)

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
ASTM F2182-11a	Radio Frequency Induced Heating On or Near Passive Implants During MRI	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
Met all applicable clauses.

DESCRIPTION
This test method covers measurement of radio frequency (RF) induced heating on or near a passive medical implant and its surroundings during magnetic resonance imaging (MRI).

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

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K160811/S001

INTEGRA
LIMIT UNCERTAINTY

November 4, 2016

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

RE: K160811, CRW Stereotactic System
Integra Response to Additional Information Letter Received May 23, 2016

Dear Sir or Madame:

Integra LifeSciences Corporation hereby submits two copies (1 eCopy and 1 paper copy) of our response to 510(k) number K160811, Request for Additional Information letter received on May 23, 2016. A copy of the Additional Information request can be found in Appendix 1 of this response.

Per the instructions outlined in the FDA Guidance, "eCopy Program for Medical Device Submissions" issued December 3, 2015 an electronic copy is being provided with this submission. The electronic copy is an exact duplicate of the original paper submission.

We consider our intent to market this device as confidential commercial information and request that it be treated as such by FDA. 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).

Thank you in advance for your consideration of our application. If there are any questions, concerns or requests for additional information, please do not hesitate to contact me at 609-936-5531 or via email at timothy.connors@integralife.com.

Sincerely,

Timothy D. Connors

Timothy Connors
Senior Regulatory Affairs Specialist
Integra LifeSciences Corporation

Integra • 311 Enterprise Drive, Plainsboro, NJ 08536
609-275-0500 • 800-654-2873 toll free • 609-275-5363 fax • integralife.com

INTEGRA
LIMIT UNCERTAINTY

November 4, 2016

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

RE: K160811, CRW Stereotactic System
Integra Response to Additional Information Letter Received May 23, 2016

Dear Sir or Madame:

Integra LifeSciences Corporation hereby submits two copies (1 eCopy and 1 paper copy) of our response to 510(k) number K160811, Request for Additional Information letter received on May 23, 2016. A copy of the Additional Information request can be found in Appendix 1 of this response.

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Integra LifeSciences Corporation

Integra ▪ 311 Enterprise Drive, Plainsboro, NJ 08536
609-275-0500 ▪ 800-654-2873 toll free ▪ 609-275-5362 fax ▪ integralife.com

FDA Question 1

Performance Testing

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Integra Response

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FDA Question 2

Performance Testing

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Integra Response

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FDA Question 3

Labeling

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Integra Response

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[1] For the Disposable Head Ring Screws, the Luminant Localizer, and the Universal Compact Head Ring Assembly, minimally

FDA Question 4

Labeling

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Integra Response

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FDA Question 5

Device Description

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Integra Response

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UCLF Localization

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[2] Internal Filing #I0501

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FDA Question 6

Administrative Information

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Integra Response

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FDA Question 7

Administrative Information

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Test	Test Method Summary	Results
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Integra Response

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List of Appendices

Appendix 1 – Copy of FDA Additional Information Request

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

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

K160811
Integra LifeSciences Corporation
Device Trade Name: CRW Stereotactic System
Contact Name: Mr. Timothy Connors

DEFICIENCY LIST

Performance Testing

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Labeling

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Device Description

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Administrative Information

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Test	Test Method Summary	Results
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Appendix 2 – (b)(4) Test Report

RF-Induced Heating of Integra LifeSciences' CRW Stereotactic System

Final Report

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Appendix 3 – Revised Instructions For Use (redlined and updated clean versions)

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Integra®

Disposable Head Ring Screws (DHRS)

Instructions for Use

INTEGRA®

Single Use Precautions

Single use devices are used with the CRW stereotactic system. The following precautions should be taken:

For single patient use only. The Disposable Head Ring Screws, Long and Short (DHRSS5, DHRSL5) are designed as single-use, disposable products and should not be re-sterilized or reused.

Re-sterilization and reuse may result in dullness of the screw, leading to potential head ring movement, and cross-contamination. Any Disposable Head Ring Screw, once used, should be discarded according to hospital policy.

MRI Safety Information

MR Conditional

Non-clinical testing has demonstrated that the Disposable Head Ring Screws (DHRS), Universal Compact Head Ring Assembly (UCHRA), and Luminant™ MR/CT Localizer (LL01) devices, when assembled, are MR Conditional. A patient with these devices assembled can be scanned safely under the following conditions:

- Static magnetic field of 1.5T and 3.0T
- Maximum spatial field gradient of 5,000 Gauss/cm (50 T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg in Normal Operating Mode.

Under the scan conditions defined above, the assembled devices (DHRS, UCHRA, and LL01) are expected to produce a temperature rise of less than 6ºC after 15 minutes of continuous scanning.

Caution: The RF heating behavior does not scale with static field strength. Devices which do not exhibit detectable heating at one field strength may exhibit high values of localized heating at another field strength.

In non-clinical testing, the image artifact caused by the device extends approximately 1mm from the assembled devices (DHRS, UCHRA, LL01) when imaged with either a spin-echo or a gradient echo pulse sequence and either a 1.5 T or a 3.0 T MRI system.

Disposable Head Ring Screws (MR/CT Compatible)	DHRSL5 (48 mm / box of long screws / 5 packs, 2 screws per pack) DHRSS5 (34 mm / box of short screws / 5 packs, 2 screws per pack)

Integra Radionics Disposable Head Ring Screws are designed to be used with the UCHR Universal Compact Head Ring and the HRAIM (Head Ring Intubation Assembly) and are components of the CRW® Precision and CRWASL Stereotactic Systems. For complete instructions, warnings and precautions, consult the appropriate Operator's Manual.

Instructions for Use

1. Clean and anesthetize the skull pin sites.
2. Allow the local anesthetic to take effect.

Caution: Avoid the temporalis muscle.

Note Integra recommends the use of an antibacterial ointment on the tips of the screws to help avoid infection.

3. Using the head ring wrench, insert and tighten two diagonally-opposed head ring screws.

Caution: When installing the head ring screws:

- **Only use Integra disposable head ring screws.**
- **Select the appropriate head ring screw length so that the screws protrude at least 13 mm from the outside surface of the head ring posts.**
- **Use all four (4) head ring screws to attach the head ring.**

[redacted]

INTEGRA®

Integra®
Luminant® MR/CT Localizer

Instructions for Use

CE

Rx ONLY

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INTEGRA®

Integra®
Luminant® MR/CT Localizer

Instructions for Use

CE

Rx ONLY

ENGLISH

Description

The Integra® Luminant® localizer features an open and lightweight design, and is compatible in both MR and CT imaging applications.

Designed as a simple attachment for the Integra® Universal Compact Head Ring Assembly (UCHRA) during standard MR or CT imaging, the Luminant localizer can be used with a variety of Integra software products.

Components

Part Number	Description
LL01	Localizer with storage case
LL02	Storage case only
LL03INC	One factory service, inspection and calibration

Compatibility

The Luminant MR/CT localizer is compatible with the following Integra software products:

- XKnife® RT ver. 2.1.3 or higher
- NeuroSight® Arc 1.0 or later
- StereoCalc™ 1.2
- OmniSight®™ ver. 1.1 or higher

Symbols

	Consult instructions for use
	Use by
	Fragile

	Temperature limits
	Catalog number
	Serial number
	Manufacturer
	Authorized representative in the European community.
	Device is compliant with the European Communities Council Directive 93/42/EEC, Medical Device Directive.
Rx ONLY	Federal (USA) law restricts this device to sale by or on the order of a physician.
	MR Conditional Components

Assembly

1. Remove the Luminant localizer posterior panel using the two captured thumbscrews (this is an optional step that may facilitate localizer attachment to UCHRA).
2. Position the Luminant localizer so that the anterior panel is above the UCHRA intubation hoop (without the Arc Adapter installed).
3. Secure the Luminant localizer to the UCHRA with the four attachment screws.
4. If the posterior panel was removed, reattach it by fitting the bottom of the panel over the pins on the base of the localizer. Secure the panel by tightening the captured thumbscrews into the correspond-

ing holes on the localizer frame. If the posterior panel is not replaced, only axial and coronal scans may be used.

Note Locating pins ensure that the Luminant localizer and UCHRA fit together in one orientation only—all four screws will seat fully with proper alignment. Do not attempt to assemble these parts in another orientation.

Note Finger-tighten all localizer thumbscrews; do not use tools to tighten them.

Note If the crossbar is being used, do not force the Luminant over the crossbar as there is the potential for the crossbar to interfere with the fiducial rod. The Luminant should fit over the crossbar and sit flush on the UCHRA prior to tightening the thumbscrew. Observe the relationship of the Luminant to the crossbar as the screws are tightened and verify that the fiducial rod does not contact the crossbar.

Note The crossbar design update has been made to accommodate a wider range of patient head sizes when using the UCHRA and Luminant together. Please contact technical support for additional information if your crossbar has only the engraved number 214132 without a letter designation following the number.

Note It is recommended that the Luminant MR/CT Localizer Frame be attached and secured to the Universal Compact Head Ring (UCHRA) before placing the devices on the patient.

Caution DO NOT submit the Luminant localizer to any impact, as severe jarring could cause breakage of the localizer frame and/or its fiducial rods. Return the localizer to Integra for evaluation if it is subjected to an impact.

Data Collection from the MR or CT Scan

The Luminant localizer and UCHRA are directly compatible with MR and CT imaging; no change in equipment is necessary when changing imaging modalities.

The exclusive use of MR images for stereotaxy is not recommended. MR imaging has an inherent degree of distortion that may be intrinsic to the scanner and to the types of materials within the image volume.

Note An Integra® Geometric Phantom can be purchased to measure and periodically confirm the accuracy of your scanners. Contact Integra to order part # GEOSYS and the appropriate adapter plate for your head ring.

Note The use of Integra® ImageFusion™ software can improve the accuracy of MR scans. Fusing CT and MR image sets combines the advantages of CT spatial accuracy with the superior tissue definition of MR.

Note Set the localizer type in the Integra software to either UCLF or Luminant. Both the UCLF and Luminant have the same rod locations.

MRI Safety Information

Non-clinical testing has demonstrated that the Disposable Head ring Screws (DHRS), Universal Compact head Ring Assembly (UCHRA), and Luminant® MR/CT Localizer (LL01) devices, when assembled, are MR Conditional. A patient with these devices assembled can be scanned safely under the following conditions:

- Static magnetic field of 1.5 T and 3.0 T
- Maximum spatial field gradient of 5,000 Gauss/cm (50 T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) or 2 W/kg in Normal Operating Mode.

Under the scan conditions defined above, the assembled devices (DHRS, UCHRA, LL01) are expected to produce a maximum temperature rise of less than 6 ºC after 15 minutes of continuous scanning.

Caution The RF heating behavior does not scale with static field strength. Devices which do not exhibit detectable heating at one field strength may exhibit high values of localized heating at another field strength.

In non-clinical testing, the image artifact caused by the device extends approximately 1mm from the assembled devices (DHRS, UCHRA, LL01) when imaged with either a spin-echo or a gradient echo pulse sequence and either a 1.5 T or a 3.0 T MRI system.

Once the Luminant localizer is correctly assembled to the UCHRA, proceed with scanning.

Note Make sure that the entire localizer frame is positioned within the confines of the scanner head coil.

Note While exact orientation is not necessary, use a towel or head rest beneath the superior part of the localizer to align it so that the UCHRA is perpendicular to the central axis of the scanner head coil.

Note The UCHRA intubation hoop must be in the down position to fit into the MR scanner head coil.

Caution Always keep patient movement to a minimum during the MR scan.

CT Scanning

Once the Luminant localizer is correctly assembled to the UCHRA, proceed with scanning.

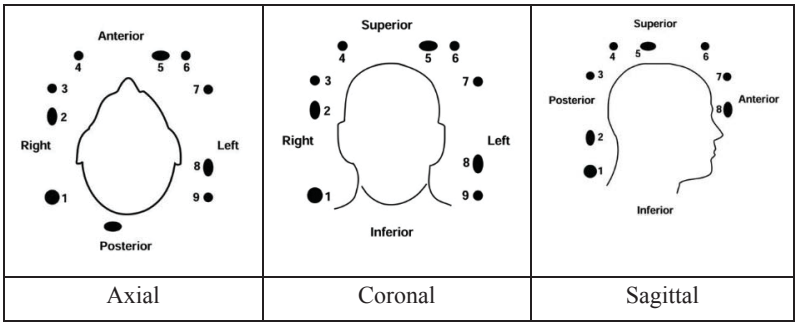
An Integra CT clamping plate attaches the UCHRA assembly to the CT couch and aligns the Luminant localizer/UCHRA assembly with the scanner.

Caution Always keep patient movement to a minimum during the CT scan.

Note To optimize automatic localization when selecting rods on CT images, Rod Threshold and Window Level settings should be adjusted. Rod thresholds between 1200 and 1500 are normally sufficient to allow selection of the rod centers. Window Level settings should be adjusted so that the rods appear clearly as rings, distinct from the other localizer components.

Rod Orientations

Confirm correct localizer placement by verifying accurate rod orientations while the patient is scanned.



Axial	Coronal	Sagittal

Caution The posterior rod in axial scans is NOT used for axial scan localization; it is only used for sagittal scan localizations.

Manual Calculations

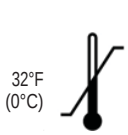
Refer to the CRW® stereotactic system User's Manual for instructions to manually calculate the CRW system target coordinates.

Cleaning

Grease or other dirt may accumulate on the frame in the course of normal use. In such cases, wipe the localizer frame with distilled water only, and dry it promptly.

Storage and Shipping

Always use the supplied case for proper localizer storage and shipping. In addition, the case must be placed into the original overshipper and shipped via next day service to avoid damage to the localizer.



Allowable temperature exposure range: 32°F to 110°F (0°C to 43°C).

Service

Caution The Luminant localizer consists of no user-serviceable parts. Return the localizer to Integra for service.

Caution In the event a localizer tube is damaged, care must be taken to avoid any effects of broken glass. The non-flowing gel component of the localizer tube does not present significant risk at the quantities and concentrations provided. As with any technical product, it is advisable to avoid repeated and prolonged exposure to materials not specifically intended for use on human skin.

First Aid Measures in Case of Contact with Gel

- Eye
  Flush eye with plenty of water immediately.
- Skin
  Wash with soap and flowing water.
- Ingestion
  Wash mouth with water.

Contact medical personnel if adverse effects appear.

Disposal

In most cases where a rod is broken, the gel will remain in the broken tube. Clean up loose gel with paper towels. Gel can be discarded in local sanitary sewer systems. Disposal should be by carefully placing the broken glass tube in a trash container.

Maintenance

The Luminant localizer's rods require regular maintenance by Integra service personnel. An expiration date may be found on the identification plate on the side of the localizer—do not use the localizer after this date. To maintain and extend your localizer warranty, contact Integra to have

periodic maintenance and calibration performed on the localizer prior to the expiration date.

INTEGRA®

PRODUCT INFORMATION DISCLOSURE

INTEGRA HAS EXERCISED REASONABLE CARE IN THE SELECTION OF MATERIALS AND THE MANUFACTURE OF THESE PRODUCTS. INTEGRA EXCLUDES ALL WARRANTIES, WHETHER EXPRESSED OR IMPLIED, INCLUDING BUT NOT LIMITED TO, ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. INTEGRA SHALL NOT BE LIABLE FOR ANY INCIDENTAL OR CONSEQUENTIAL LOSS, DAMAGE, OR EXPENSE, DIRECTLY OR INDIRECTLY ARISING FROM USE OF THIS PRODUCT. INTEGRA NEITHER ASSUMES NOR AUTHORIZES ANY PERSON TO ASSUME FOR IT ANY OTHER OR ADDITIONAL LIABILITY OR RESPONSIBILITY IN CONNECTION WITH THESE PRODUCTS. INTEGRA INTENDS THAT THIS DEVICE SHOULD BE USED ONLY BY PHYSICIANS HAVING RECEIVED PROPER TRAINING IN THE USE OF THE DEVICE.

Integra LifeSciences Corporation
4900 Charlemar Drive, Building A
Cincinnati, OH 45227
USA (800) 997-4868
FAX (888) 980-7742
www.integralife.com

EC REP

Integra LifeSciences Services (France) SAS
Immeuble Sequoia 2
97 allée Alexandre Borodine
Parc Technologique de la Porte des Alpes
69800 Saint Priest – France
Telephone: 33 (0) 4 37 47 59 10
Fax: 33 (0) 4 37 47 59 29

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Integra®

CRW® Universal Compact

Head Ring Assembly (UCHRA)

OPERATOR'S MANUAL

United States, Canada, Asia, Pacific, Latin America
USA 800-997-4868 · 888-980-7742 fax
Outside USA 609-936-5400 · 609-750-4259 fax
integralife.com

Europe, Middle-East, Africa

International: +33 (0)4 37 47 59 50 · +33 (0)4 37 47 59 25 fax
Benelux: +32 (0)2 257 4130 · +32 (0)2 253 2466 fax
France: +33 (0)4 37 47 59 10 · +33 (0)4 37 47 59 29 fax
Germany: +49 (0) 210255356200 · +49 (0)21025536636 fax
Switzerland: +41 (0)22 721 23 00 · +41 (0)22 721 23 99 fax
United Kingdom: +44 (0)1264345780 · +44 (0)1264363782 fax

integralife.eu

CE 0086

EC REP EC REP Integra LifeSciences Services (France) SAS
Immeuble Sequoia 2
97 allée Alexandre Borodine
Parc Technologique de la Porte des Alpes
69800 Saint Priest – France

Telephone: 33 (0) 4 37 47 59 10 · Fax: 33 (0) 4 37 47 59 29

Manufacturer:
Integra LifeSciences Corporation
4900 Charlemar Drive, Building A
Cincinnati, OH 45227

USA (800) 997-4868 FAX (888) 980-7742
www.integralife.com

INTEGRA®

Notices

Warranty

Integra Lifesciences, Inc. ("Integra") warrants to the original purchaser only that each new Integra product is free from manufacturing defects in material and workmanship under normal use and service for a period of one year from the date of delivery by Integra to the first purchaser, but in no event beyond the expiration date stated on any product labeling.

- Surgical instruments are guaranteed to be free from defects in material and workmanship when maintained and cleaned properly and used normally for their intended purpose.
- Any covered product that is placed by Integra under a lease, rental or installment purchase agreement and that requires repair service during the term of such placement agreement shall be repaired in accordance with the terms of such agreement.

If any covered defect occurs during the warranty period or term of such placement agreement, the purchaser should communicate directly with the Integra home office. If purchaser seeks to invoke the terms of this warranty, the product must be returned to Integra at its home office. The defective product should be returned promptly, properly packaged and postage prepaid. Loss or damage in return shipment to Integra shall be at Customer's risk. Integra' sole responsibility under this warranty shall be repair or replacement, at the sole discretion and expense of Integra, subject to the terms of this warranty and applicable agreements.

IN NO EVENT SHALL INTEGRA BE LIABLE FOR ANY INCIDENTAL, INDIRECT, CONSEQUENTIAL OR PUNITIVE DAMAGES IN CONNECTION WITH THE ACQUISITION OR USE OF ANY INTEGRA PRODUCT. Further, this warranty shall not apply to, and Integra shall not be responsible for, any loss arising in connection with the purchase or use of any Integra product that has been repaired by anyone other than an authorized Integra service representative or altered in any way so as, in Integra' judgment, to affect its stability or reliability, or which has been subject to misuse, negligence or accident, or which has been used otherwise than in accordance with the instructions furnished by INTEGRA. THIS LIMITED WARRANTY IS EXCLUSIVE AND IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, AND OF ALL OTHER OBLIGATIONS OR LIABILITIES ON THE PART OF INTEGRA, AND INTEGRA NEITHER ASSUMES NOR AUTHORIZES ANY REPRESENTATIVE OR OTHER PERSON TO ASSUME FOR IT ANY OTHER LIABILITY IN CONNECTION WITH INTEGRA PRODUCTS.

INTEGRA DISCLAIMS ALL OTHER WARRANTIES, EXPRESS OR IMPLIED INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR APPLICATION OR WARRANTY OF QUALITY AS WELL AS ANY EXPRESS OR IMPLIED WARRANTY TO PATIENTS. No warranty or guarantee may be created by any act or statement nor may this Standard Warranty be modified in any way, except as a result of a writing signed by an officer of Integra. These limitations on the creation or modification of this warranty may not be waived or modified orally or by any conduct.

Definitions of Alerts Used in this Manual

Warning: An operation or maintenance procedure, practice, condition, statement, etc. which, if not strictly adhered to, could result in injury, long term health hazard, or death of a patient or personnel.

Caution: **An operation or maintenance procedure, practice, condition, statement, etc. which, if not strictly adhered to, could result in damage to or destruction of part or all of the device, or could result in displaying erroneous information.**

Note: An important point of interest or instruction which may simplify a procedure or prevent unnecessary labor.

Table of Contents

Chapter 1 About the Universal Compact Head Ring

About this User's Manual

This manual supports the Universal Compact Headring (UCHR) and Universal Compact Headring Assembly (UCHRA) and is not intended to be a clinical medical

document. This publication details the mechanical/functional features of the system and describes how to properly assemble, use, sterilize and maintain the equipment in the system. Read and become familiar with these instructions before using the system in surgery.

About UCHRA System Compatibility

The UCHR is designed to be used in conjunction with the Integra CRW® Precision Stereotactic System, the CRWASL Stereotactic System, and the XKnife Radiosurgery System. The UCHRA is configured to be CT and MRI compatible.

Indications for Using the UCHRA

Standard Stereotactic Procedures

The CRW System is a stereotactic system to be used for neurosurgical procedures that require precise target localization, such as craniotomies, biopsies, and functional Stereotaxy

Note: Localization is performed using CT or MR imaging.

Contraindications for Using the UCHRA

- The head ring is contraindicated for infants whose coronal sutures have not yet closed.
- The CRW system is contraindicated for patients with Creutzfeldt–Jakob disease.

Single Use Precautions

Single use devices are used with the CRW stereotactic system. The following precautions should be taken:

For single patient use only. The Disposable Head Ring Screws, Long and Short (DHRSS5, DHRSL5) are designed as single-use, disposable products and should not be re-sterilized or reused.

Re-sterilization and reuse may result in dullness of the screw, leading to potential head ring movement, and cross contamination. Any Disposable Head Ring Screw, once used, should be discarded according to hospital policy.

For single patient use only. The Apuzzo Stereotactic Drapes (ASD1 and ASD1B) are designed as single-use, disposable products and should not be re-sterilized or reused.

Reuse of this device may result in cross contamination or compromised sterility of the drape and sterile field. Any drape, once used, should be discarded according to hospital policy.

To ensure proper accuracy and function of the CRW system, do not subject any of the CRW system's parts or accessories to any forces that may affect its use or calibration.

Always inspect the UCHR prior to use. If any of the parts or accessories are damaged in a way that may potentially affect the system's accuracy or function, please return the system to Integra for service (see page 77 for packaging instructions).

Using the CRW® System with Electrosurgical Devices

If the UCHR is to be used with a ground–referenced electrosurgical device (monopolar or bipolar electrode), the headring should not contact the patient. Maintain a gap (at least 1/4 inch) between the head ring and the patient's body.

- Follow safety procedures consistent with the use of anesthetizing gases when using the UCHR with electrosurgical equipment.
- Review the system and its accessories prior to surgery to ensure that all items are available and functional.

Chapter 2 Using the CRW® System in a Magnetic Resonance Imaging Environment

MRI Safety Information

MR Conditional

Non-clinical testing has demonstrated that the Disposable Head Ring Screws (DHRS), Universal Compact head Ring Assembly (UCHRA), and Luminant® MR/CT Localizer (LL01) devices, when assembled, are MR Conditional. A patient with these devices assembled can be scanned safely under the following conditions:

- Static magnetic field of 1.5 T and 3.0 T
- Maximum spatial field gradient of 5,000 Gauss/cm (50 T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2.0 W/kg in Normal Operating Mode

Under the scan conditions defined above, the assembled devices (DHRS, UCHRA, LL01) are expected to produce a maximum temperature rise of less than 6 °C after 15 minutes of continuous scanning.

Caution: The RF heating behavior does not scale with static field strength. Devices which do not exhibit detectable heating at one field strength may exhibit high values of localized heating at another field strength.

In non-clinical testing, the image artifact caused by the device extends approximately 1mm from the assembled devices (DHRS, UCHRA, LL01) when imaged with either a spin-echo or a gradient echo pulse sequence and either a 1.5 T or a 3.0 T MRI system.

MR Unsafe Components

The following components of the CRW® System are MR Unsafe:

Cat. No.	Device Description	Metallic Materials
UCHREBA	Ear Bar Assembly	6061-T6 Aluminum
HRW	Head Ring Wrench	303, 416 Stainless Steel
TAP	Cleaning Tap	High Speed Tool Steel

Chapter 3 Assembling the Universal Compact Head ring Assembly

List of UCHR Components and Accessories

Head Rings and Accessories		
UCHRA (Universal Compact Head Ring Assembly)	UCHRA	
UCHRAP (Adapter Plate)	UCHRAP	
UCHRA Storage and Sterilization Case	UCHRCASE	

Head Rings and Accessories		
UCHRHK (UCHRA Hardware Kit)	UCHRHK	**UCHRHK** This kit includes: (4) Adapter plate attachment screws (2) Intubation hoop attachment screws (4) Head post attachment screws (2) Ear bar assembly attachment screws (2) Ear bar assembly nylon thumb screws
UCHRP (Composite Post & Cross Bar Kit)	UCHRP	
UCHREBA (Head Ring Ear Bar Kit) UCHREB (Individual Ear Bars for UCHREBA)	UCHREBA UCHREB	
HRW (Head Ring Wrench)	HRW	

Head Rings and Accessories		
TAP (Cleaning Tap for HRP and UCHRP)	TAP	
HRKTP (Head Ring Positioner)	HRKTP	
CSS (Conical T-Bolt Screws)	CSS	

Imaging Localizers		
BRWLF (CT Localizer Frame)	BRWLF	
LL01 (Luminant® (MR/CT Localizer))	LL01	

Sterile Devices (Single Use Only)		
Apuzzo Stereotactic Drape	ASD1 (sterile drape) ASD1B (10 sterile drapes)	
Disposable Head Ring Screws (MR/CT Compatible)	DHRSL5 (48 mm / box of long screws / 5 packs, 2 screws per pack) DHRSS5 (34 mm / box of short screws /5 packs, 2 screws per pack)	

Assembling the Universal Compact Head Ring (UCHR)

1. Attach the 4 head ring posts onto the head ring. Use the head ring wrench to tighten the head post attachment screws.

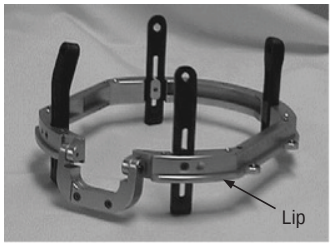
Note The anterior head ring posts are longer than the posterior posts, and are angled rather than straight.

Caution: Assemble the head ring posts onto the head ring prior to installing the head ring screws. Failure to do so could potentially place increased stress on the head ring post assembly.

2. See the picture to the right for a sample of a properly assembled head ring.

Note The "lip" that goes around the head ring should be on the bottom.

Note To prevent breaking the head post attachment screws, ensure that the post screws are tightened so that the post is flush with the head ring before tightening the disposable head ring screws.

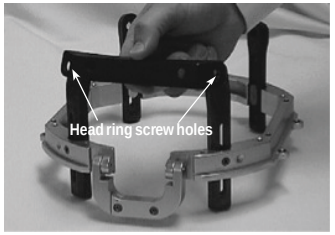


Attaching the Head Ring Screw Cross Bar (Optional)

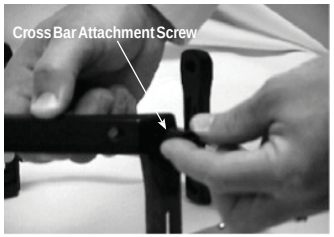
Note If you are not using the optional head ring screw cross bar, proceed to "Installing the Ear Bars (Optional)" on page 21).

Caution: To avoid placement of the head ring screws into the temporalis muscle, use head ring cross bar.

1. Align the cross bar holes with the head ring screw holes of the anterior head ring posts.



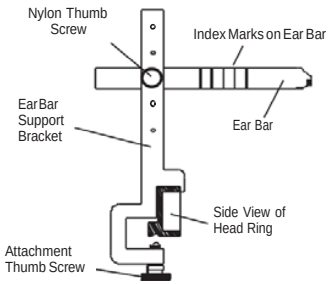
2. Attach the cross bar with the cross bar attachment screws to the anterior head ring posts.



Installing the Ear Bars (Optional)

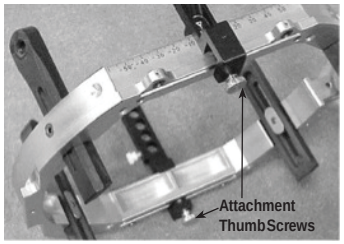
Assembling the Ear Bar

1. Loosen the nylon thumb screw on the ear bar support bracket to place the ear bar in the bracket.



2. Fit the support brackets on opposite sides of the head ring, then finger tighten the attachment thumb screws.

Note The scales on the sides of the head ring are for reference only and allow for alignment of the head ring to the patient.



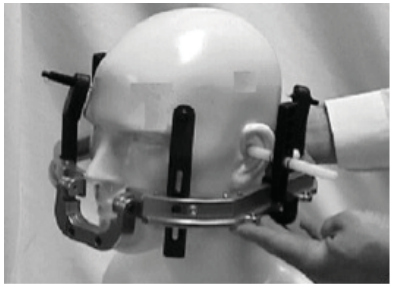
Placing the Head Ring Assembly on the Patient

Note Placing the head ring assembly is easier if multiple people perform the procedure.

1. The first person should hold the head ring in the desired position over the patient's head.
2. The second person may arrange the ear bars so that the rounded end of each bar rests comfortably in the patient's outer ear.

Note Use the index marks on each ear bar to help center the assembly.

Note Fit the head ring to the patient's skull while the patient is in a sitting position.



Caution: To reduce patient discomfort, do not allow the weight of the head ring assembly to rest on the ear bars.

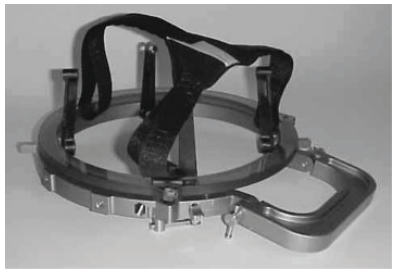
Caution: Use of the Velcro strap (GTCSVS) helps position the head ring assembly and take the weight off the ear bars. For more information on this strap, see page 26.

3. Finger-tighten nylon thumb screw on each support bracket to secure the ear bars.

Place the HRKTP head ring positioner onto the head ring (Optional)

Note Using the head ring positioner helps support the weight of the head ring assembly during placement on the patient.

Head Ring Positioner (HRKTP



1. Place the head ring over the patient's head.

Note The head ring can be placed in any rotational orientation on the patient's head; targeting is not affected. It should be placed on the patient's head inferior to the target in order for the localization frame to encapsulate the target.

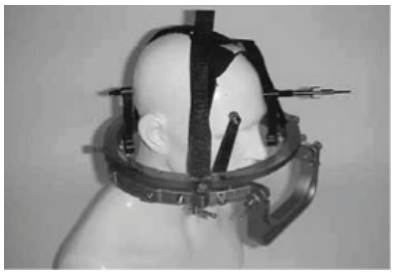
Caution: Avoid the temporalis muscle.

1. Clean and anesthetize the skull pin sites.

2. Allow the local anesthetic to take effect.

Note Integra recommends the use of an antibacterial ointment on the tips of the screws to help avoid infection.

3. Using the head ring wrench, insert and tighten two diagonally-opposed head ring screws.

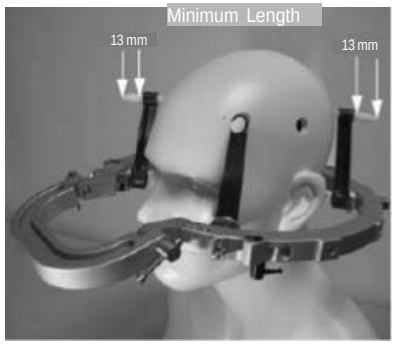


Caution: When installing the head ring screws:

- **Only use Integra disposable head ring screws.**
- **Select the appropriate head ring screw length so that the screws protrude at least 13 mm from the outside surface of the head ring posts.**
- **Use all four (4) head ring screws to attach the head ring.**

4. After securing the first pair of head ring screws, install the second pair.

Note Hand-tighten all screws with the head ring wrench.



Caution: Oversrtightening the head ring screws can cause premature failure of the head ring posts and/or head ring screws.

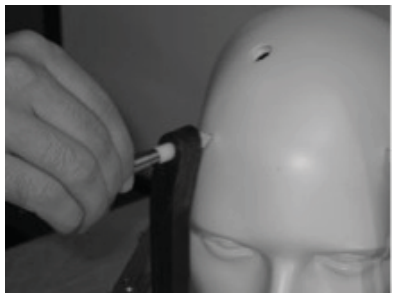
Installing the Head Ring Screws

Caution: When installing the head ring screws:

- **Only use Integra disposable head ring screws.**
- **Select the appropriate head screw length so that the screws protrude at least 13 mm from the outside surface of the head ring posts.**
- **Use all four (4) head ring screws to attach the head ring.**

1. Cleanse the patient's scalp and apply local anesthesia through the head ring post openings (or cross bar openings, if applicable).
2. Allow the local anesthetic to take effect.
3. Use the head ring wrench to drive the head ring screws into the patient's skull.

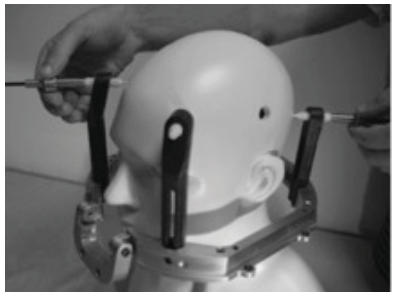
Note Integra recommends the use of an antibacterial ointment on the tips of the screws to help avoid infection.



4. Insert and tighten two diagonally-opposed head ring screws at a time.

Note Using the head ring wrench, hand-tighten each screw equally and alternately.

5. After securing the first pair of screws, install the second pair.
6. Be sure that the head ring assembly is securely in place, then remove the two ear bars from the support brackets.
7. Loosen the thumb screws and remove the ear bar support brackets from the head ring assembly.
8. Remove the head ring positioner (HRKTP) and/or Velcro strap if used.



Caution: Overtightening of the head ring screws can cause premature failure of the head ring posts and/or the head ring screws.

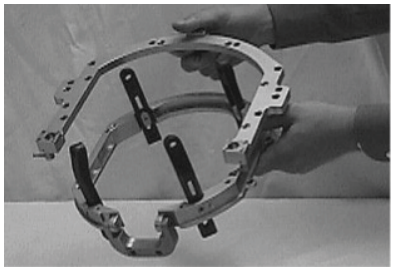
The head ring is now ready for Luminant® localizer attachment. If attaching the BRWLF to the head ring, proceed to the next page for further assembly instructions.

Attaching the Arc Adapter Plate to the UCHRA

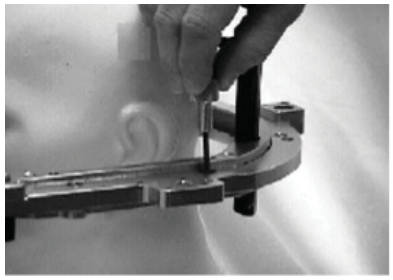
Note You must attach the arc adapter plate to the head ring before you can place the BRWLF on the head ring.

1. Position the arc adapter plate so that the open end faces the head ring assembly anterior.

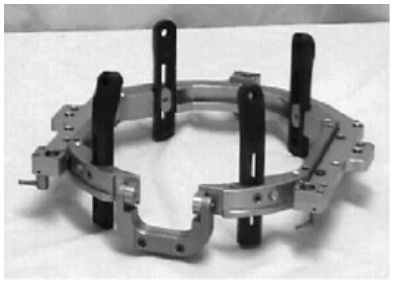
Note The arc adapter is used to attach the BRWLF to the head ring for CT scanning, and also attach the CRW system to the head ring.



2. Use the head ring wrench to tighten the attachment screws, securing the arc adapter plate to the head ring assembly.



3. The UCHRA with the arc adapter plate in place.



Assembling the Localizer Frames

The CRW supports the BRWLF and Luminant® localizer frames.

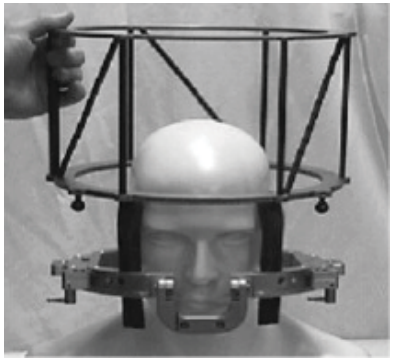
Assembling the BRWLF on the UCHRA

The BRW localizer frame is CT imaging-compatible only. The BRW localizer frame is not indicated for use with MR imaging.

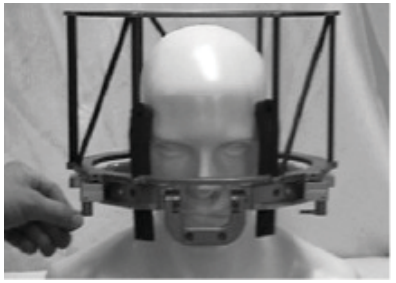
Note To ensure proper attachment of the localizer to the head ring, inspect the balls on the bottom of the localizer prior to assembly to verify that they are not damaged or loose.

1. Place the BRW localizer frame (BRWLF) onto the UCHRA (with the arc adapter installed):

- The BRWLF on the UCHRA is shown:



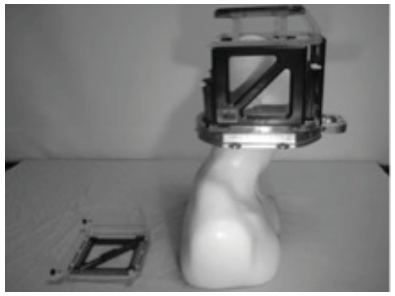
2. Lock the cams to fasten the localizer frame to the Adapter Plate of the UCHRA.



Assembling the Luminant® on the UCHRA

Note For MR setup, do not attach the arc adapter to the UCHRA.

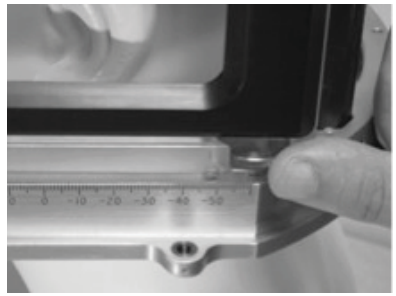
1. Remove the Luminant® localizer posterior panel and position the localizer so that the anterior panel is above the intubation hoop on the head ring assembly (without the arc adapter installed).



Note The UCHRA intubation hoop must be in the down position to fit into the MR scanner head coil - the illustration at the right displays the hoop in the Up position. Use the head wring wrench (HRW) to loosen/tighten the intubation hoop for positioning.

2. Secure the Luminant localizer by thumb-tightening the four attachment screws into the four threaded holes on the top of the head ring.

Note The Luminant localizer and UCHRA fit together in one orientation only --all four screws will align properly. Do not attempt to assemble these parts in another orientation.

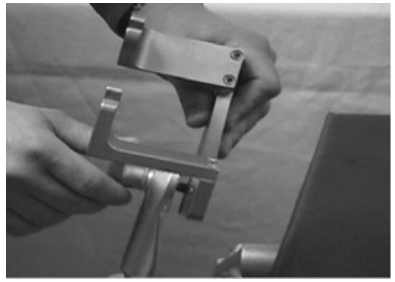


Attaching the Universal Compact Head Ring (UCHRA) to the Operating Table

This procedure requires the MAYFIELD® Adapter or flat MAYFIELD® Adapter and the CSS bolts.

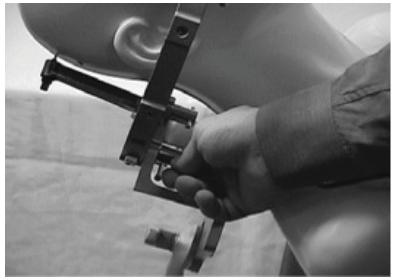
Note The following procedure outlines the use of the MAYFIELD Adapter; the same steps should be followed when using the flat MAYFIELD Adapter.

1. Clamp the MAYFIELD Adapter to the operating table as shown.



2. Attach the UCHRA to the MAYFIELD Adapter using the short T-Bolts.

Note Place the CSS T-bolts onto the head ring and guide the patient onto the head ring and guide the patient onto the CRWMA MAYFIELD Adapter to prevent the binding of the MAYFIELD Adapter to the MAYFIELD Swivel or Tri-Star Swivel Adapter.



Chapter 4 Cleaning, Sterilizing and Maintaining the Universal Compact Head Ring

Cleaning the Universal Compact Head Ring

Note The use of Betadine® and other related fluids containing iodine may stain the surface of the stereotactic system. To minimize discoloration, wipe off any traces of Betadine® and similar solutions as soon as a possible during or following the surgery.

Use the following guidelines when cleaning the Universal Compact Head Ring (UCHR) components (head ring, posts, and screws):

Caution: Do not use saline, as it will attack the metal surface. Do not use corrosive agents, such as Clorox® or Cidex®. Do not use alcohol or hydrogen peroxide on any black composite materials.

- After each procedure, clean components with de-ionized distilled water to remove any residue of Betadine®, blood, CSF or other debris.
- Thoroughly dry and wrap components for sterilization.
- Remove any liquids from components as soon as possible after surgery to prevent corrosion or tarnishing of the surfaces.
- The cleaning tap (TAP) may be used to remove debris from inside the head ring post threads. Insert fully and remove the tap to cleanse the thread.

Packing the UCHR Components

Pack the UCHR components into the sterilization trays after cleaning and before sterilization.

Sterilizing the UCHR Components

Whenever virus–contact with the instrumentation is possible, proper sterilizing measures must be followed. It is the responsibility of hospital personnel to review sterilization procedures for susceptible components and to implement procedures addressing such hazards.

Caution: Do not sterilize the localizer frame. Sterilization may damage the component and render it inoperable.

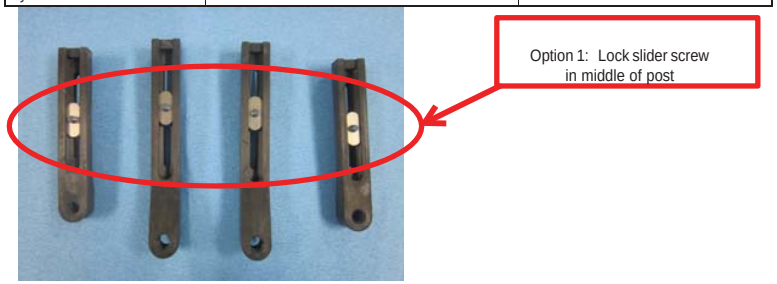
Parameters for Sterilizing the UCHR Components

The following tables provide recommended sterilization parameters for the UCHR components. Due to variations in sterilization chambers and load configurations, it is the responsibility of the facility to determine a sterilization protocol that ensures sterility of the device.

EtO(100% EtO)	
Parameters:	Cycle 1
Concentration:	883 mg/L
Temperature:	131°F / 55°C
Exposure Time:	>= 60 minutes
Humidity:	>= 50% RH

Steam AutoClave (Pre-Vacuum)			
Parameters:	Option 1	Option 2	Option 3
Temperature:	270°F / 132°C	275°F / 135°C	273°F / 134°C
Exposure Time:	4 minutes	3 minutes	18 minutes
Dry Time:	20 minutes	16 minutes	20 minutes

Sterrad®		
Parameters:	Option 1	Option 2
System:	100S	100NX
Position of Slider Screw on Composite Post (UCHRP):	Lock into center of slot prior to sterilization (see picture below)	Any position
Containment	Single self-seal sterilization pouch	Single self-seal sterilization pouch
Cycle:	Standard	Standard



Summary of UCHR Sterilization Procedures

Component	Description	EtO	Steam Autoclave	Sterrad®
UCHR	Universal Compact Head Ring	Yes	Yes	No
UCHRPA, UCHRPP	Composite Head Ring Posts, Cross Bar & attached screws	Yes	No	Yes
HRW	Head Ring Wrench	Yes	Yes	No
UCHRAP	UCHR Adapter Plate	Yes	Yes	No
UCHREBA	Ear Bar Assembly Kit	Yes	Yes	No
UCHREB	Ear Bar	Yes	Yes	No

Appendix 4 – Revised Labels (redlined)

INTEGRA

Manufacturer: Integra LifeSciences Corporation
4900 Charlemar Drive, Building A,
Cincinnati, OH 45227
USA (800)997-4868 Fax (888)980-7742
www.integralife.com

REF HRW
Catalog Number

LOT XXXXXXXXXXXX
Lot Number

Head Ring Wrench
Cle pour Serre-tete
Chiave per Anello Craniale
Kopfring-Schraubenschlusse
Llave para aro p/Cabeza
Sleutel voor Hoofdring

QTY: (1X)

Rx ONLY

Consult Instructions for Use

YYYY-MM-DD
Date of Manufacture

NON STERILE

CE 0086

Product complies with the requirements of directive 93/42/EEC

MR Unsafe

+M248HRW1P

+$$8017LLLLLLLLLLLLLP3

Made in USA

14770001 Rev. J

INTEGRA

Manufacturer: Integra LifeSciences Corporation
4900 Charlemar Drive, Building A,
Cincinnati, OH 45227
USA (800)997-4868 Fax (888)980-7742
www.integralife.com

REF TAP
Catalog Number

LOT XXXXXXXXXXXXX
Lot Number

Tap for Head Ring Posts
Canelle de la broche
Presa per colonna craniale
Kopfatift-Gewindeboher
Perforador de soporte picabeza
Dutch Translation

QTY: (1X)

Rx ONLY

CE 0086
Product complies with the requirements of directive 93/42/EEC

Consult Instructions for Use

MR Unsafe

YYYY-MM-DD
Date of Manufacture

NON STERILE

+M248TAP1D

+$$8017LLLLLLLLLLLLDY

Made in USA

14970003 Rev. G

INTEGRA

Manufacturer: Integra LifeSciences Corporation
4900 Charlemar Drive, Building A
Cincinnati, OH 45227
USA (800)997-4868 Fax (888)890-7742
www.integralife.com

REF UCHRA
Catalog Number

SN XXXXXXXXXXXX
Serial Number

UCHR Assembly

(1)Sterilization case; (1) CRW User's manual; (1)Tap • ; (2) Wrenches• ; (1) Cross bar▲ ;(2) Cross bar locking screws▲ ;(2) Anterior head posts ▲ ;(2) Posterior head posts ▲ ; (1) Head ring ▲ ; (1) Adapter ring ▲ ; (2) Ear bar assemblies• ; (4) Post screws ▲

Ensemble UCHR (Arceau de tête compact universel)

(1) Boîtier de stérilisation; (1) Manuel d'utilisation CRW; (1) Taraud •; (2) Clés •; (1) Barre transversale ▲ ; (2) Vis à verrouillage de la barre transversale ▲ ; (2) Tenons de tête antérieurs ▲ ; (2) Tenons de tête postérieurs ▲ ; (1) Arceau de tête ▲ ; (1) Arceau adaptateur ▲ ; (2) Ensembles de barre d'oreille •; (4) Vis de tenon ▲

Ensamblaje ACCU

(1) Caja de esterilización; (1) Manual del usuario de CRW; (1) Conformador de rosca • ; (2) Llaves •; (1) Barra cruzada ▲ ; (2)Tornillos de bloqueo de la barra cruzada ▲ ; (2) postes anteriores de la cabeza ▲ ; (2) Postes posteriores de la cabeza ▲ ; (1) Anillo de la cabeza ▲ ; (1) Anillo adaptador ▲ ; (2) Montajes de las barras de las orejas •; (4) Tornillos de los postes ▲

UCHR-Baugruppe (Universal-Kompaktkopfring)

(1) Sterilisationskassette; (1) CRW-benutzerhandbuch; (1) Gewindebohrer • ; (2) Schlüssel •; (1) Querstange ▲ ; (2) Feststellschrauben für quesrstange ▲ ; (2) Anteriore kopfstangen ▲ ; (2) Posteriore kopfstangen ▲ ; (1) Kopfring ▲ ; (1) Adapterring ▲ ; (2) Ohrstangenanordnungen •; (4) Schrauben für stangen ▲

Gruppo UCHRA (anello universale compatto per testa)

(1) Cassetta di sterilizzazione; (1) Manuale d'uso del sistema CRW; (1) Maschio • ; (2) Chiavi •; (1) Barra transversale ▲ ; (2) Viti di bloccaggio barra transversale ▲ ; (2) Aste anteriori testa ▲ ; (2) Aste posteriori testa ▲ ; (1) Anello testa ▲ ;(1) Anello adattatore ▲ ; (2) Gruppi barra auricolare •; (4) Viti per aste ▲

UCHR-samenstel

(1) Sterilisatiedoos; (1)Gebruikershandleiding CRW; (1) Tap • ; (2) Moersleutels •; (1) Dwarsstang ▲ ; (2)Borgschroeven voor dwarsstang ▲ ; (2) Anterieure hoofdstijlen ▲ ; (2)Posterieure hoofdstijlen ▲ ; (1) Hoofdring ▲ ; (1)Adapterring ▲ ; (2) Oorstang samenstellen•; (4) Stijlschroeven ▲

QTY: (1X)

Rx ONLY

+M248UCHRA12

+$$8017LLLLLLLLLLLLL2N

Consult Instructions For Use

YYYY-MM-DD
Date of Manufacture

NON STERILE

• Component

MR Unsafe

▲ Component

MR Conditional

CE 0086

Product complies with the requirements of directive 93/42/EEC

Made in USA 37870001 Rev. N

Manufacturer: Integra LifeSciences Corporation
4900 Charlemar Drive, Building A,
Cincinnat', OH 45227
USA (800)997-4868 Fax (888)980-7742
www.integralife.com

REF UCHRAP
Catalog Number

LOT XXXXXXXXXXXXX
Lot Number

UCHR ARC Adapter Plate
Plaque d'adaptateur ARC
Paistra adaltmento ARC
ARC Adapter-Platie
Planoha adapladora p/ARC
Dutch Translation

QTY: (1X)

Rx ONLY

CE 0086

YYYY-MM-DD
Date of Manufacture

NON STERILE

Consult Instructions For Use

Product complies with the requirements of directive 93/42/EEC

MR

MR Conditional

+M248UCHRAP1R

+$$8017LLLLLLLLLLLLLR5

Made in USA

37870005 Rev. G

INTEGRA

Manufacturer: Integra LifeSciences Corporation
4900 Charlemar Drive, Building A,
Cincinnati, OH 45227
USA (800)997-4868 Fax (888)980-7742
www.integralife.com

REF UCHRCBS
Catalog Number

LOT XXXXXXXXXXXXX
Lot Number

UCHR Cross Bar Screw, (1)

Vlis de Barre Transversale UCHR (1)

Viti Barre Transversale UCHR, (1)

UCHR Quersstangenschrauben, (1)

Tornillos para Barre Transversal UCHR, (1)

UCHR Cross Bar Screw, (1)

QTY: (1X)

DO NOT AUTOCLAVE

YYYY-MM-DD
Date of Manufacture

Rx ONLY

Consult Instructions for Use

NON STERILE

CE 0086

Product complies with the requirements of directive 93/42/EEC

MR

MR Conditional

+M248UCHRCBS10

+$$8017LLLLLLLLLLLLoL

Made in USA
37870008 Rev. J

INTEGRA

Manufacturer: Integra LifeSciences Corporation
4900 Charlemar Drive, Building A,
Cincinnati, OH 45227
USA (800)997-4868 Fax (888)980-7742
www.integralife.com

REF UCHRHK
Catalog Number

LOT XXXXXXXXXXXXX
Lot Number

Hardware Kit for UCHR

(4) Adapter Plate Attachment Screws •;(2) Intubation Hoop Attachment Screws▲;
(4) Head Post Attachment Screws •;(2) Ear Bar Assmebly Nylon Thumb Screws •

Trousse d'équipement UCHR

Kit Accessori UCHR

Material -Satz UCHR

Kit de Ferretería, UCHR

Hardwareset voor UCHR

QTY: (1X)

Rx ONLY

CE 0086

Product complies with the requirements of directive 93/42/EEC

Consult Instructions for Use

NON STERILE

YYYY-MM-DD
Date of Manufacture

+M248UCHRHK1T

+$$8017LLLLLLLLLLLT7

▲ Component

MR Conditional

MR Conditional

• Component

MR Unsafe

Made in USA 37870011 Rev. J

INTEGRA

Manufacturer: Integra LifeSciences Corporation
4900 Charlemar Drive, Building A,
Cincinnati, OH 45227
USA (800)997-4868 Fax (888)980-7742
www.integralife.com

REF UCHR-EBA
Catalog Number

LOT XXXXXXXXXXXXX
Lot Number

UCHR Ear Bar Assembly
Assemblage Barre Auriculaire UCHR
Gruppo Barre Orecchie UCHR
UCHR Ohrenstangen-Baugruppe
Conjunto de Barre para la Oreja, UCHR
UCHR oorstaafconstructie

QTY: (1X)

Do Not Autoclave

YYYY-MM-DD
Date of Manufacture

Rx ONLY

NON STERILE

CE 0086
Product complies with the requirements of directive 93/42/EEC

Consult Instructions for Use

MR Unsafe

+M248UCHREBA1K

+$$8017LLLLLLLLLLLL

Made in USA

38370001 Rev. J

LUMINANT
MR/CT Localizer

MR Conditional

INTEGRA

INTEGRA

Manufacturer:
Integra LifeSciences Corporation
4900 Charlemar Drive, Building A
Cincinnati, OH 45227
USA 1(866)942-869 Fax 1(877) 558-6227
www.integralife.com

REF DHRSL5 LOT XXXXXXXXX
Catalog Number Lot Number

+$$01MMYYLLLLLLLLLH

Long, Disposable, HRS

Disposable Head Ring Screw, Long

Einmal-Kopfringschraube, Lang

Hovedringsskrue til engangsbrug, Lang

Engangsskruv till skallstativ, Lang

Parafuso anelar descartável, Comprido

Engangs hoderingskrue, Lang

Hoofdringschroef voor eenmalig gebruik, Lang

Vite con testa ad anello monouso, Linga

Vis à oeilleton jetable, Longue

Tornillo desechable para la cabeza, Largo

CE 0086 Rx ONLY QTY: (5X2)

YYYY-MM-DD
Date of Manufacture

YYYY-MM-DD
Use By

MR
MR Conditional

+M248DHRSL51H

70DHRSL5
Rev. J

INTEGRA

Manufacturer:
Integra LifeSciences Corporation
4900 Charlemar Drive, Building A
Cincinnati, OH 45227
USA 1 (866)942-8698 Fax 1 (877) 558-6227
www.integralife.com

REF DHRSS5 LOT XXXXXXXXX
Catalog Number Lot Number

Short, Disposable, HRS

Disposable Head Ring Screw, Short

Einmal-Kopfringschraube, Kurz

Hovedringsskrue til engangsbrug, Kort

Engangsskruv till skallstativ, Kort

Parafuso anelar descartável, Curto

Engangs hoderingskrue, Kort

Hoofdringschroef voor eenmalig gebruik, Kort

Vite con testa ad anello monouso, Corta

Vis à oeilleton jetable, Courte

Tornillo desechable para la cabeza, Corto

+$$801MMYYLLLLLLLLO1

CE 0086 Rx ONLY QTY: (5X2)

YYYY-MM-DD
Date of Manufacture

YYYY-MM-DD
Use By

MR
MR Conditional

+M248DHRSS51O

70DHRSS5
Rev. J

INTEGRA

Manufacturer: Integra LifeSciences Corporation
4900 Charlemar Drive, Building A,
Cincinnati, OH 45227
USA (800) 997-4868 Fax (888) 980-7742
www.integralife.com

REF LL01
Catalog Number

SN XXXXXXXXXXXXX
Serial Number

Luminant® Localizer
Localisateur Luminant®
Localizador Luminant®
Luminant® -Lokalisator
Localizzatore Luminant®
Luminant® lokalisator

QTY: (1X)

Rx ONLY

Consult Instructions For Use

CE 0086
Product complies with the requirements of directive 93/42/EEC

YYYY-MM-DD
Use By

YYYY-MM-DD
Date of Manufacture

NON STERILE

Do Not Autoclave

Temperature Limitation

Fragile, Handle with Care

MR
MR Conditional

+M248LL011Z

+$$801MMYYLLLLLLLLLLZY

Made in USA

70LL01 Rev. G

INTEGRA

Manufacturer: Integra LifeSciences Corporation
4900 Charlemar Drive, Building A,
Cincinnati, OH 45227
USA (800) 997-4868 Fax (888) 980-7742
www.integralife.com

REF UCHRCB1
Catalog Number

LOT XXXXXXXXXXXXX
Lot Number

UCHR Cross Bar and Screws

(1) UCHR Cross Bar, (2) UCHR Cross Bar Screws

Crossbar, Vis de barre transversale UCHR

(1) Crossbar UCHR, (2) Vis de barre transversale UCHR

UCHR Befestigungssch r. Querstange, Quersangenschrauben

(1) UCHR Befestigungeschrauben f. Querstange, (2) UCRA Quersatangenschrauben

Barra trsversale, Viel barra tresversale UCHR

(1) Barra trasversale UCHR, (2) Viel barra tresversale UCHR

Barra transversal,Tornillos para transversal, UCHR

(1) Barra trasversal UCHR, (2) Tornillos para barra transversal UCHR

Dutch Translation

QTY: (1X)

DO NOT AUTOCLAVE

YYYY-MM-DD
Date of Manufacture

Rx ONLY

Consult Instructions For Use

NON STERILE

CE 0086

Product complies with the requirements of directive 93/42/EEC

MR

MR Conditional

+M248UCHRCB11K

+$$8017000000XXXXXXKC

Made in USA

70UCHRCB1 Rev. F

INTEGRA

Manufacturer: Integra LifeSciences Corporation
4900 Charlemar Drive, Building A,
Cincinnati, OH 45227
USA (800)997-4868 Fax (888)980-7742
www.integralife.com

REF UCHREB
Catalog Number

LOT XXXXXXXXXXXX
Lot Number

UCHR Ear Bar
Barre auriculaire UCHR
Barra orecchie UCHR
UCHR Ohrenstangen
Barra para lo oreja, UCHR
Oorstaafje voor UCHR

QTY: (1X)

Rx ONLY

Consult Instructions For Use

YYYY-MM-DD
Date of Manufacture

MR Unsafe

NON STERILE

CE 0086

Product complies with the requirements of directive 93/42/EEC

Do Not Autoclave

+M248UCHREB1H

*+$$8017LLLLLLLLLLLLLH *

Made in USA

70UCHREB Rev. D

INTEGRA

Manufacturer: Integra LifeSciences Corporation
4900 Charlemar Drive, Building A,
Cincinnati, OH 45227
USA (800) 997-4868 Fax (888) 980-7742
www.integralife.com

REF UCHRP
Catalog Number

LOT XXXXXXXXXXXX
Lot Number

UCHR Post and Cross Bar Kit

(2) UCHR Anterior Head Posts,, (2) UCHR Posterior Head Posts, (1) UCHR Cross Bar, (2) UCHR Cross Bar Screws

Jau de Pièces UCHR Broche Crossbar

(2) Broche UCHR,anterieure, (2) Broche UCHR, posterieure, (1) Crossbar UCHR, (2) Vis de barre transversale UCHR

UCHR Kopfetift Befestigungssch f. Querstange Kit

(2) UCHR Kopfstift, anteroar, (2) UCHR Kopftift, posterior, (1) UCHR Befestigungeschrauben f. Querstange, (2) UCRA Quersatangenschrauben

Kit Colonna testa Barre trasversale, UCHR

(2) Colonra testa, anteriore, (2) Colonna testa, posteriore, UCHR, (1) Barra trasversale UCHR, (2) Viel barra tresversale UCHR

Kit de Soporte para la cabeza Barra transversal, UCHR

(2) Soporte anterior para la cabeza, UCHR, (2) Soporte poserior para la cabeza, UCHR, (1) Barra trasversal UCHR, (2) Tornillos para barra transversal UCHR

Dutch Translation

QTY: (1X)

DO NOT AUTOCLAVE

YYYY-MM-DD
Date of Manufacture

Rx ONLY

Consult Instructions For Use

NON STERILE

CE 0086

Product complies with the requirements of directive 93/42/EEC

MR

MR Conditional

+M248UCHRP1K

+$$8017000000XXXXXXKC

Made in USA

70UCHRP Rev. E

INTEGRA

Manufacturer: Integra LifeSciences Corporation
4900 Charlemar Drive, Building A,
Cincinnati, OH 45227
USA (800)997-4868 Fax (888)980-7742
www.integralife.com

REF UCHRPA
Catalog Number

LOT XXXXXXXXXXXX
Lot Number

UCHR Post, Anterior
Broche UCHR, Antérieure
Colonna testa Anteriore UCHR
UCHR Kopfstift, Anterior
Soporte Anterior para la Cabeza, UCHR
UCHR-pin Anterieur

QTY: (1X)

Rx ONLY

NON STERILE

CE 0086
Product complies with the requirements of directive 93/42/EEC

Do Not Autoclave

Consult Instructions for Use

YYYY-MM-DD
Date of Manufacture

MR

MR Conditional

+M248UCHRPA1R

+$$8017LLLLLLLLLLLLR5

Made in USA

70UCHRPA Rev. F

INTEGRA

Manufacturer: Integra LifeSciences Corporation
4900 Charlemar Drive, Building A,
Cincinnati, OH 45227
USA (800)997-4868 Fax (888)980-7742
www.integralife.com

REF UCHRPP
Catalog Number

LOT XXXXXXXXXXXXX
Lot Number

UCHR Post, Posterior
Broche UCHR, Postérieure
Colonna Testa Posteriore UCHR
UCHR Kopfstift, Posterior
Soporte Posterior Para la Cabeza, UCHR
UCHR-Pin, Anterieur

QTY: (1X)

Do Not Autoclave

YYYY-MM-DD
Date of Manufacture

Rx ONLY

Consult Instructions for Use

NON STERILE

CE 0086

Product complies with the requirements of directive 93/42/EEC

MR

MR Conditional

+M248UCHRPP1%

+$$8017LLLLLLLLLLLL%K

Made in USA

70UCHRPP Rev. F

INTEGRA

Manufacturer: Integra LifeSciences Corporation
4900 Charlemar Drive, Building A,
Cincinnati, OH 45227
USA (800)997-4868 Fax (888)980-7742
www.integralife.com

REF UCHR
Catalog Number

LOT XXXXXXXXXXXX
Lot Number

Universal Compact Head Ring
Anneau Crânien Compact Universel
Anello per Testa Compatto Universale
Universeller Kompaktkopfring
Sujeción Craneal Universal Compacta
Universele Compacte Hoofdring

QTY: (1X)

Rx ONLY

CE 0086
Product complies with the requirements of directive 93/42/EEC

Consult Instructions for Use

YYYY-MM-DD
Date of Manufacture

NON STERILE

MR
MR Conditional

+M248UCHR1Z

+$$8017LLLLLLLLLLLLZD

Made in USA

PKG0000025 Rev. C

Appendix 5 – K946252 Excerpt

Device Description

Introduction

The StereoPlan system is a graphic planning tool that allows for pre-operative planning of stereotactic neurosurgical procedures using the BRW and CRW stereotactic arcs of Radionics. The system includes the following functions as well as others described throughout this document:

- Use of CT, MRI (axial, sagittal, coronal), and digitized angiograms for target localization;
- Use of up to three image sets for each planning session;
- Display of CT or MRI image slices in the 3-D reconstructed space, to enable registration between CT and MRI, and between the 2-D images and the 3-D space;
- Ability to use the UCLF localizer in both CT and MRI scanning so that only one patient fixed head ring is required;
- Capability to save and restore previous plans;

Intended Use

StereoPlan is a stereotactic surgical planning system which enables the neurosurgeon to not only pre-plan a stereotactic procedure, but also devise an optimal plan prior to entering the operating room. StereoPlan makes use of all image modalities (CT, MRI, and Angiogram) for visual assessment. Based on the Radionics BRW Stereotactic system, StereoPlan makes use of the stereotactic transformations already in use by thousands of physicians.

Inherent within StereoPlan is the ability to contour critical structures, as well as the patient's skin (or external volume), displaying the maximal amount of information for the surgeon's assessment.

The indication for the typical use of the StereoPlan system is for the preoperative planning of stereotactic procedures such as tumor resection and biopsies performed with the BRW or CRW stereotactic systems. The physician is responsible for deciding the appropriateness of the stereotactic procedure and once an optimal plan is achieved, the arc system settings can be printed and taken to the operating room. With a stereotactic procedure, targets are localized using CT, MRI scans, and/or digitized angiographic film.

Technological Characteristics

The StereoPlan system consists of treatment planning software and stereotactic equipment. StereoPlan uses MRI, CT and Angiograms to allow the user to graphically reconstruct anatomy, determine targets, and devise an optimal approach.

The StereoPlan system is compatible with Radionics, Inc. Stereotactic Instrumentation which includes patient attachment, localization, Phantom Base, etc. The Stereotactic hardware components include the Head Ring which is attached to the patient's head and is used to hold the patient and localization instrumentation during the scanning process, the localizers, the BRW or CRW arc system which attaches to the head ring and provides a rigid frame to position and hold operative instrumentation, and the phantom base used to confirm proper target settings on either arc system. The BRW and MRI head ring, BRW localizer, MRIA localizer, and SGVAL angiographic localizer are the same Radionics stereotactic components that are used with the XKnife system (K912630).

In summary, StereoPlan allows the surgeon to visually pre-plan an entire operative procedure without introducing a single instrument into the patient's head. Through the power of the computer, the patient's anatomy can be graphically contoured allowing for an optimal approach with precise target localization. Using StereoPlan, the surgeon knows what to expect prior to entering the operating room.

Example Summary of Clinical Use

The following is an example of the clinical and planning procedures for a case using CT, MRI, and angiographic imaging:

The MRI head ring is attached to the patient. The MRI localizer is attached to the MRI head ring and an MRI scan (axial, coronal, or sagittal) is performed. The data tape is written. The MRI localizer is then removed. The CT head ring is attached concentrically around the MRI head ring, and the BRW localizer frame is attached to the CT head ring. A CT scan is taken and the data tape is written. The angiographic localizer replaces the CT localizer and AP/PA and Lateral angiographic films are taken.

After imaging, the CT and MRI tapes are loaded into the tape drive and read into the StereoPlan computer. The two angiographic films are scanned into the computer.

Once the StereoPlan program is launched, in the software Patient Browser, three image sets, CT, MRI (axial, sagittal, or coronal) and Angiogram are selected. The CT and MRI localizer types are identified for each image set and the localizing session begins.

The user manually inputs the location of the fiducial rods on the first CT slice. StereoPlan automatically detects the rest. The system then displays the first slice of the MRI-axial data set. The user manually inputs the location of the fiducial rods on the first MRI slice. StereoPlan automatically detects the rest. The system then displays the two angiographic films. The user manually inputs the location of the fiducials on both images.

The lesion and other critical structures seen in the CT, MRI, and angiographic data sets are contoured and 3-D reconstructions are performed by the computer. The ability to contour structures in the three data sets provides unique information to aid in planning a neurosurgical procedure. Using multiple imaging protocols allows the same and/or different structures to be displayed and analyzed for the procedure. For example, this allows for the same or different structures seen previously with CT to be contoured using MRI or Angiographic information.

The user begins the planning stage. The spatial relationship between the 3-D contoured structures from CT, MRI, and Angiograms are important considerations in planning. The target point is positioned and moved on the chosen slice. The entry point is positioned and moved on the chosen slice. Both are visualized in the 3-D display and other image sets.

A 3-D reconstruction of the CRW or BRW arc is available to display the trajectory and approach for the procedure. Once the planning is complete, printouts are generated which give the settings for either arc system.

The patient and printout information are brought to the operating room, the arc system is set with the information from the printouts, it is attached to the patient's head ring, and the stereotactic procedure is begun.

Appendix 6 – Internal Filing for Device Modification Assessment

Luminant Localizer
Internal Filing (b)(4)

(b) (4) (b) (6)

Device Name: Luminant Localizer

Classification Information: The classification of the Luminant Localizer is Class II, as per Title 21 of the Code of Federal Regulations, Section: 882.4560: Sterotaxic instruments for neurological applications, Product Code HAW.

Information Relating to Performance Standards and Special Controls: No performance standards applicable to stereotaxic instruments have been established by the Food and Drug Administration.

Device Description: The Luminant Localizer (LL01) is a modification of the Universal Compact Localizer Frame(UCLF). It is an MR and CT stereotactic localization device for use with Universal Compact Head Ring (UCHR) platform. A stereotactic localizer is a rigid frame that is attached to a patient via a holding device such as a headring or baseboard. The frame contains fiducial rods which are visible in a CT and or MR scan allowing a treatment planning software to determine the location of the desired target. The fiducial rods for the UCLF required the user to fill the rods with water. This required the user to ensure that the rods were filled without air bubbles. Also overtime the plastic rods would crack resulting in leaks.

The rods of the LL01 unlike the UCLF, do not need to be refilled. They are sealed glass rods filled with a proprietary gel formulation that is visible in MRI scanners and the glass portion of the rod is visible in CT. The rods appear as fiducial spots on both CT and MR scans. The arrangement of the rods in the LL01 is identical to the arrangement in the UCLF allowing the LL01 To be used with the same treatment planning software.

The frame is designed to fit the UCHR during standard MR or CT imaging. The Luminant Localizer allows the patient to be scanned in both CT and MRI scanners while attaching only one head ring to the patient. The LL01 is designed to fit within the design envelope of the UCLF.

The LL01 Localizer Frame is mounted to the UCHR head ring by means of four Titanium thumbscrews and 2 locating pins. The patient is placed in the MRI head coil. It is important that the bottom of the localizer be placed completely inside the coil so that the rods closest to the head ring are imaged clearly.

The device will be returned to Radionics for periodic replacement of the rods. The interval will be based on the results of the age testing.

A drawing of the device can be found in Attachment I.

Indications for Use: The Luminant Localizer is used for precise spatial localization of physiologic target coordinates from patient diagnostic scans for stereotactic neurosurgical procedures such as craniotomies, biopsies, functional neurosurgery, and radiation therapy.

Labels/Labeling: An IFU (Instructions for use) was generated for the device. The part number is LL01 IFU, 92901039.

Sterilization Information: N/A, the device is not intended to be sterilized.

Biocompatibility: During use there will at most be superficial contact between the patient and the device. Therefore, no biocompatibility testing is required.

Commercially Available Device Information: UCLF was included with the StereoPlan submission and was cleared via 510(k), K946252, on March 14, 1995.

Comparison to Commercially Available Device: The LL01 is similar to the UCLF

Comparison Matrix

	Luminant Localizer	Universal Compact Localizer Frame
Use	MRI and CT localization	MRI and CT localization
Design	non-invasive, rigid frame that contains fiducial rods and attaches to a head ring.	non-invasive, rigid frame that contains fiducial rods and attaches to a head ring.
Images that can be acquired	MRI axial, sagittal, coronal CT	MRI axial, sagittal, coronal CT
Attachment to headring	four thumbscrews	four screws
arrangement of fiducial rods	"N" rod pattern	"N" rod pattern
number of fiducial rods	22 rods	22 rods
Type of fiducial rods	sealed glass rods filled with a gel formulation	plastic tubes that are filled with water by user.
Posterior Panel	removable	hinged

Verification and Validation:
A summary of the testing is below. Please see the LL01 for the full reports.

Luminant Localizer Validation and Verification: Gel Rod Accelerated Aging Report, #
(b)(4)
(b)(4)

Luminant Localizer Validation and Verification: Temperature Testing Report, # (b)(4)

(b)(4)

(b)(4)

Luminant Localizer Validation and Verification: Unpackaged Drop Test Report, # P01242

(b)(4)

Luminant Localizer Validation and Verification: Functional and Dimensional Test Report, # (b)(4)

(b)(4)

Luminant Localizer Validation and Verification: Verification with Radionics Software, # (b)(4)

(b)(4)

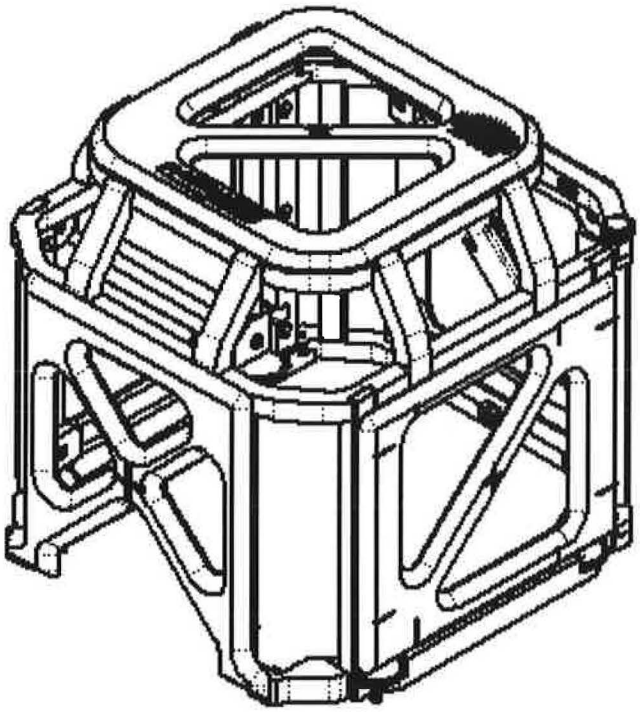
Do the Modifications Have The Same Technological Characteristics, e.g., Design, Materials, etc.? (b)(4)

(b)(4)

Do the Modifications Affect Safety or Efficacy?(

(b)(4)

Attachment I: Drawing of Device



Luminant Localizer, LLO1

Appendix 7 – Revised Indications for Use Form (redlined and updated clean version)

Indications for Use

510(k) Number (if known): _____

Device Name: **CRW-1 System**

Indications For Use:

The CRW-1 System is a stereotactic system to be used for neurosurgical procedures that require precise target localization, such as craniotomies, biopsies, and functional stereotaxy.

Localization is performed using CT or MR imaging.

Prescription Use ___X___ **AND/OR** **Over-The Counter Use_____**
(Per 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use

510(k) Number (if known): _____

Device Name: **CRW-1 System**

Indications For Use:

The CRW-1 System is a stereotactic system to be used for neurosurgical procedures that require precise target localization, such as craniotomies, biopsies, and functional stereotaxy.

Localization is performed using CT or MR imaging.

Prescription Use ___X___ **AND/OR** **Over-The Counter Use_____**
(Per 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

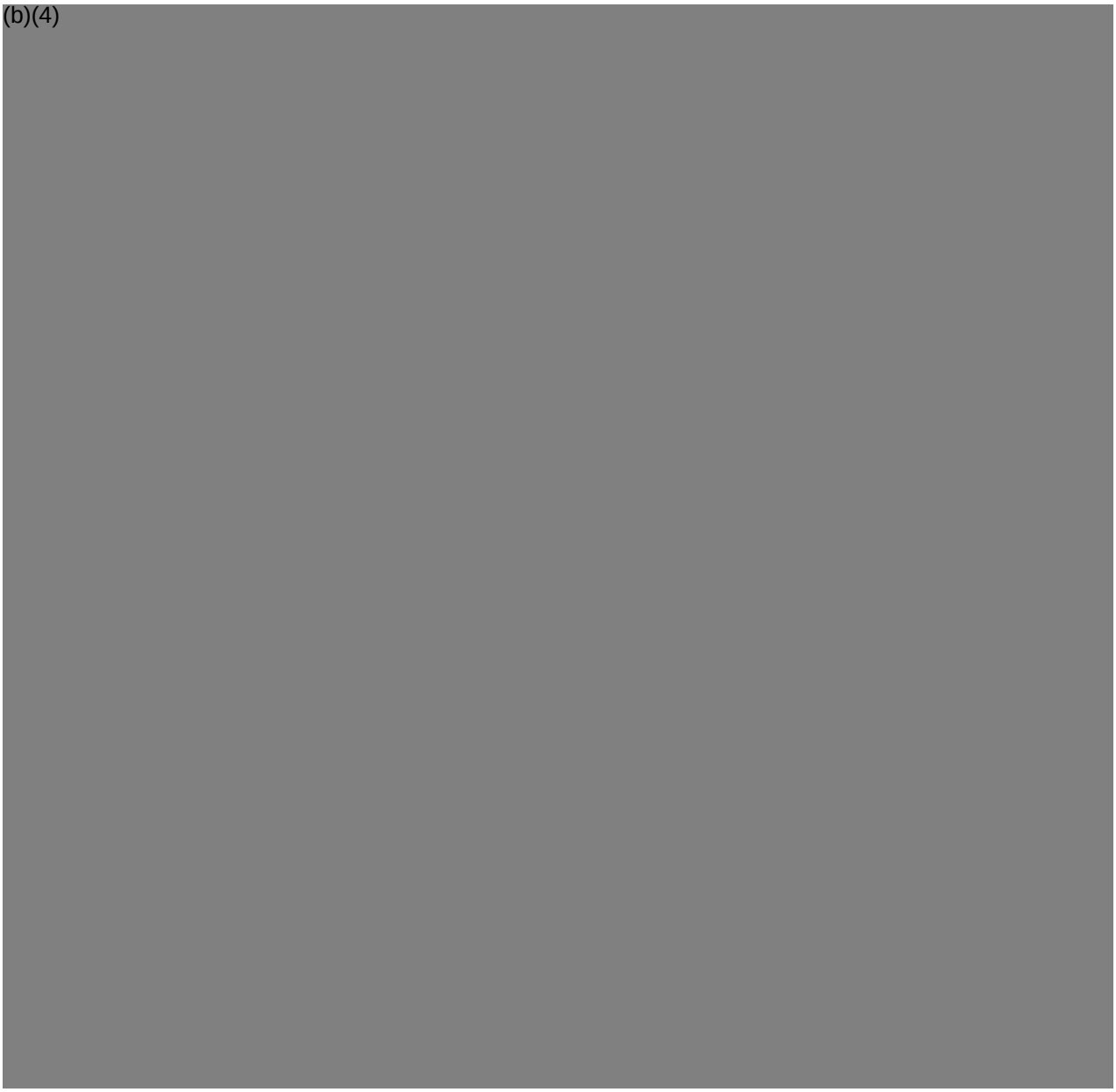
Appendix 8 – Revised 510(k) Summary (redlined and updated clean version)

510(k) SUMMARY

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92.

(b)(4)

(b)(4)



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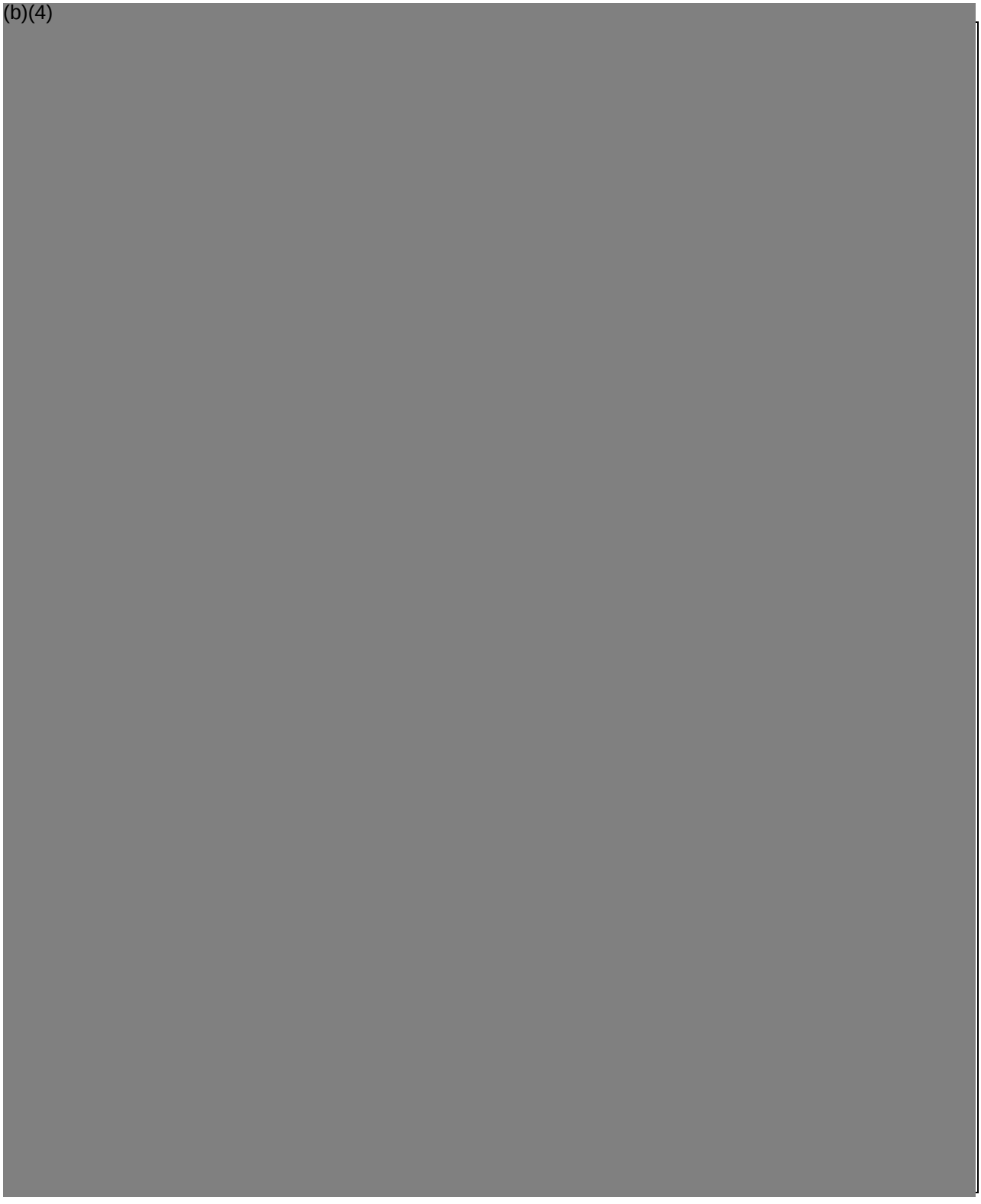

(b)(4)

510(k) SUMMARY

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92.

807.92(a)(1) – Submitter information	
Name	Integra LifeSciences Corporation
Address	311 Enterprise Drive Plainsboro, NJ 08536 USA
Phone Number	609-936-5531
Fax Number	NA
Establishment Registration Number	3003418325
Name of Contact Person	Timothy Connors, Senior Regulatory Affairs Specialist
Date Prepared	March 24, 2016
807.92(a)(2) – Name of device	
Trade or Propriety Name	CRW™ Stereotactic System
Common or Usual Name	Universal Compact Head Ring Luminant Localizer Frame Disposable Head Ring Screws
Classification Name	Neurological Stereotaxic Instrument
Classification Panel	Neurology
Regulation	882.4560
Product Code(s)	HAW
807.92(a)(3) - Legally marketed device(s) to which equivalence is claimed	
CRW-1 SYSTEM; K944463	
807.92(a)(4) - Device description	

Part of the CRW™ Stereotactic System is comprised of the following components:

- Universal Compact Head Ring (UCHR),
- Luminant Localizer Frame (LL01)
- Disposable Head Ring Screws (DHRSS- Short, DHRSL- long)

The Universal Compact Head Ring is placed on the patient and secured with the Disposable Head Ring Screws. The Luminant Localizer Frame is then attached to the base ring and the patient is taken to the neuroradiology department where a CT or MR imaging is performed. The image obtained in conjunction with the localizer allows the neurosurgeon to compute the exact three dimensional position of the region of interest.

807.92(a)(5) – Intended use of the device	
Indications for Use	The CRW-1 System is a stereotactic system to be used for neurosurgical procedures that require precise target localization, such as craniotomies, biopsies, and functional stereotaxy. Localization is performed using CT or MR imaging.
807.92(a)(6) Summary of the technological characteristics of the device compared to the predicate	
The CRW™ Stereotactic System design is not changing as a result of this submission; this submission is primarily for a labeling change to add an MR Conditional claim and associated MRI safety information. CRW Stereotactic System and the predicate device have the same device classification, product code and measureable parameters as outlined within the submission.	
807.92(b)(1-2) – Nonclinical tests submitted	
CRW Stereotactic System was tested in accordance with FDA's Guidance: *Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance Environment* (August 21, 2008) and the relevant ASTM Standards covered in the guidance document. Testing includes Magnetic Resonance testing only to support an MR conditional claim for components used in the MR environment. Additional tests to support sterilization information, shelf life information and biocompatibility have also been included. The table below outlines the testing performed, test method summary and the results of the testing.	

Test	Test Method Summary	Results
MR testing	Testing on the device assembly was executed per the suite of ASTM standards called out in the FDA Guidance regarding passive implants in the MR environment. Standards used for testing include ASTM F2052, ASTM F2213, ASTM F2182 and ASTM F2119.	Results met pre-established acceptance criteria. MR labeling included in the submission is in compliance with FDA Guidance and ASTM F2503. The results demonstrate substantial equivalence by complying with current FDA Guidance and consensus standards requirements.
Sterilization – Devices provided to the user sterile	Testing was executed on the worst-case sample from a device family to demonstrate the subject devices could be sterilized to the SAL of 10^{-6}. The testing was performed in accordance with FDA Guidance regarding devices packaged sterile.	Results met pre-established acceptance criteria, demonstrating substantial equivalence to the predicate device in terms of sterility for devices provided to the user sterile.
Sterilization – Devices to be sterilized by the end user	Three different types of end user sterilization cycles were tested to demonstrate the cycles could sterilize the devices to the SAL of 10^{-6}: EtO, steam and Sterrad®.	Results met pre-established acceptance criteria, demonstrating substantial equivalence to the predicate device in terms of sterility for devices intended to be sterilized by the end user.
Shipping/Stability	The worst-case sample was identified of those devices provided to the user sterile. Ship testing and stability testing were executed according to ASTM D4169 and ASTM F1980 to support a three-year shelf life claim.	Results met pre-established acceptance criteria, demonstrating substantial equivalence to the predicate device of the sterile device packaging in terms of shipping integrity and stability.

Biocompatibility	Biocompatibility testing was executed for patient contacting devices, as identified in ISO 10993-1, per ISO 10993-5, ISO 10993-10 and ISO 10993-11.	Results met pre-established acceptance criteria, demonstrating substantial equivalence to the predicate device in terms of biocompatibility.

807.92(b)(3) – Conclusions drawn from non-clinical data

All necessary testing has been conducted per ASTM standards for the relevant CRW Stereotactic System components to be used in an MR environment (1.5 T and 3.0 T) and the test results support the addition of an MR conditional claim to the device labeling. All other testing performed raised no additional concerns of safety or efficacy. In conclusion, the components are safe and effective for use under conditions specified in the product labeling and the device is substantially equivalent to the predicate device.

Dear Mr. Connors:

Thank you for your recent S001 supplement to the K160811 submission. I have copied the information from your submitted Indications Form to our current form, and have attached a copy for your records.

Have a great Thanksgiving,

-Ian

Ian Broverman
Medical Device Reviewer & Roboticist, CDRH/ODE/DNPMD/NDNB
NDNB - Neurodiagnostic and Neurosurgical Devices Branch - NEW
DNPMD - Division of Neurological and Physical Medicine
ODE - Office of Device Evaluation
CDRH - Center for Devices & Radiological Health
U.S. Food and Drug Administration
Tel: (301) 796-9696
ian.broverman@fda.hhs.gov<mailto:ian.broverman@fda.hhs.gov>
[cid:image001.png@01D1C57E.DFA022A0]<http://www.fda.gov/>

[cid:image002.jpg@01D1C57E.DFA022A0]<https://www.facebook.com/FDA>
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<http://www.youtube.com/user/USFoodandDrugAdmin>
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<http://www.flickr.com/photos/fdaphotos/>
[cid:image006.jpg@01D1C57E.DFA022A0]
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Medical Device Reviewer & Roboticist, CDRH/ODE/DNPMD/NDNB
NDNB – Neurodiagnostic and Neurosurgical Devices Branch - NEW
DNPMD – Division of Neurological and Physical Medicine
ODE - Office of Device Evaluation
CDRH - Center for Devices & Radiological Health
U.S. Food and Drug Administration
Tel: (301) 796-9696
ian.broverman@fda.hhs.gov


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. . . . .

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160811

Device Name
CRW-1 System

Indications for Use *(Describe)*
The CRW-1 System is a stereotactic system to be used for neurosurgical procedures that require precise target localization, such as craniotomies, biopsies, and functional stereotaxy.

Localization is performed using CT or MR imaging.

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.

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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."

May 23, 2016</br></br> We have reviewed your submission K160811 and have determined that additional information is required. Your file is being placed on hold pending a complete response to the attached deficiencies.

Please submit your response, referencing the submission number K160811 to:

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

Please refer to the eCopy guidance at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM313794.pdf for current information on the number of copies and the format (paper versus eCopy) you must submit.

Your response is due within 180 days from the date of this request, which is November 19, 2016. If a complete response is not received in CDRH's Document Control Center within 180 days, we will consider this submission to be withdrawn, and we will delete it from our review system.

You may not market this device until you have received a letter from FDA allowing you to do so. If you market the device without FDA clearance, you will be in violation of the Federal Food, Drug, and Cosmetic Act.

If you would like a meeting or teleconference with the review team and management to discuss your planned approach for responding to the attached deficiencies, please submit your request for feedback as a Submission Issue Q-Submission (Q-Sub). Please note that a Submission Issue Q-Sub does not take the place of a formal response to this email notification. As noted above, FDA will consider this submission to be withdrawn if FDA does not receive, in a submission to the Document Control Center, a complete response to all of the attached deficiencies within 180 calendar days of the date of this request.

Should you have questions about this email, you may contact Ian Broverman, the lead reviewer assigned to your submission.

 *** This is a system-generated email notification ***

April 8, 2016</br></br>
Acceptance Review Notification - Accepted

An administrative acceptance review was conducted on your premarket notification (510(k)) K160811, and it was found to contain all of the necessary elements and information needed to proceed with the substantive review. We will contact you should we require any additional information during the course of the substantive review. The lead reviewer assigned to your submission is Ian Broverman.

 *** This is a system-generated email notification ***

December 6, 2016</br></br> We have completed our review. Please refer to the attached letter for details.

If you have any questions, please contact the lead reviewer assigned to your submission, Ian Broverman.

 *** This is a system-generated email notification ***

510(k) SUMMARY

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92.

807.92(a)(1) – Submitter information	
Name	Integra LifeSciences Corporation
Address	311 Enterprise Drive Plainsboro, NJ 08536 USA
Phone Number	609-936-5531
Fax Number	NA
Establishment Registration Number	3003418325
Name of Contact Person	Timothy Connors, Senior Regulatory Affairs Specialist
Date Prepared	March 24, 2016
807.92(a)(2) – Name of device	
Trade or Propriety Name	CRW™ Stereotactic System
Common or Usual Name	Universal Compact Head Ring Luminant Localizer Frame Disposable Head Ring Screws
Classification Name	Neurological Stereotaxic Instrument
Classification Panel	Neurology
Regulation	882.4560
Product Code(s)	HAW
807.92(a)(3) - Legally marketed device(s) to which equivalence is claimed	
CRW-1 SYSTEM; K944463	
807.92(a)(4) - Device description	
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807.92(a)(5) – Intended use of the device	
Indications for Use	The CRW-1 System is a stereotactic system to be used for neurosurgical procedures that require precise target localization, such as craniotomies, biopsies, and functional stereotaxy. Localization is performed using CT or MR imaging.
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807.92(b)(3) – Conclusions drawn from non-clinical data

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DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

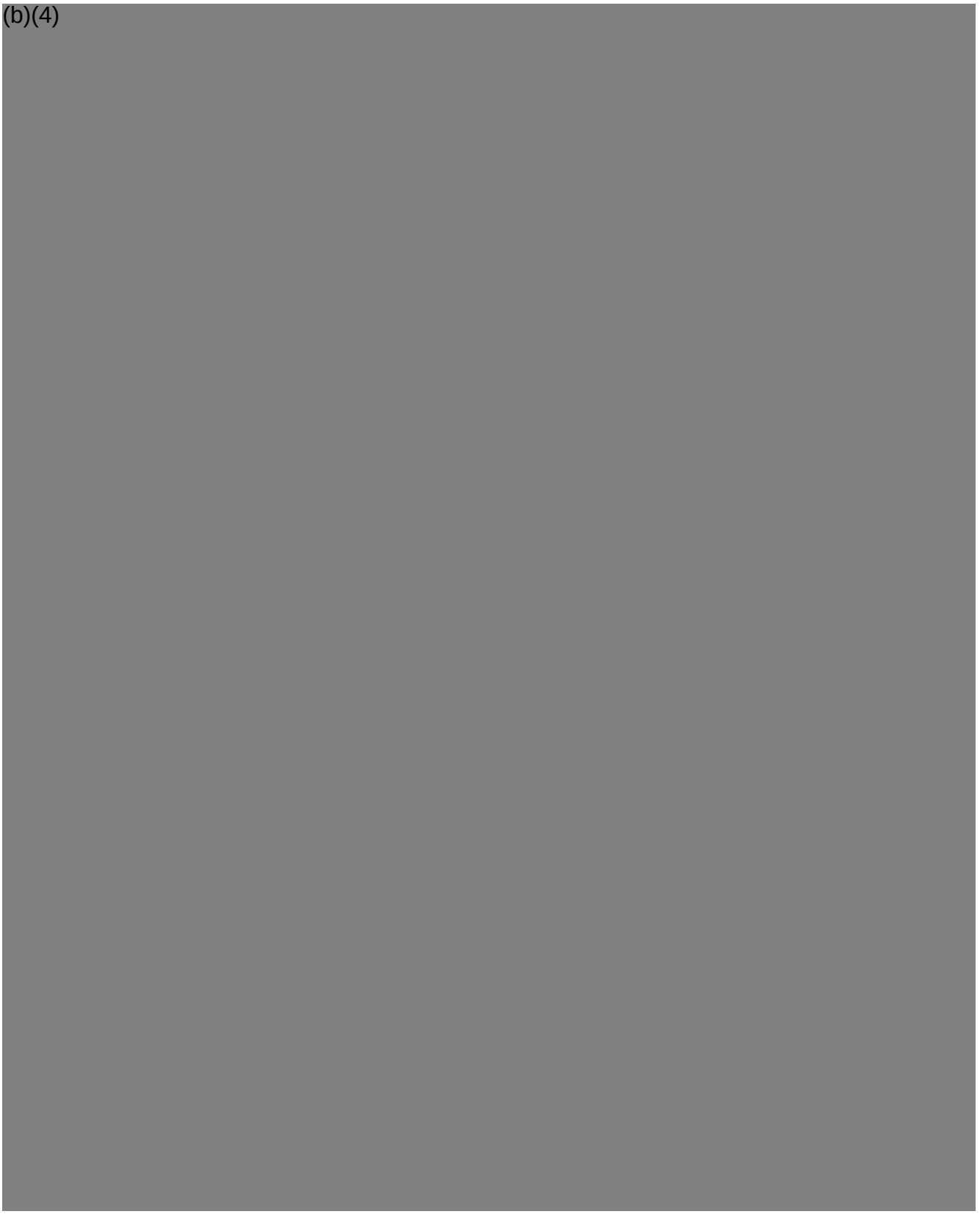
Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

K160811
Integra LifeSciences Corporation
Device Trade Name: CRW Stereotactic System
Contact Name: Mr. Timothy Connors

DEFICIENCY LIST

(b)(4)

(b)(4)



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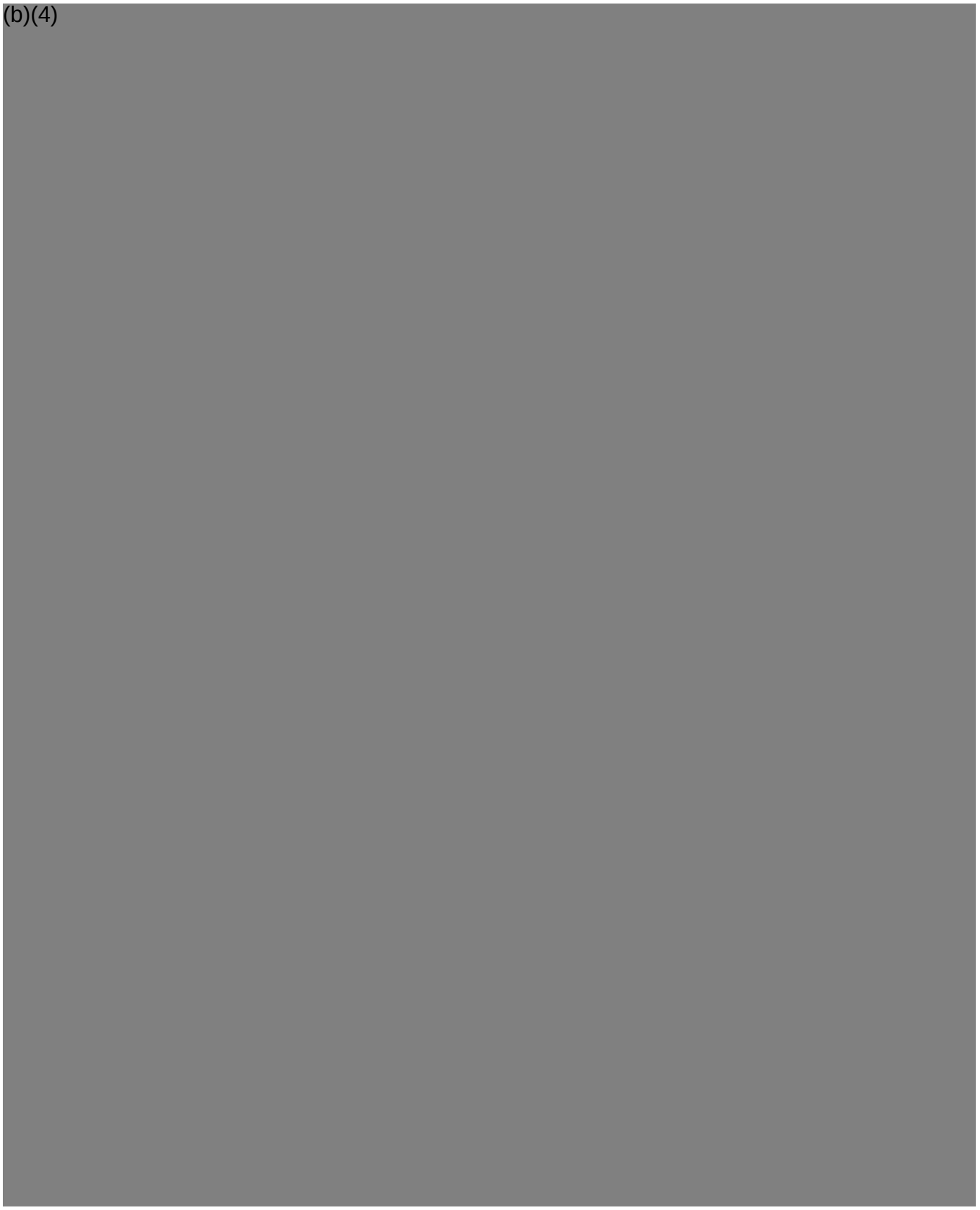

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160811

Device Name
CRW Stereotactic System

Indications for Use *(Describe)*
The CRW Stereotactic System is a stereotactic system to be used for neurosurgical procedures that require precise target localization, such as craniotomies, biopsies, and functional stereotaxy.

Localization is performed using CT or MR imaging.

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)

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DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

December 6, 2016

Integra Lifesciences Corporation
Timothy Connors
Senior Regulatory Affairs Associate
311 Enterprise Drive
Plainsboro, New Jersey 08536

Re: K160811
Trade/Device Name: CRW Stereotactic System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: HAW
Dated: November 4, 2016
Received: November 7, 2016

Dear Mr. Connors:

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

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

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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

Sincerely yours,

Michael J. Hoffmann -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

December 6, 2016

Integra Lifesciences Corporation
Timothy Connors
Senior Regulatory Affairs Associate
311 Enterprise Drive
Plainsboro, New Jersey 08536

Re: K160811
Trade/Device Name: CRW Stereotactic System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: HAW
Dated: November 4, 2016
Received: November 7, 2016

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Sincerely yours,

Michael J. Hoffmann -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160811

Device Name
CRW Stereotactic System

Indications for Use *(Describe)*
The CRW Stereotactic System is a stereotactic system to be used for neurosurgical procedures that require precise target localization, such as craniotomies, biopsies, and functional stereotaxy.

Localization is performed using CT or MR imaging.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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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."

510(k) SUMMARY

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92.

807.92(a)(1) – Submitter information	
Name	Integra LifeSciences Corporation
Address	311 Enterprise Drive Plainsboro, NJ 08536 USA
Phone Number	609-936-5531
Fax Number	NA
Establishment Registration Number	3003418325
Name of Contact Person	Timothy Connors, Senior Regulatory Affairs Specialist
Date Prepared	March 24, 2016
807.92(a)(2) – Name of device	
Trade or Propriety Name	CRW™ Stereotactic System
Common or Usual Name	Universal Compact Head Ring Luminant Localizer Frame Disposable Head Ring Screws
Classification Name	Neurological Stereotaxic Instrument
Classification Panel	Neurology
Regulation	882.4560
Product Code(s)	HAW
807.92(a)(3) - Legally marketed device(s) to which equivalence is claimed	
CRW-1 SYSTEM; K944463	
807.92(a)(4) - Device description	

Part of the CRW™ Stereotactic System is comprised of the following components:

- Universal Compact Head Ring (UCHR),
- Luminant Localizer Frame (LL01)
- Disposable Head Ring Screws (DHRSS- Short, DHRSL- long)

The Universal Compact Head Ring is placed on the patient and secured with the Disposable Head Ring Screws. The Luminant Localizer Frame is then attached to the base ring and the patient is taken to the neuroradiology department where a CT or MR imaging is performed. The image obtained in conjunction with the localizer allows the neurosurgeon to compute the exact three dimensional position of the region of interest.

807.92(a)(5) – Intended use of the device	
Indications for Use	The CRW-1 System is a stereotactic system to be used for neurosurgical procedures that require precise target localization, such as craniotomies, biopsies, and functional stereotaxy. Localization is performed using CT or MR imaging.
807.92(a)(6) Summary of the technological characteristics of the device compared to the predicate	
The CRW™ Stereotactic System design is not changing as a result of this submission; this submission is primarily for a labeling change to add an MR Conditional claim and associated MRI safety information. CRW Stereotactic System and the predicate device have the same device classification, product code and measureable parameters as outlined within the submission.	
807.92(b)(1-2) – Nonclinical tests submitted	
CRW Stereotactic System was tested in accordance with FDA's Guidance: *Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance Environment* (August 21, 2008) and the relevant ASTM Standards covered in the guidance document. Testing includes Magnetic Resonance testing only to support an MR conditional claim for components used in the MR environment. Additional tests to support sterilization information, shelf life information and biocompatibility have also been included. The table below outlines the testing performed, test method summary and the results of the testing.	

Test	Test Method Summary	Results
MR testing	Testing on the device assembly was executed per the suite of ASTM standards called out in the FDA Guidance regarding passive implants in the MR environment. Standards used for testing include ASTM F2052, ASTM F2213, ASTM F2182 and ASTM F2119.	Results met pre-established acceptance criteria. MR labeling included in the submission is in compliance with FDA Guidance and ASTM F2503. The results demonstrate substantial equivalence by complying with current FDA Guidance and consensus standards requirements.
Sterilization – Devices provided to the user sterile	Testing was executed on the worst-case sample from a device family to demonstrate the subject devices could be sterilized to the SAL of 10^{-6}. The testing was performed in accordance with FDA Guidance regarding devices packaged sterile.	Results met pre-established acceptance criteria, demonstrating substantial equivalence to the predicate device in terms of sterility for devices provided to the user sterile.
Sterilization – Devices to be sterilized by the end user	Three different types of end user sterilization cycles were tested to demonstrate the cycles could sterilize the devices to the SAL of 10^{-6}: EtO, steam and Sterrad®.	Results met pre-established acceptance criteria, demonstrating substantial equivalence to the predicate device in terms of sterility for devices intended to be sterilized by the end user.
Shipping/Stability	The worst-case sample was identified of those devices provided to the user sterile. Ship testing and stability testing were executed according to ASTM D4169 and ASTM F1980 to support a three-year shelf life claim.	Results met pre-established acceptance criteria, demonstrating substantial equivalence to the predicate device of the sterile device packaging in terms of shipping integrity and stability.

Biocompatibility	Biocompatibility testing was executed for patient contacting devices, as identified in ISO 10993-1, per ISO 10993-5, ISO 10993-10 and ISO 10993-11.	Results met pre-established acceptance criteria, demonstrating substantial equivalence to the predicate device in terms of biocompatibility.

807.92(b)(3) – Conclusions drawn from non-clinical data

All necessary testing has been conducted per ASTM standards for the relevant CRW Stereotactic System components to be used in an MR environment (1.5 T and 3.0 T) and the test results support the addition of an MR conditional claim to the device labeling. All other testing performed raised no additional concerns of safety or efficacy. In conclusion, the components are safe and effective for use under conditions specified in the product labeling and the device is substantially equivalent to the predicate device.

510(k) SUMMARY

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DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

K160811
Integra LifeSciences Corporation
Device Trade Name: CRW Stereotactic System
Contact Name: Mr. Timothy Connors

DEFICIENCY LIST

(b)(4)

(b)(4)

(b)(4)

(b)(4)

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

December 6, 2016

Integra Lifesciences Corporation
Timothy Connors
Senior Regulatory Affairs Associate
311 Enterprise Drive
Plainsboro, New Jersey 08536

Re: K160811
Trade/Device Name: CRW Stereotactic System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: HAW
Dated: November 4, 2016
Received: November 7, 2016

Dear Mr. Connors:

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

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

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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

Sincerely yours,

Michael J. Hoffmann -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

December 6, 2016

Integra Lifesciences Corporation
Timothy Connors
Senior Regulatory Affairs Associate
311 Enterprise Drive
Plainsboro, New Jersey 08536

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Regulation Number: 21 CFR 882.4560
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Sincerely yours,

Michael J. Hoffmann -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Contains Nonbinding Recommendations

Print Form

Acceptance Checklist for Abbreviated 510(k)s

(Should be completed within 15 days of DCC receipt)

The following information is not intended to serve as a comprehensive review.
FDA recommends that the submitter include this completed checklist as part of the submission.

510(k) #: K160811 Date Received by DCC: Mar 25, 2016

Lead Reviewer: Ian Broverman

Branch: NNDB Division: DNPMD Center/Office: CDRH/ODE

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 the RTA review and that the element will be assessed during the substantive review.

IMPORTANT - Many checklist elements include additional details regarding information to address the element that can be seen by hovering over the element (Example - Element 4 in Section A of the checklist).

Preliminary Questions

Answers in the shaded blocks indicate consultation with a Center advisor is needed. (Boxes checked in this section represent FDAs preliminary assessment of these questions at the time of administrative review.)	Yes	No	N/A
1) Is the product a device (per section 201(h) of the FD&C Act) or a combination product (per 21 CFR 3.2(e)) with a device constituent part subject to review in a 510(k)? If it appears not to be a device (per section 201(h) of the FD&C Act) or such a combination product, or you are unsure, consult with the CDRH Jurisdictional Officer or the CBER Product Jurisdiction Liaison to determine the appropriate action, and inform division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If the product does not appear to be a device or such a combination product, mark "No."	X		
Comments:			
2. Is the submission with the appropriate Center? If the product is a device or a combination product with a device constituent part, is it subject to review by the Center in which the submission was received? If you believe the submission is not with the appropriate Center or you are unsure, consult with the CDRH Jurisdictional Officer or CBER Product Jurisdiction Liaison to determine the appropriate action and inform your division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If submission should not be reviewed by your Center mark "No."	X		
Comments:			
3) If a Request for Designation (RFD) was submitted for the device or combination product with a device constituent part and assigned to your center, identify the RFD # and confirm the following: **a) Is the device or combination product the same (e.g., design, formulation) as that presented in the RFD submission?** **b) Are the indications for use for the device or combination product identified in the 510(k) the same as those identified in the RFD submission?** If you believe the product or the indications presented in the 510(k) have changed from the RFD, or you are unsure, consult with the CDRH Jurisdictional Officer or the CBER Product Jurisdiction Liaison to determine the appropriate action and inform your division management. *Provide summary of Jurisdictional Officer's/Liaison's determination.* If the answer to either question above is no, mark "No." If there was no RFD, mark "N/A."			X
Comments:			

4) Is this device type eligible for a 510(k) submission? If a 510(k) does not appear to be appropriate (e.g., Class III type and PMA required, or Class I or II type and 510(k)-exempt), you should consult with the CDRH 510(k) Program Director or appropriate CBER staff during the acceptance review. If 510(k) is not the appropriate regulatory submission, mark "No."	X		
Comments:			
5) Is there a pending PMA for the same device with the same indications for use? If yes, consult division management and the CDRH 510(k) Program Director or appropriate CBER staff to determine the appropriate action.		X	
Comments:			
6) If clinical studies have been submitted, is the submitter the subject of an Application Integrity Policy (AIP)? If yes, consult with the CDRH Office of Compliance/Division of Bioresearch Monitoring (OC/DBM) or CBER Office of Compliance and Biologics Quality/Division of Inspections and Surveillance/Bioresearch Monitoring Branch (OCBQ/DIS/BMB) to determine the appropriate action. Check on web at http://www.fda.gov/ICECI/EnforcementActions/ApplicationIntegrityPolicy/ucm134453.htm If no clinical studies have been submitted, mark "N/A."			X
Comments:			

- If the answer to 1 or 2 appears to be "No," then stop review of the 510(k) and issue the "Original Jurisdictional Product" letter.
- If the answer to 3a or 3b appears to be "No," then stop the review and contact the CDRH Jurisdictional Officer or CBER Office of Jurisdiction Liaison.
- If the answer to 4 is "No," the lead reviewer should consult division management and other Center resources to determine the appropriate action.
- If the answer to 5 is "Yes," then stop review of the 510(k), contact the CDRH 510(k) Staff and PMA Staff, or appropriate CBER staff.
- If the answer to 6 is "Yes," then contact CDRH/OC/DBM or CBER/OCBQ/DIS/BMB, provide a summary of the discussion with DBM or BMB Staff, and indicate their recommendation/action.

Abbreviated 510(k) Criteria

(See "The New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications - Final Guidance" and "Format for Traditional and Abbreviated 510(k)s")

In order to qualify for review as an Abbreviated 510(k), one of the following criteria (1 or 2 or 3) should be met. Submission should be converted and reviewed as a Traditional 510(k) if one of these criteria is not met. Complete the Refuse to Accept Checklist for a Traditional 510(k) if submission is converted.

*Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
1) Submission relies on a device-specific guidance document, other than a special controls guidance document, and a summary report is provided that:	X				
a) Includes a description of adherence to the relevant guidance document to support substantial equivalence	X				
b) Includes a description of how the guidance document was used to satisfy the requirements of 21 CFR 807.87 (e.g., data to support substantial equivalence) and lists any deviations.	X				
2) Submission relies on a special control(s), either in a device-specific regulation or special controls document, as defined in Section 513(a)(1)(B) of the FD&C Act, to demonstrate substantial equivalence and a summary report is provided that:			X		
3) Submission relies on FDA-recognized consensus standard(s) (See section 514(c)).	X			X	
For each cited standard:					
a) Submission includes: - the device specific conformity statement as specified in device-specific guidance document (e.g., latex condoms) or - a declaration for conformity to the device specific standard **OR** The items below for use of FDA-recognized consensus standards	X				
i) An identification of the applicable FDA-recognized consensus standards (full citation including version number)	X				
ii) An identification, for each consensus standard, of any adaptations of the standard for evaluation of the device under review (e.g., an identification of an alternative series of tests that were performed)	X				
iii) An identification, for each consensus standard, of any items (e.g., normative requirements of the standard) applicable to your device	X				
iv) A specification of any deviations from each applicable standard (e.g., deviations from international standards which are necessary to meet U.S. infrastructure conventions such as the National Electrical Code (ANSI/NFPA 70))			X		
v) A specification of the differences that may exist, if any, between the tested device and the device to be marketed and a justification for the applicability of the test results in these areas of differences.	X				

Comments: Cited standards are referenced in the FDA guidance: Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment - August 21, 2008. This is not the most current guidance document. A new MR guidance document was issued on December 11, 2014. However, on page 30, the applicant states that they are aware of the guidance update, and that the information provided is compliant with the current guidance.

Does the submission meet one of the criteria 1, 2, or 3 above?

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

Organizational Elements

Failure to include these items should not result in an RTA designation.

*Submitters including the checklist with their submission should identify the page numbers where requested information located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	*Page #
1) Submission contains a Table of Contents	X		
2) Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)	X		
3) All pages of the submission are numbered.	X		
4) Type of 510(k) is identified (i.e., Traditional, Abbreviated, or Special).	X		
Comments:			

Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

- Any "No" answer will result in a "Refuse to Accept" decision; however, FDA staff has discretion to determine whether missing items are needed to ensure that the submission is administratively complete to allow the submission to be accepted or to request missing checklist items interactively from submitters during RTA review.
- 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.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
A. Administrative					
1) All content used to support the submission is written in English (including translations of test reports, literature articles, etc.)	X				
2) Submission identifies the following (FDA recommends use of the CDRH Premarket Review Submission Cover Sheet form [Form 3514]):					
a) Device trade/proprietary name	X				
b) Device class and panel or Classification regulation or Statement that device has not been classified with rationale for that conclusion	X				
3) Submission contains an Indication for Use Statement with Rx and/or OTC designated (see also 21 CFR 801.109, and FDA's guidance "Alternative to Certain Prescription Devices Labeling Requirements.") *See recommended* format . *(http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM360431.pdf).*	X				
4) Submission contains a 510(k) Summary or 510(k) Statement.	X				
5) Submission contains a Truthful and Accuracy Statement per 21 CFR 807.87(k) *See recommended format.* *(http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142707.htm).*	X				
6) Submission is a Class III 510(k) device.			X		
7) Submission contains clinical data			X		
8) The submission identifies prior submissions for the same device included in the current submission (e.g., submission numbers for a prior not substantially equivalent [NSE] determination, prior deleted or withdrawn 510(k), Pre-Submission, IDE, PMA, etc.). **OR** States that there were no prior submissions for the subject device.	X				
a) If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence from prior submissions for this device are addressed.			X		
B. Device Description					
9) The device has a device-specific guidance document, special controls document, and/or requirements in a device-specific regulation regarding device description that is applicable to the subject device.			X		
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).	X				
11) The submission includes descriptive information for the device, including the following:					
a) A description of the principle of operation or mechanism of action for achieving the intended effect.	X				
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.	X				
c) A list and description of each device for which clearance is requested.	X				

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
d) Submission contains representative engineering drawing(s), schematics, illustrations, photos and/or figures of the device. **OR** Submission includes a statement that engineering drawings, schematics, etc. are not applicable to the device (e.g., device is a reagent and figures are not pertinent to describe the device).	X				
12) Device is intended to be marketed with multiple components, accessories, and/or as part of a system.	X			X	
a) Submission includes a list of all components and accessories to be marketed with the subject device.	X				
b) Submission includes a description (as detailed in item 11(a), 11(b) and 11(d) above) of each component or accessory.	X				
c) A 510(k) number is provided for each component or accessory that received a prior 510(k) clearance **AND** A statement is provided that identifies components or accessories that have not received prior 510(k) clearance.	X				
Comments: The applicant refers to the accessory list in the original 510(k), but does not re-list in this submission.					
C. Substantial Equivalence Discussion					
13) Submitter has identified a predicate device(s), including the following information:					
a) Predicate device identifier provided (e.g., 510(k) number, de novo number, reclassified PMA number, regulation number if exempt or statement that the predicate is a preamendment device). For predicates that are preamendments devices, information is provided to document preamendments status. *Information regarding documenting preamendment status is available online. (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/MedicalDeviceQualityandCompliance/ucm379552.htm).*	X				
b) The identified predicate(s) is consistent throughout the submission (e.g., 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).	X				
14) Submission includes a comparison of the following for the predicate(s) and subject device and a discussion why any differences between the subject and predicate(s) do not impact safety and effectiveness [see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f)] *See "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]" guidance document for more information on comparing intended use and technological characteristics.*					
a) Indications for Use	X				
b) Technology, including features, materials, and principles of operation	X				
D. Proposed Labeling (see also 21 CFR part 801 and 809 as applicable)					
15) Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual).	X				

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
a) Indications for use are stated in labeling and are identical to Indications for Use form and 510(k) Summary (if 510(k) Summary provided).	X				
b) Labeling includes: - Statements of conditions, purposes or uses for which the device is intended (e.g., hazards, warnings, precautions, contraindications) (21 CFR 801.5) **AND** - Includes adequate directions for use (see 21 CFR 801.5) **OR** - Submission states that device qualifies for exemption per 21 CFR 801 Subpart D	X				
16) Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1).	X				
17) Labeling includes the prescription statement [see 21 CFR 801.109(b)(1)] or Rx Only symbol (see also Section 502(a) of the FD&C Act and FDA's guidance "Alternative to Certain Prescription Device Labeling Requirements").	X				
18) The device has a device-specific guidance document, special controls document, and/or requirements in a device-specific regulation regarding labeling that is applicable to the subject device.			X		
19) If the device is an in vitro diagnostic device, provided labeling includes all applicable information required per 21 CFR 809.10.			X		
E. Sterilization					
If an *in vitro* diagnostic (IVD) device and sterilization is not applicable, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.					
Submission states that the device, and/or accessories, and/or components are: (one of the below must be checked)					
X Provided sterile, intended to be single-use					
X Requires processing during its use-life					
Non-sterile when used (and no processing required)					
Information regarding the sterility status of the device is not provided. (If this box is checked, please also check one of the two boxes below.)					
Sterility status not needed for this device (e.g., software-only device)					
Sterility status needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *Please refer to the guidance document titled "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling" for additional information.*					
20) Assessment of the need for cleaning and subsequent disinfection or sterilization information					
a) Identification of device, and/or accessories, and/or components that are provided sterile.	X				
b) Identification of device, and/or accessories, and/or components that are end user sterilized or disinfected.	X				
c) Identification of device, and/or accessories, and/or components that are reusable.	X				

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
21) If the device, and/or accessory, and/or a component is provided sterile:					
a) Sterilization method is stated for each component (including dose for radiation sterilization).	X				
b) A description of method to validate the sterilization parameters is provided for each proposed sterilization method (e.g., half-cycle method and full citation of FDA-recognized standard, including date).	X				
c) For devices sterilized using chemical sterilants such as ethylene oxide (EO) and hydrogen peroxide, submission states maximum levels of sterilant residuals remaining on the device and sterilant residual limits.	X				
d) Sterility Assurance Level (SAL) is stated.	X				
e) Submission includes description of packaging.	X				
f) For products labeled "non-pyrogenic," a description of the method used to make the determination stated (e.g., limulus amebocyte lysate [LAL]).			X		
22) If the device, and/or accessory, and/or a component is reusable or end user sterilized or disinfected:					
a) Cleaning method is provided in labeling for each device, and/or accessory, and/or component.	X				
b) Disinfection method is provided in labeling for each device, and/or accessory, and/or component.			X		
c) Sterilization method is provided in labeling for each device and/or accessory, and/or component.	X				
d) Device types in this submission are listed in Appendix E of the FDA's guidance "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling."			X		
i) If device types in this submission are included in Appendix E of the reprocessing guidance, the submission includes protocols and test reports for validating the reprocessing instructions.			X		
23) The device has a device-specific guidance document, special controls document, and/or requirement in a device-specific regulation regarding sterility and/or reprocessing that is applicable to the subject device.			X		
F. Shelf Life					
24) Proposed shelf life/expiration date stated **OR** Statement that shelf-life is not applicable because of low likelihood of time-dependent product degradation	X				
25) For a sterile device, submission includes summary of methods used to establish that device packaging will maintain a sterile barrier for the entirety of the proposed shelf life.	X				
26) Submission includes summary of methods used to establish that device performance is maintained for the entirety of the proposed shelf-life (e.g., mechanical properties, coating integrity, pH, osmolality, etc.). **OR** Statement why performance data is not needed to establish maintenance of device performance characteristics over the shelf-life period.	X				

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
G. Biocompatibility					
If an vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.					
Submission states that there: (one of the below must be checked)					
X Are direct or indirect patient-contacting components.					
Are no direct or indirect patient-contacting components.					
Information regarding patient contact status of the device is not provided (if this box checked, please also check one of the two boxes below).					
Patient contact information not needed for this device (e.g., software-only device)					
Patient contact information needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					
27) Submission includes a list identifying each of patient-contacting device component (e.g., implant, delivery catheter) and associated materials of construction for each component, including identification of color additives, if present.	X				
28) Submission identifies contact classification (e.g., surface-contacting, less then 24 hour duration) for each patient-contacting device component (e.g., implant, delivery catheter)	X				
29) Biocompatibility assessment of patient-contacting components Submission includes: Test protocol (including identification and description of test article), methods, pass/fail criteria, and results provided for each completed test. **OR** A statement that biocompatibility testing is not needed with a rationale (e.g., materials and manufacturing/processing are identical to the predicate).	X				
H. Software					
Submission states that the device: (one of the below must be checked)					
Does contain software/firmware					
X Does not contain software/firmware					
Information on whether device contains software/firmware is not provided. (If this box is checked, please also check one of the two boxes below.)					
Software/firmware information not needed for this device (e.g., surgical suture, condom)					
Software/firmware information is needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					
I. Electrical Safety and EMC					
Electrical Safety Submission states that the device: (one of the below must be checked)					
Does require electrical safety evaluation					

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
× Does not require electrical safety evaluation					
Information on whether device requires electrical safety evaluation is not provided. (If this box is checked, please also check one of the two boxes below.)					
Electrical safety information not needed for this device (e.g., surgical suture, condom)					
Electrical safety information is needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					
EMC Submission states that the device: (one of the below must be checked)					
Does require EMC evaluation					
× Does not require EMC evaluation					
Information on whether device requires EMC evaluation is not provided. (If this box is checked, please also check one of the two boxes below.)					
EMC information not needed for this device (e.g., surgical suture, condom)					
EMC information is needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					
J. Performance Data - General					
If an in vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from checklist if "N/A" is selected. Performance data criteria relating to IVD devices is addressed in Section K.					
34) Full test report is provided for each completed test. A full test report includes: objective of the test, description of the test methods and procedures, study endpoint(s), pre-defined pass/fail criteria, results summary, conclusions.	×				
a) Submission includes an explanation of how the data generated from each test report supports a finding of substantial equivalence (e.g., comparison to predicate device testing, dimensional analysis, etc.).	×				
35) The device has a device-specific guidance document, special controls document, and/or requirements in a device-specific regulation regarding performance data that is applicable to the subject device.	×			×	
a) The submission addresses performance data recommendations outlined in the device-specific guidance. **OR** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria.	×				

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
b) The submission includes performance data that addresses relevant mitigation measures set forth in a special controls document or device-specific regulation applicable to the device. **OR** The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness.			X		
Comments: The applicant uses the performance testing recommendations specified in the MR guidance document.					
36) If literature is referenced in the submission, submission includes:			X		
37) For each completed animal study, the submission provides the following:			X		
K. Performance Characteristics - In Vitro Diagnostic Devices Only **(Also see 21 CFR 809.10(b)(12))**					
Submission states that the device: (one of the below must be checked)					
	is an in vitro diagnostic device.				
X	is not an in vitro diagnostic device.				
If "is not" is selected, the performance data-related criteria below are omitted from the checklist.					

Decision: (•) Accept ( ) Refuse to Accept

If Accept, notify applicant.

If Refuse to Accept, notify applicant electronically and include a copy of this checklist.

Digital Signature Concurrence Table

Reviewer Sign-Off	Ian P. Broverman -S Digitally signed by Ian P. Broverman -S DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=2000792945, cn=Ian P. Broverman -S Date: 2016.03.30 17:44:39 -04'00'
Branch Chief Sign-Off (digital signature optional)*	
Division Sign-Off (digital signature optional)*	

* Branch and Division review of checklist and concurrence with decision required. Branch and Division digital signature optional.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug
Administration

Memorandum

K160811
Integra CRW Stereotactic System

Date: 16 MAY 2016

To: Ian Broverman
CDRH\ODE\DNPMD\NNDB

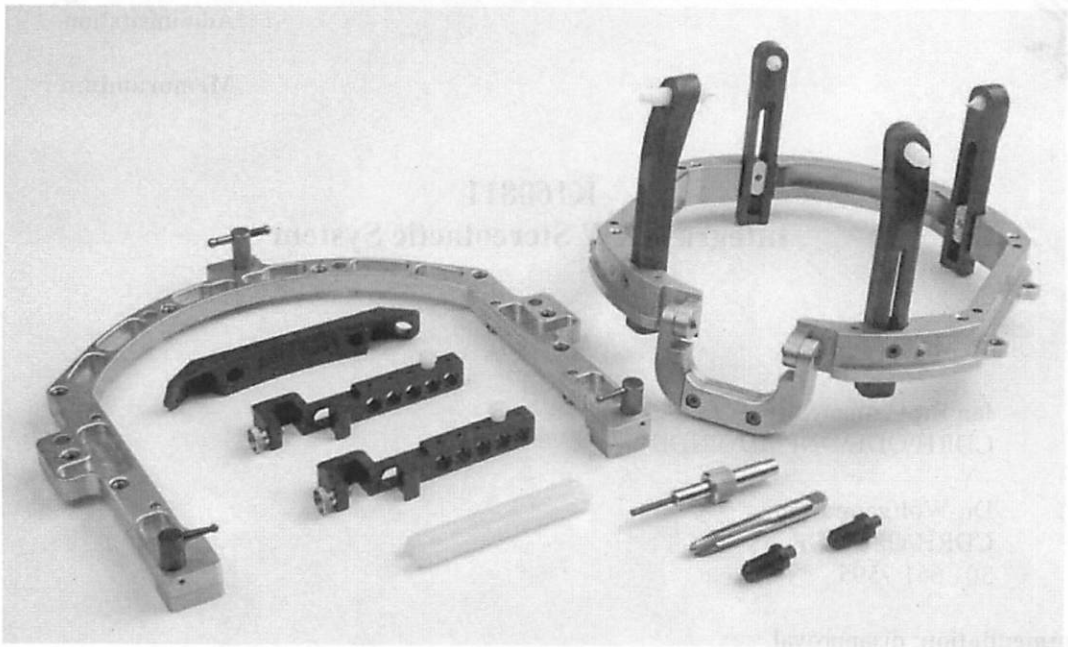
From: Dr. Wolfgang Kainz
CDRH/OSEL/DP
301 661 7595

Recommendation: disapproval

Device Description
The Integra CRW Stereotactic System is a stereotactic system used to aid in neurosurgical procedures that require precise target localization, such as craniotomies, biopsies, and functional Stereotaxy for Deep Brain Stimulation and electrode placement. The system utilizes various components, such as a head ring, head ring screws, localizer frame, CRW Arc and stereotactic planning software, to aid in accurate, precise target localization to achieve access to targeted regions in the brain. A cranial stabilization Head Ring is instrumented on the patient's head utilizing self-penetrating Head Ring screws that are screwed into the skull for rigid fixation.

Head Rings serve as the general stereotactic treatment platform. Head Rings are used to provide a reference frame for instrumentation used for precise spatial localization and treatment of physiologic targets for stereotactic neurosurgical procedures such as craniotomies, biopsies, functional neurosurgery, and radiation therapy. Head Rings are delivered to the user non-sterile, and are reusable. The Luminant Localizer Frame is a universal localizer designed for use in both MR and CT imaging. The localizer frames are delivered to the user non-sterile and are reusable.

The Disposable Head Ring Screws are used with the CRW Stereotactic System to assist in anchoring the head ring to the patient's skull. The screws are provided in two sizes: the long head ring screws are 48mm and short head ring screws are 36mm. The screws contain an inner aluminum pin to provide strength. The screws are provided sterile and for single use. The present screws are made of acetal polymer, Celcon M-90 with an aluminum rod and were formerly made of Delrin with a stainless steel rod. The Celcon M-90 is not in patient contact. The aluminum used is 7075-T6 grade aluminum.



RF-induced heating assessment

(b)(4)

Conclusion

(b)(4)

I recommend disapproval.

Deficiencies:

(b)(4)

Dr. Wolfgang Kainz
Division of Biomedical Physics
OSEL / CDRH / FDA

DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=PIV, serialNumber=D72A10D821086D914090CDA1685A190850146488872A8243E4
Date: 2016.05.16 11:31:23 -04'00'

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug
Administration

Review Memorandum

Date: May 18, 2016

To: Ian Borverman ODE\DNPMD

From: Terry O. Woods, Ph.D.
OSEL\DAM
301-796-2503

Terry O. Woods -S

Digitally signed by Terry O. Woods -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Terry O. Woods -S, 0.9.2342.19200300.100.1.1=1300085350
Date: 2016.05.18 11:47:06 -04'00'

Re: K160811 Integra Lifesciences CRW Stereotactic System, MR induced force, torque and imaging artifact testing and labeling

Recommendation: Additional information. Deficiencies are at the end of the memo.

SCOPE of REVIEW

I reviewed the proposed MRI safety labeling and associated testing related to MR induced force, torque, and image artifact. Wolfgang Kainz is reviewing RF heating related testing and labeling.

DEVICE DESCRIPTION

"The components of the CRW Stereotactic System include:
☐Universal Compact Head Ring Assembly
☐Luminant Localizer Frame
☐Disposable Head Ring Screws (DHRSS- Short, DHRSL- Long)
The Universal Compact Head Ring is placed on the patient and secured with the Disposable Head Ring Screws – See **Figures 11.1 and 11.2**. The Luminant Localizer Frame, **Figure 11.3,** is then attached to the base ring and the patient is taken to the neuroradiology department where a CT or MR imaging is performed. The image obtained in conjunction with the localizer allows the neurosurgeon to compute the exact three dimensional position of the region of interest. The surgeon enters data from the localized scan in target planning software to obtain the Anterior/Posterior, Lateral and Vertical target coordinates. (Alternatively, these coordinates are computed manually). Then the Luminant Localizer Frame is removed and the patient is then taken to the operating room."

INDICATIONS FOR USE

"The CRW-1 System is a stereotactic system to be used for neurosurgical procedures that require precise target localization, such as craniotomies, biopsies, and functional stereotaxy."

Figure 11.1 Universal Compact Head Ring Assembly

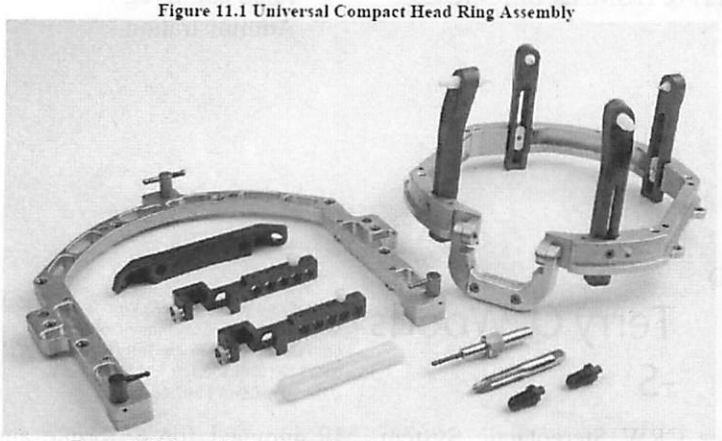


Figure 11.2 Disposable Head Ring Screws

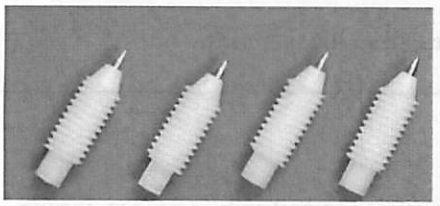


Figure 11.3 Luminant MR/CT Localizer

Component Material Composition:

Head Ring Screws
"The Head Ring Screws are now disposable and supplied sterile; they are sterilized by ethylene oxide. The present screws are made of acetal polymer, Celcon M-90 with an aluminum rod and were formerly made of Delrin with a stainless steel rod. The Celcon M-90 is not in patient contact. The aluminum used is 7075-T6 grade aluminum."

Luminant Localizer
"The Luminant Localizer (LL01) is a replacement for the original component UCLF. The fiducial rods for the UCLF required the user to fill the rods with water. This required the user to ensure that the rods were filled without air bubbles. To address customer concerns, a modification was made to this component. The rods of the LL01 unlike the UCLF do not need to be refilled. They are sealed glass rods filled with a proprietary gel formulation that is visible in MRI scanners and the glass portion of the rod is visible in CT. The arrangement of the rods in the LL01 is identical to the arrangement in the UCLF allowing the LL01 to be used with the same treatment planning software. (The software is used during surgery only and not during imaging and is covered under a separate 510(k)."

Universal Compact Head Ring Post, Anterior (UCHRPA) and Universal Compact Head Ring Post, Posterior (UCHRPP)
"The UCHRPA and UCHRPP are carbon fiber posts which are used to attach the head ring to the patient. The posts are attached to the head ring using a nut and bolt. The post is slotted to allow adjustment of the height of the post on the head ring. Head ring screws are threaded through the tops of the post and into the patient's skull. A Head Ring Cross Bar, which attaches to the UCHRPA, is also available for use when the patient's head is small or when it is difficult to properly place the anterior Head ring screws. The physical modifications of the posts include:
1) Capture of the nut in slot to ease assembly for the user;

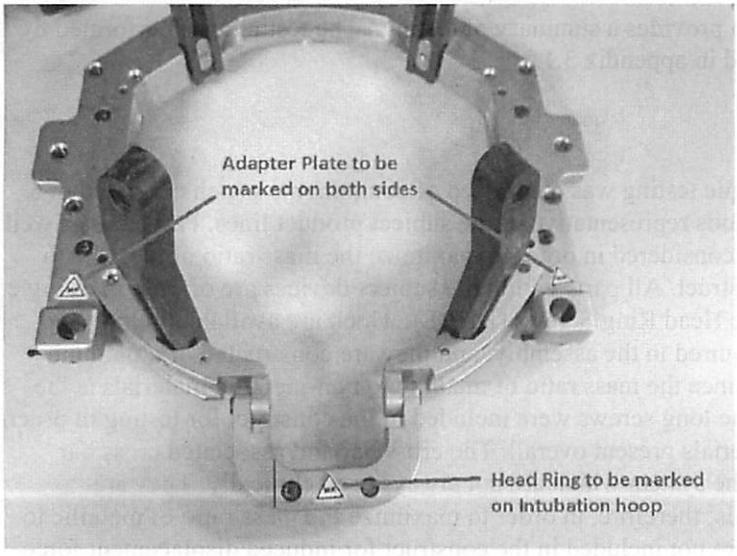
2) Changing the alignment of the threaded hole on the posts to 90 degrees from the body of the post, this matches the alignment of the posts used with the Brown Roberts Well (BRW) system
3) Threaded holes on the crossbar were modified to match the change to anterior post;
4) The resin in the carbon fiber has a slightly higher melting/glass transition point. The basic design and function of the head posts has not changed. The nut is now captured in the post instead of being separate. The alignment of the threaded holes matches the design of the predicate posts. Capturing the nut in the post is an added convenience for the user when assembling the device. There was a change in the resin used with the carbon fiber; however, the posts do not have direct patient contact."

Information Included in MR Marking

"The proposed draft labeling for the CRW Stereotactic System is provided. The Instructions for Use documents for the components are included in this submission and contain relevant information from the MR testing to support an MR conditional claim. Labels for the system components are provided and bear the MR Conditional symbol as applicable.
Labels for the accessories are also provided and bear the MR Unsafe Symbol where applicable.

For physical product markings the UCHR and the UHRAP will be marked for the MR Conditional symbol, see Figure 13.1. The markings will be machined into the raw aluminum part, then the finished machined part is sent for anodization, and lastly the anodized part will be painted using high-temperature black paint. This process is already established for the gradient markings on the side of the UCHR."

Figure 13.1 Identification of MR Conditional Markings



Description of Accessories
"Accessory components are available and have been covered in the original 510(k). No accessory components are required for use in an MR environment."

Table 13.1 Identification of MR Indication Labeling

Component	MR Direct Mark (Y/N)	Applicable MR Labeling
UCHRA	N/A	Both MR Unsafe and MR Conditional – labeling to identify based on component
UCHR - Head Ring	Y	MR Conditional
UCHRAP - Adapter Plate	Y	MR Conditional
UCHREBA - Assembly	N	MR Unsafe
UCHREBA - Ear Bar	N	
UCHREBA - Ear Bar Post	N	
UCHREBA - Ear Bar Screw	N	
UCHRP	N	MR Conditional
UCHRCB1 - Cross Bar	N	
UCHRCBS - Cross Bar Screws	N	
UCHRPA - Anterior Posts	N	
UCHRPP - Posterior Posts	N	
HRW - Wrench	N	MR Unsafe
UCHRCASE	N	
TAP - Cleaning Tap	N	
UCHRHK	N	Both MR Unsafe and MR Conditional – labeling to identify based on component
LL01 - Luminant	Y	MR Conditional
LL02 - Luminant Case	N	N/A
DHRS - Head Ring Screws	N	MR Conditional

Testing:

Section 18 Performance Testing – Bench provides a summary of testing. The testing was performed by (b)(4) in December 2013 and is found in appendix 3.1.

Test Samples:

(b)(4)

(b)(4) The test sample selection and rationale are summarized in Table 6."

Table 5. Sample selection rationale for displacement force and torque testing.

(b)(4)

Table 6. Sample selection rationale for artifact testing.

(b)(4)

Force testing:

(b)(4)

Calculated displacement force based on an assumed angular displacement of 1.0° at the test location.

(b)(4)

Calculated maximum allowable spatial gradient (force ratio factor of safety: 2).

(b)(4)

Torque testing:

(b)(4)

Image artifact testing:

(b)(4)

(b)(4)

(b)(4)

Table 14. Maximum artifact through axial cross-section of the gel rods at 1.5 T and 3.0 T (abbreviations: GE - gradient-echo, SE - spin-echo; AP - anterior/posterior, RL - right/left).

(b)(4)

SNR of the test construct H/A images as compared to the Control images. (abbreviations: GE - gradient-echo, SE - spin-echo; AP - anterior/posterior, RL - right/left).

(b)(4)

Proposed labeling:

Using the CRW© System in a Magnetic Resonance Imaging Environment

MR Conditional

Non-clinical testing has demonstrated that the DHRS, UCHRA, and LL01 devices, when assembled, are MR Conditional. This construct can be scanned safely under the following conditions::

- Static magnetic field of 1.5-Tesla (1.5 T) or 3.0-Tesla (3.0 T)
- Spatial gradient field of up to:
  - 11,440 G/cm (114.40 T/m) for 1.5 T systems
  - 5,720 G/cm (57.20 T/m) for 3.0 T systems
- Maximum whole body averaged specific absorption rate (SAR) of:
  - 2.0 W/kg for 15 minutes of scanning in Normal Operating Mode at 1.5 T
  - 2.0 W/kg for 15 minutes of scanning in Normal Operating Mode at 3.0 T

1.5 T RF heating

In non-clinical testing with body coil excitation, components on the DHRS, UCHRA, and LL01 devices that may be in contact with a patient when assembled produced a temperature rise of 2.4 °C or less at a maximum whole body averaged specific absorption rate (SAR) of 2.0 W/kg, as assessed for 15 minutes of scanning in a 1.5 T Siemens Espree (MRC30732) MR scanner with SYNGO MR B19 software.

3.0 T RF heating

In non-clinical testing with body coil excitation, components on the DHRS, UCHRA, and LL01 devices that may be in contact with a patient when assembled produced a temperature rise of 1.1 °C or less at a maximum whole body averaged specific absorption rate (SAR) of 2.0 W/kg, as assessed for 15 minutes of scanning in a 3.0 T Siemens Trio (MRC20587) MR scanner with SYNGO MR A35 4VA30A software.

Caution: The RF heating behavior does not scale with static field strength. Devices which do not exhibit detectable heating at one field strength may exhibit high values of localized heating at another field strength.

MR Artifact

MR image quality may be compromised if the area of interest is in the same area or relatively close to the position of the device. Therefore, it may be necessary to optimize MR imaging parameters for the presence of this implant. In testing using a 1.5 T and 3.0 T system with spin-echo and gradient-echo sequences, the shape of the image artifact follows the approximate contour of the device and extends radially less than 1 mm from the device.

Disposable Head Ring Screws (MR/CT Compatible)	DHRSL5 (48 mm / box of long screws / 5 packs, 2 screws per pack) DHRSS5 (34 mm / box of short screws /5 packs, 2 screws per pack)

Integra Radionics Disposable Head Ring Screws are designed to be used with the UCHR Universal Compact Head Ring and the HRAIM (Head Ring Intubation Assembly) and are components of the CRW® Precision and CRWASL Stereotactic Systems. For complete instructions, warnings and precautions, consult the appropriate Operator's Manual.

DEFICIENCIES

(b)(4)

RECOMMENDATION: Additional Information. Deficiencies are immediately above.

The testing for magnetically induced force, torque, and artifact was appropriately done and is acceptable. I have requested they make some changes in the labeling to make it conform to the form given in the passive implant guidance. All of these requirements are covered in the above deficiencies. Please check with Wolfgang to see if he has additional recommendations for changes in the labeling.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug
Administration

Memorandum

K160811-S001
Integra CRW Stereotactic System

Date: 17 NOV 2016

To: Ian Broverman
CDRH\ODE\DNPMD\NNDB

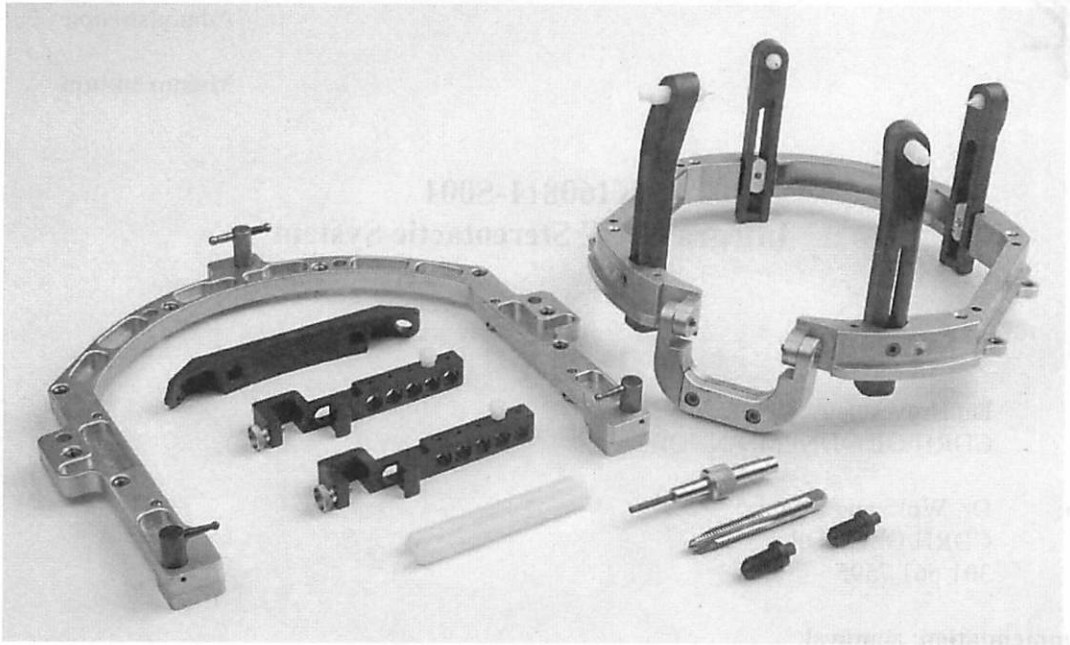
From: Dr. Wolfgang Kainz
CDRH/OSEL/DP
301 661 7595

Recommendation: approval

Device Description
The Integra CRW Stereotactic System is a stereotactic system used to aid in neurosurgical procedures that require precise target localization, such as craniotomies, biopsies, and functional Stereotaxy for Deep Brain Stimulation and electrode placement. The system utilizes various components, such as a head ring, head ring screws, localizer frame, CRW Arc and stereotactic planning software, to aid in accurate, precise target localization to achieve access to targeted regions in the brain. A cranial stabilization Head Ring is instrumented on the patient's head utilizing self-penetrating Head Ring screws that are screwed into the skull for rigid fixation.

Head Rings serve as the general stereotactic treatment platform. Head Rings are used to provide a reference frame for instrumentation used for precise spatial localization and treatment of physiologic targets for stereotactic neurosurgical procedures such as craniotomies, biopsies, functional neurosurgery, and radiation therapy. Head Rings are delivered to the user non-sterile, and are reusable. The Luminant Localizer Frame is a universal localizer designed for use in both MR and CT imaging. The localizer frames are delivered to the user non-sterile and are reusable.

The Disposable Head Ring Screws are used with the CRW Stereotactic System to assist in anchoring the head ring to the patient's skull. The screws are provided in two sizes: the long head ring screws are 48mm and short head ring screws are 36mm. The screws contain an inner aluminum pin to provide strength. The screws are provided sterile and for single use. The present screws are made of acetal polymer, Celcon M-90 with an aluminum rod and were formerly made of Delrin with a stainless steel rod. The Celcon M-90 is not in patient contact. The aluminum used is 7075-T6 grade aluminum.



RF-induced heating assessment

Based on FDA's recommendation the sponsor provides an completely revised RF-induced heating assessment.

(b)(4)

(b)(4)

(b)(4)

Conclusion

The sponsor's revised heating assessment is scientifically sound and can be used to determine the heating of the Integra CRW Stereotactic System. (b)(4)

(b)(4)

(b)(4) I also reviewed the proposed MR Conditional labeling and have no further comments.

I recommend approval.

Wolfgang Kainz

DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=PIV, serialNumber=D72A10D821086D914090CDA1685A19085014 6488872A8243E4
Date: 2016.11.17 11:37:16 -08'00'

Dr. Wolfgang Kainz
Division of Biomedical Physics
OSEL / CDRH / FDA

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug
Administration

Review Memorandum

Date: November 18, 2016

To: Ian Borverman ODE\DNPMD

From: Terry O. Woods, Ph.D.
OSEL\DAM
301-796-2503

Terry O. Woods -S

Digitally signed by Terry O. Woods -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Terry O. Woods -S, 0.9.2342.19200300.100.1.1=1300085350
Date: 2016.11.18 13:00:10 -05'00'

Re: K160811\S001 Integra Lifesciences CRW Stereotactic System, MR induced force, torque and imaging artifact testing and labeling

Recommendation: SE. No further questions.

SCOPE of REVIEW

I reviewed the response to deficiency 3. Wolfgang Kainz is reviewing the responses to questions 1 and 2.

DEVICE DESCRIPTION

"The components of the CRW Stereotactic System include:
☐Universal Compact Head Ring Assembly
☐Luminant Localizer Frame
☐Disposable Head Ring Screws (DHRSS- Short, DHRSL- Long)
The Universal Compact Head Ring is placed on the patient and secured with the Disposable Head Ring Screws – See **Figures 11.1 and 11.2**. The Luminant Localizer Frame, **Figure 11.3,** is then attached to the base ring and the patient is taken to the neuroradiology department where a CT or MR imaging is performed. The image obtained in conjunction with the localizer allows the neurosurgeon to compute the exact three dimensional position of the region of interest. The surgeon enters data from the localized scan in target planning software to obtain the Anterior/Posterior, Lateral and Vertical target coordinates. (Alternatively, these coordinates are computed manually). Then the Luminant Localizer Frame is removed and the patient is then taken to the operating room."

INDICATIONS FOR USE

"The CRW-1 System is a stereotactic system to be used for neurosurgical procedures that require precise target localization, such as craniotomies, biopsies, and functional stereotaxy."

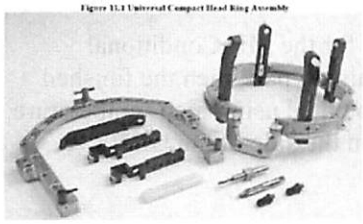
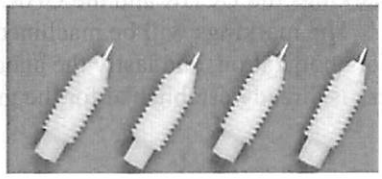


Figure 11.2 Disposable Head Ring Screws



Component Material Composition:

Head Ring Screws
"The Head Ring Screws are now disposable and supplied sterile; they are sterilized by ethylene oxide. The present screws are made of acetal polymer, Celcon M-90 with an aluminum rod and were formerly made of Delrin with a stainless steel rod. The Celcon M-90 is not in patient contact. The aluminum used is 7075-T6 grade aluminum."

Luminant Localizer
"The Luminant Localizer (LL01) is a replacement for the original component UCLF. The fiducial rods for the UCLF required the user to fill the rods with water. This required the user to ensure that the rods were filled without air bubbles. To address customer concerns, a modification was made to this component. The rods of the LL01 unlike the UCLF do not need to be refilled. They are sealed glass rods filled with a proprietary gel formulation that is visible in MRI scanners and the glass portion of the rod is visible in CT. The arrangement of the rods in the LL01 is identical to the arrangement in the UCLF allowing the LL01 to be used with the same treatment planning software. (The software is used during surgery only and not during imaging and is covered under a separate 510(k)."

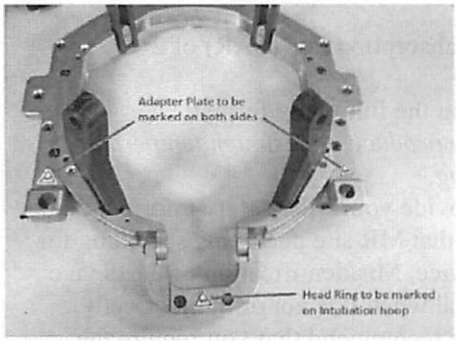
Universal Compact Head Ring Post, Anterior (UCHRPA) and Universal Compact Head Ring Post, Posterior (UCHRPP)
"The UCHRPA and UCHRPP are carbon fiber posts which are used to attach the head ring to the patient. The posts are attached to the head ring using a nut and bolt. The post is slotted to allow adjustment of the height of the post on the head ring. Head ring screws are threaded through the tops of the post and into the patient's skull. A Head Ring Cross Bar, which attaches to the UCHRPA, is also available for use when the patient's head is small or when it is difficult to properly place the anterior Head ring screws. The physical modifications of the posts include:
1) Capture of the nut in slot to ease assembly for the user;
2) Changing the alignment of the threaded hole on the posts to 90 degrees from the body of the post, this matches the alignment of the posts used with the Brown Roberts Well (BRW) system
3) Threaded holes on the crossbar were modified to match the change to anterior post;
4) The resin in the carbon fiber has a slightly higher melting/glass transition point. The basic design and function of the head posts has not changed. The nut is now captured in the post instead of being separate. The alignment of the threaded holes matches the design of the predicate posts. Capturing the nut in the post is an added convenience for the user when assembling the device. There was a change in the resin used with the carbon fiber; however, the posts do not have direct patient contact."

Information Included in MR Marking

"The proposed draft labeling for the CRW Stereotactic System is provided. The Instructions for Use documents for the components are included in this submission and contain relevant information from the MR testing to support an MR conditional claim. Labels for the system components are provided and bear the MR Conditional symbol as applicable.
Labels for the accessories are also provided and bear the MR Unsafe Symbol where applicable.

For physical product markings the UCHR and the UHRAP will be marked for the MR Conditional symbol, see Figure 13.1. The markings will be machined into the raw aluminum part, then the finished machined part is sent for anodization, and lastly the anodized part will be painted using high-temperature black paint. This process is already established for the gradient markings on the side of the UCHR."

Figure 13.1 Identification of MR Conditional Markings



Description of Accessories

"Accessory components are available and have been covered in the original 510(k). No accessory components are required for use in an MR environment."

Table 13.1 Identification of MR Indication Labeling

Component	MR Direct Mark (Y/N)	Applicable MR Labeling
UCHRA	N/A	Both MR Unsafe and MR Conditional – labeling to identify based on component
UCHR - Head Ring	Y	MR Conditional
UCHRAP - Adapter Plate	Y	MR Conditional
UCHREBA - Assembly	N	MR Unsafe
UCHREBA - Ear Bar	N	
UCHREBA - Ear Bar Post	N	
UCHREBA - Ear Bar Screw	N	
UCHRP	N	MR Conditional
UCHRCB1 - Cross Bar	N	
UCHRCBS - Cross Bar Screws	N	
UCHRPA - Anterior Posts	N	
UCHRPP - Posterior Posts	N	
HRW - Wrench	N	MR Unsafe
UCHRCASE	N	
TAP - Cleaning Tap	N	
UCHRHK	N	Both MR Unsafe and MR Conditional – labeling to identify based on component
LL01 - Luminant	Y	MR Conditional
LL02 - Luminant Case	N	N/A
DHRS - Head Ring Screws	N	MR Conditional

FDA Question 3

Labeling

(b)(4)

[redacted]

b. (b)(4)
1) (b)(4)
2) (b)(4)
3) (b)(4)
(b)(4)
c. (b)(4)
(b)(4)

Integra Response

(b)(4)

MRI Safety Information

MR Conditional

Non-clinical testing has demonstrated that the Disposable Head Ring Screws (DHRS), Universal Compact Head Ring Assembly (UCHRA), and Luminant™ MR/CT Localizer (LL01) devices, when assembled, are MR Conditional. A patient with these devices assembled can be scanned safely under the following conditions:

- Static magnetic field of 1.5T and 3.0T
- Maximum spatial field gradient of 5,000 Gauss/cm (50 T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg in Normal Operating Mode.

Under the scan conditions defined above, the assembled devices (DHRS, UCHRA, and LL01) are expected to produce a temperature rise of less than 6°C after 15 minutes of continuous scanning.

Caution: The RF heating behavior does not scale with static field strength. Devices which do not exhibit detectable heating at one field strength may exhibit high values of localized heating at another field strength.

In non-clinical testing, the image artifact caused by the device extends approximately 1mm from the assembled devices (DHRS, UCHRA, LL01) when imaged with either a spin-echo or a gradient echo pulse sequence and either a 1.5 T or a 3.0 T MRI system.

Disposable Head Ring Screws (MR/CT Compatible)	DHRSL5 (48 mm/box of long screws/5 packs, 2 screws per pack) DHRSS5 (34 mm/box of short screws/5 packs, 2 screws per pack)

Integra Radionics Disposable Head Ring Screws are designed to be used with the UCHR Universal Compact Head Ring and the HRAIM (Head Ring Intubation Assembly) and are components of the CRW® Precision and CRWASL Stereotactic Systems. For complete instructions, warnings and precautions, consult the appropriate Operator's Manual.

RECOMMENDATION: SE, no further questions.

The revised labeling and proposal for providing the IFUs on the website are acceptable. Please confirm with Wolfgang that the 6 degree temperature rise is supported by the responses to questions 1 and 2.

Food and Drug Administration
CDRH/ODE/DNPMD/NNDB
WO66 RMG450
10903 New Hampshire Ave
Silver Spring, MD 20993-0002
301-796-9696

Premarket Notification 510(k) Review

Date: November 23, 2016

Reviewer: Ian Broverman

Subject: Abbreviated 510(k)# K160811-S001

Applicant: Integra Lifesciences Corporation

Device Trade Name: CRW Stereotactic System

Contact Name: Timothy Connors

Contact Title: Senior Regulatory Affairs Associate

Correspondent Firm: Integra Lifesciences Corporation

Phone: (609) 936-5531 **Email:** timothy.connors@integralife.com

Received Date: November 7, 2016

Due Date: December 7, 2016

Pro Code(s): HAW **Class:** II **Reg #:** 882.4560

Reg Name: Stereotaxic Instrument

Predicate Devices:

Submission #	Pro Code	Device Trade Name	Owner
K944463	HAW	CRW-1 System	Radionics Software Applications, Inc.

Review Summary

The 510(k) holder would like to introduce the CRW Stereotactic System into interstate commerce. The device system is identical to the K944463 predicate; but now the sponsor is seeking to add MR Conditional language to the labeling by performing the recommended testing.

Additionally, the sponsor has described three design changes made prior to this submission that did not warrant filing a new 510(k). The descriptions were provided to update FDA's records.

The submission was placed on AI Hold on 5/23/16, due to deficiencies raised by the RF Heating consultant, Dr. Kainz, labeling deficiencies raised by the MR Safety consultant, Dr. Woods, and other miscellaneous deficiencies.

The S001 Supplement was received on 11/7/16, and the consultants confirmed that RF heating and MR safety and labeling deficiencies were resolved. I recommend the system be found Substantially Equivalent (SESE) to the predicate.

Recommendation

I recommend that the CRW Stereotactic System is/are Substantially Equivalent (SESE)

Review Team

Lead Reviewer — Ian Broverman (ODE/DNPMD/NNDB) ← Branch changed to NDNB

Consult	Consultant	CTS #	Deficiencies	Supplement CTS #
MRCOMP	Wolfgang Kainz (OSEL/DBP)	CON169650	#1 & 2	CON1624491
	Assessment of RF induced heating and associated labeling			
MRCOMP	Terry Woods (OSEL/DAM)	CON169649	#3	CON1624492
	Assessment of MRI safety and associated labeling			

I. Purpose and History

TPLC Information Recall Information Historyfalls

Prior Submissions:

K141671 – Withdraw By Sponsor
Sponsor submitted K141671 dated June 20, 2014 and received June 23, 2014 to request clearance for the CRW Stereotactic System. The submission was submitted as an abbreviated 510(k) and requested permission to add MR safety information to the product labeling.

K141671 was found to not be administratively completed and the decision for K141671 was Refuse to Accept (RTA1). Sponsor submitted K141671/WD001 dated December 8, 2014 and received December 9, 2014 to notify FDA of the withdrawal of K141671. The withdrawal letter noted that Integra is in the process of confirming the sterilization parameters and product shelf-life and will re-submit the application when testing is completed.

II. 510(k) Summary/Statement

510(k) Summary/Statement		
Was a 510(k) Summary or Statement provided?	Summary	Undo

Reviewer Notes
- FINAL VERSION OF THE 510(k) SUMMARY IS IN THE S001 SUPPLEMENT
- S001 UPDATE: Details of the labeling change and the testing used to justify that change have been added to the Summary.

Reviewer Recommendation
The 510(k) Summary/Statement is ACCEPTABLE.

III. Device/System Description

Device Characteristics		Inadequate Or Marked
Is the intended use or fundamental technology new?	No	☐
Is the device life-supporting or life sustaining?	No	☐
Are there any direct or indirect patient contacting components?	Yes	☐
• Is the device or a component an implant?	Yes	☐
Does the device use software/firmware?	No	☐
Does the device or a component need sterilization (by manufacturer or user)?	Yes	☐
The device/system uses or is...	a reusable multi-patient use device(s)	☐
The environment for use of the device/system includes...	MR, Hospital	☐

Device Characteristics		Inadequate Or Marked
Is the device a combination product?	N - Not a Part 3 Combination Product	☐
Is the device/system electrical (battery or wall powered)?	No, the device is not electrical	☐

Check the attributes that are applicable to this submission.

	Nanotechnology	Reprocessed SUD	Companion Diagnostic	Medical Counter Measures
Yes	☐	☐	☐	☐
No	☒	☒	☒	☒
Unknown	☐	☐	☐	☐

Device Description Table: Summary of important device characteristics

Background

This submission was made to justify the addition of a **MR Conditional claim** to the labeling of the Cosman-Roberts Wells (CRW) System. Since the only addition in this submission is covered by FDA's guidance, "Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment", issued August 21, 2008 & updated on December 11, 2014, the submission was entered as an ABBREVIATED 510(k) with respect to that guidance.

The CRW System is a stereotactic system used in neurosurgical procedures that require precise target localization, such as craniotomies, biopsies, and functional Stereotaxy for Deep Brain Stimulation and electrode placement. The system uses various components, such as a head ring, head ring screws, localizer frame, CRW Arc and stereotactic planning software, for target localization for access to targeted regions in the brain. A cranial stabilization Head Ring is instrumented on the patient's head using self-penetrating Head Ring screws that are screwed into the skull for rigid fixation. Planning and localization of the target is achieved by a combination of radiographic imaging with a localizer frame attached to the Head Ring, and planning software (StereoCalc™, covered under a separate 510(k)) to provide stereotactic coordinates and settings for the CRW Arc part of the system.

The CRW is comprised of the CRW Stereotactic System and the CRW Arc System. This 510(k) covers the CRW Stereotactic System which is comprised of three components that are used prior to surgery and would be the components used in an MR environment:

- Universal Compact Head Ring Assembly (UCHR/UCHRA) - provide a reference frame for instrumentation used for precise spatial localization and treatment of physiologic targets for stereotactic neurosurgical procedures. Delivered EtO-sterile; reusable. (Figure 3.1)
- Luminant Localizer Frame (LL01) - universal localizer designed for use in both MR and CT imaging. Delivered non-sterile; reusable. (Figure 3.2)
- Disposable Head Ring Screws (DHRSS- Short, DHRSL- Long) - anchor the head ring to the patient's skull. Screws are provided in two sizes: long head ring screws are 48mm and short head ring screws are 36mm. The screws contain an inner aluminum pin to provide strength. Delivered gamma sterilized; single use. (Figure 3.3)

These components were reported as passing MR testing and will be labeled **MR Conditional**. More information is provided in the performance testing section of this memo.

Three of the accessories (Figure 3.4) that a user might inadvertently bring to an MR environment were also tested. These accessories were reported as not passing MR testing and will be labeled **MR Unsafe**.

- Ear Bar Assembly
- Head Ring Wrench

- Cleaning Tap

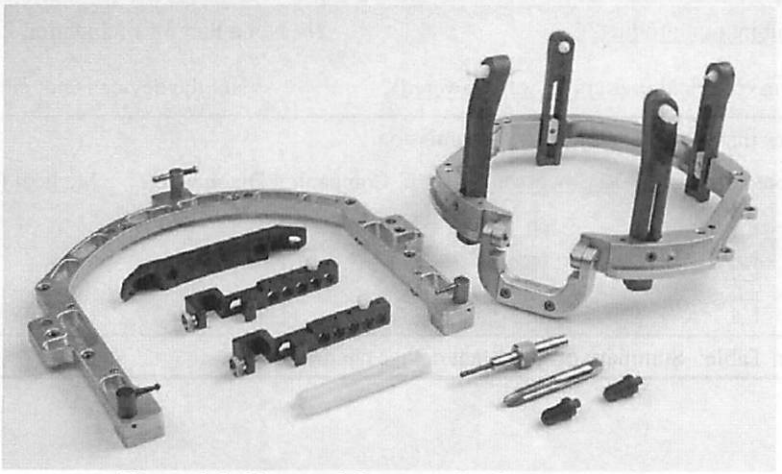


Figure 3.1: Universal Compact Head Ring Assembly

Figure 3.2: Localizer Frame

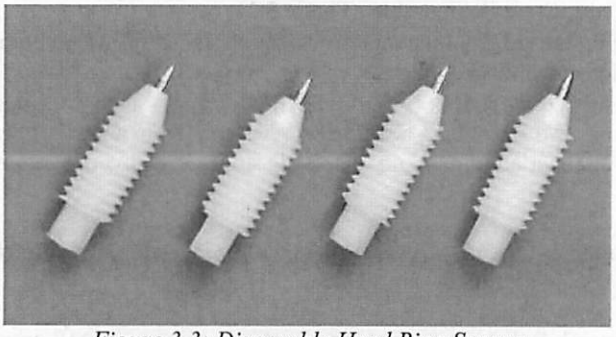


Figure 3.3: Disposable Head Ring Screws

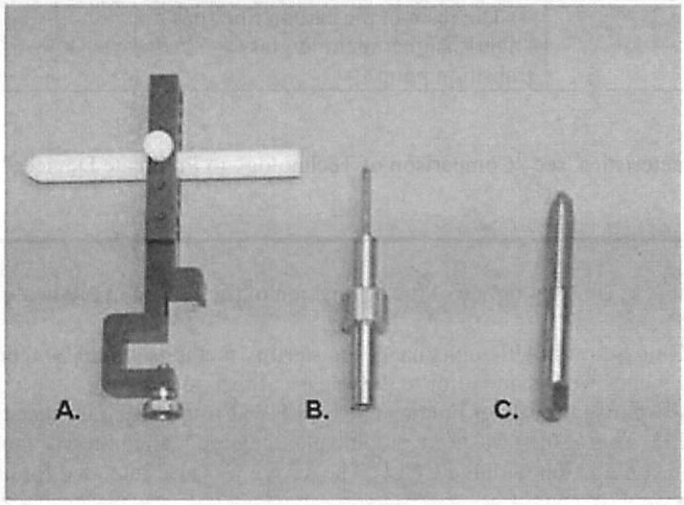


Figure 3.4: Accessories – (A) Ear Bar Assy., (B) Head Ring Wrench, and (C) Cleaning Tap

Prior non-510(k) changes

The sponsor listed three physical device changes made to the subject components since the clearance of the original 510(k) as an informational update for the FDA, but not to be considered a part of this submission. In the cover letter, they stated that none of these changes required the filing of a new 510(k). The sponsor evaluated these changes as not warranting a 510(k):

Change	Subject K160811	Predicate K944463
Head Ring Screws NOTE: Change was made in 1993 prior to release of FDA's **Deciding When to Submit a 510(k) for a Change to an Existing Device (K97-1)**, Jan 10, 1997.	Disposable, EtO sterilized Non-contacting Material: Acetal polymer (Celcon M-90) Contacting Material: 7075-T6 aluminum	Reusable, User sterilized Non-contacting Material: Delrin Contacting Material: 7075-T6 aluminum
Localizer Frame	Luminant Localizer (LL01) Contains sealed glass rods filled with a proprietary gel formulation that is visible in MRI scanners and the glass portion of the rod is visible in CT	UCLF The fiducial rods for the UCLF required the user to fill the rods with water
Universal Compact Head Ring Post, Anterior (UCHRPA) and Universal Compact Head Ring Post, Posterior (UCHRPP) These are carbon fiber posts that attach the head ring to the head ring screws. The posts are attached to the head ring with a nut and bolt; the head ring screws are installed through threaded holes.	The reported physical modifications of the posts are: 1) Capture of the nut in slot to ease assembly for the user; 2) Changing the alignment of the threaded hole on the posts to 90 degrees from the body of the post, this matches the alignment of the posts used with the Brown Roberts Well (BRW) system 3) Threaded holes on the crossbar were modified to match the change to anterior post;	

	4) The resin in the carbon fiber has a slightly higher melting/glass transition point.	

For a table of device characteristics, see "Comparison of Technology to Predicate Devices" below.

Reviewer Notes

- Integra Life Sciences Co. sent notice of the acquisition of the K944463 predicate on April 20, 2006.
- Prior non-510(k) changes
  - Head Ring Screws: Although changes to sterility methods would be reportable under K97-1, these changes were made prior to the release of that document. [redacted]
  - **S001 Response:** Localizer Frame: The UCLF was originally introduced and cleared under K946252. This 510(k) was for a graphic planning tool called StereoPlan, which was intended to work in conjunction with the UCLF. The device was also intended for use with the CRW system [redacted].
  - Posts (UCHRPA & UCHRPP): These components are non-patient contacting, and the changes described don't alter function. This change does not require a 510(k) submission. [redacted].

Reviewer Recommendation

The Device Description is [redacted].

V. Comparison of Indications for Use to Predicate Devices

Comparison of Indications for Use

Subject

510(k) #: K160811 Rx/OTC:

Intended Population	Adults Only	Adults and Pediatrics	Transitional Adolescent A	Transitional Adolescent B	Adolescent	Child	Infant	Neonate/ Newborn
Yes	☐	☐	☐	☐	☐	☐	☐	☐
No	☐	☐	☐	☐	☐	☐	☐	☐
Unknown	☒	☒	☒	☒	☒	☒	☒	☒

Indications for Use:

The CRW-1 System is a stereotactic system to be used for neurosurgical procedures that require precise target localization, such as craniotomies, biopsies, and functional stereotaxy.
Localization is performed using CT or MR imaging.

Predicate(s)

Submission#: K944463 Rx/OTC: Rx

Intended Population:

Indications for Use: The CRW-1 System is a stereotactic system to be used for neurosurgical procedures that require precise target localization, such as craniotomies, biopsies, and functional stereotaxy.
[Reviewer Note: No Indication was listed. The above statement was listed as an Intended Use]

Indications for Use Table: Compares the indications for use of the subject and predicate devices.

Reviewer Notes

- FINAL VERSION OF THE IFU FORM IS IN THE S001 SUPPLEMENT. However, the sponsor used the old form, so I copied the information into the current IFU form and emailed a

copy to the sponsor on 11/23/16.
- S001 UPDATE: "Localization is performed using CT or MR imaging." added to IFU at FDA request

Reviewer Recommendation
The Comparison of the Indications for Use is ACCEPTABLE.

VI. Comparison of Technology to Predicate Devices

Device & Predicate Device(s):	K160811	K944463
General Device Characteristics		
MR Labeling	Labeled components as MR Conditional and MR Unsafe	No MR labeling

Reviewer Recommendation
The Comparison of the Technology to Predicate Devices is ACCEPTABLE.

VII. Labeling

Labeling Review Needed?	Undo	No
Usability Consult Needed?	Undo	No

Reviewer Notes
- Labelling was evaluated for MRI safety labeling by Ian Broverman (Lead Reviewer) and Terry Woods (MR Safety Consult)

Reviewer Recommendation
The Labeling is ACCEPTABLE.

VIII. Reprocessing, Sterilization, and Shelf-Life

Sterility Review Needed?	Undo	No
Sterility Consult Needed?	Yes	No

Reviewer Recommendation
This Abbreviated 510(k) is for revised MR labeling claims. No changes have been made to the reprocessing, sterilization, and shelf life. ACCEPTABLE.

IX. Biocompatibility

Biocompatibility Review Needed?	Yes	No
Biocompatibility Consult Needed?	Yes	No

Reviewer Recommendation
This Abbreviated 510(k) is for revised MR labeling claims. No changes have been made to the biocompatibility.
ACCEPTABLE.

X. Software/Firmware

Reviewer Recommendation
The devices in this review do not contain software. **Not Applicable.**

XI. EMC & Electrical, Mechanical and Thermal Safety & Risk Analysis

Reviewer Recommendation
The EMC, EMT and Risk Analysis are **Not Applicable.**

XII. Performance Testing

A Bench Testing

The following tests were performed:

- Magnetically Induced Displacement Force
- Magnetically Induced Torque
- RF-Induced Heating
- MR Image Artifact

All test samples were completed production parts that underwent recommended sterilization. Samples of the three components and three accessories described in the device description section of this memo were tested.
Components:

- Universal Compact Head Ring Assembly (UCHR/UCHRA)
- Luminant Localizer Frame (LL01)
- Disposable Head Ring Screws

Accessories:

- Ear Bar Assembly
- Head Ring Wrench
- Cleaning Tap

Results:
The 3 components were determined to pass tests for MR Conditional labeling.

Sponsor's Summary of Results (Components)		
Evaluation Test	**Field Strength**	**Component Results**
(b)(4)		

(b)(4)

The 3 accessories were determined to be MR Unsafe.

B Animal Testing
Not applicable

C Clinical Testing
Not applicable

Reviewer Notes

- Bench testing was reviewed by Terry Woods (OSEL/DAM) for MR safety and Wolfgang Kainz (OSEL/DBP) for RF heating.
- Terry Woods did not identify any deficiencies regarding safety. ACCEPTABLE.
- (b)(4)
  - **S001 Update:** New testing was provided by the Sponsor. Dr. Kainz found the methods and results to be ACCEPTABLE.

Reviewer Recommendation

The Performance Testing [Bench] is ACCEPTABLE.

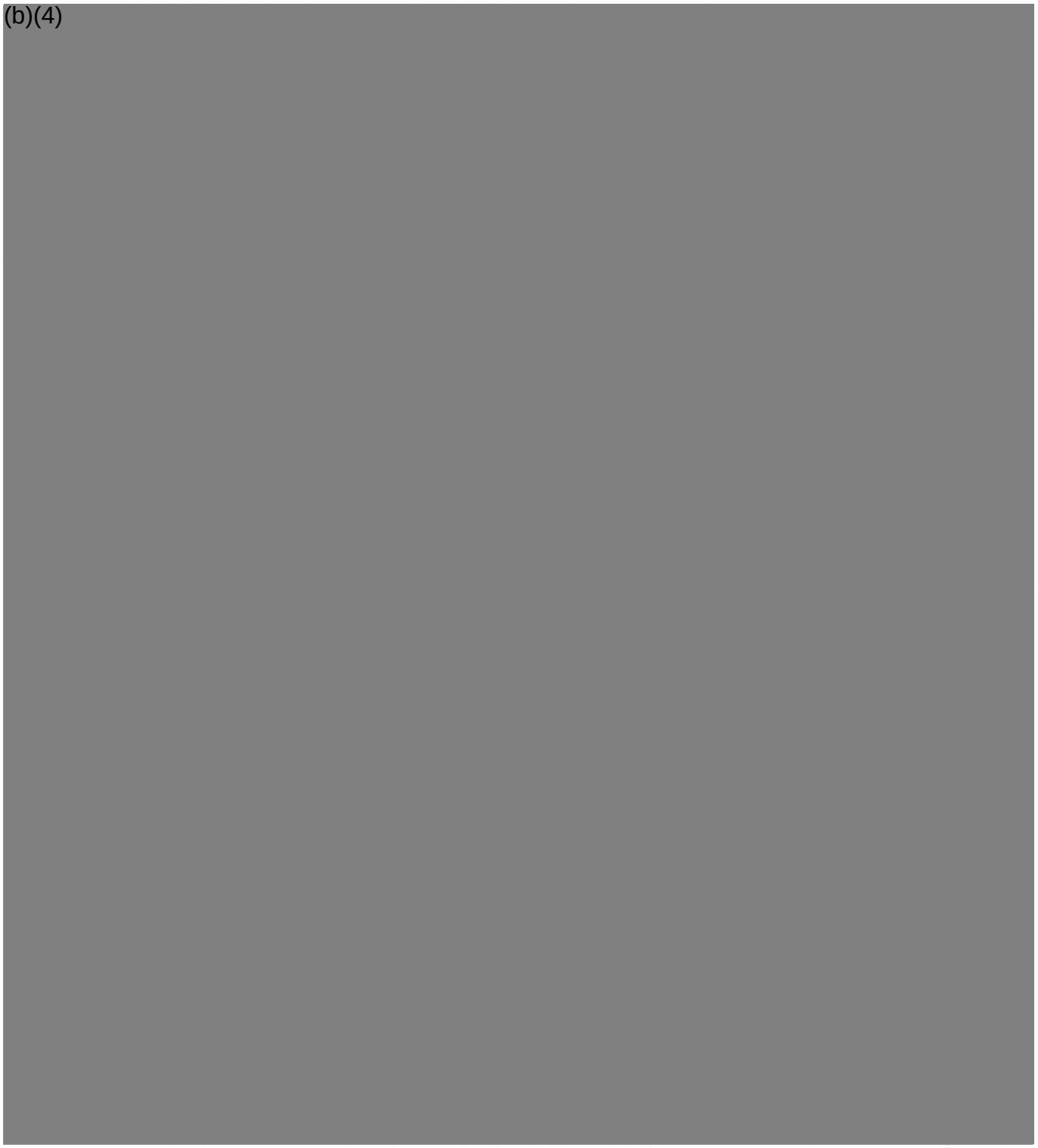
XIII. SE Flowchart Questions

Substantial Equivalence Determination	Yes	No
Is the predicate device legally marketed?	☒	☐
Do the devices have the same intended use?	☒	☐
Please explain how the intended use of the subject device is similar to or different from the predicate device: Use is identical. MR labeling is being changed.		
Do the devices have the same technological characteristics?	☐	☒
Please describe the different technological characteristics: New MR labeling		
Do the different technological characteristics of the devices raise different questions of safety and effectiveness?	☐	☒
Are the methods acceptable?	☒	☐
Do the data demonstrate equivalence and support the Indications for Use?	☒	☐

Please explain how the data do or do not demonstrate substantial equivalence:
Sponsor has demonstrated that new MR labeling is ACCEPTABLE.

XIV. Original Deficiencies

(b)(4)



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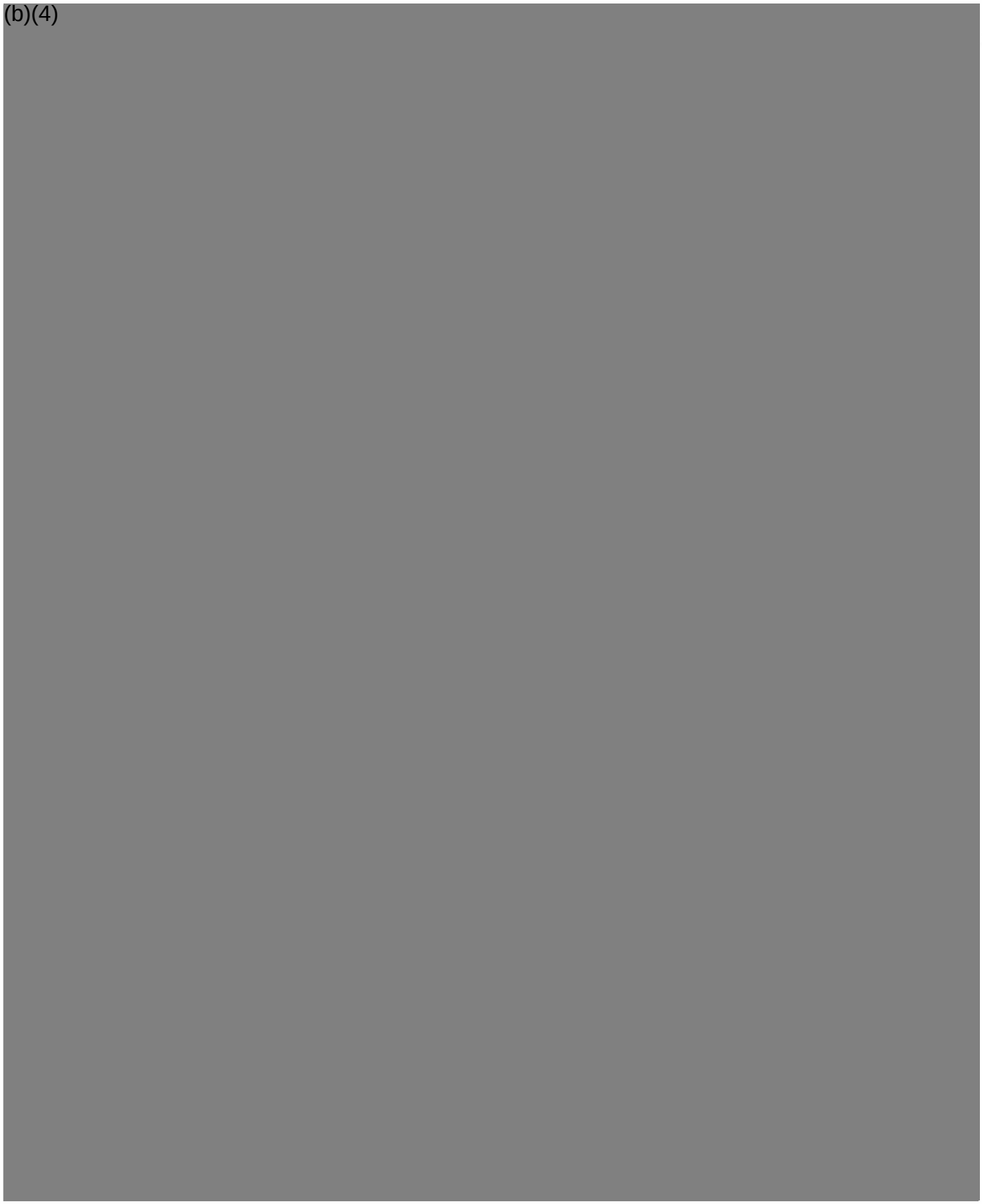

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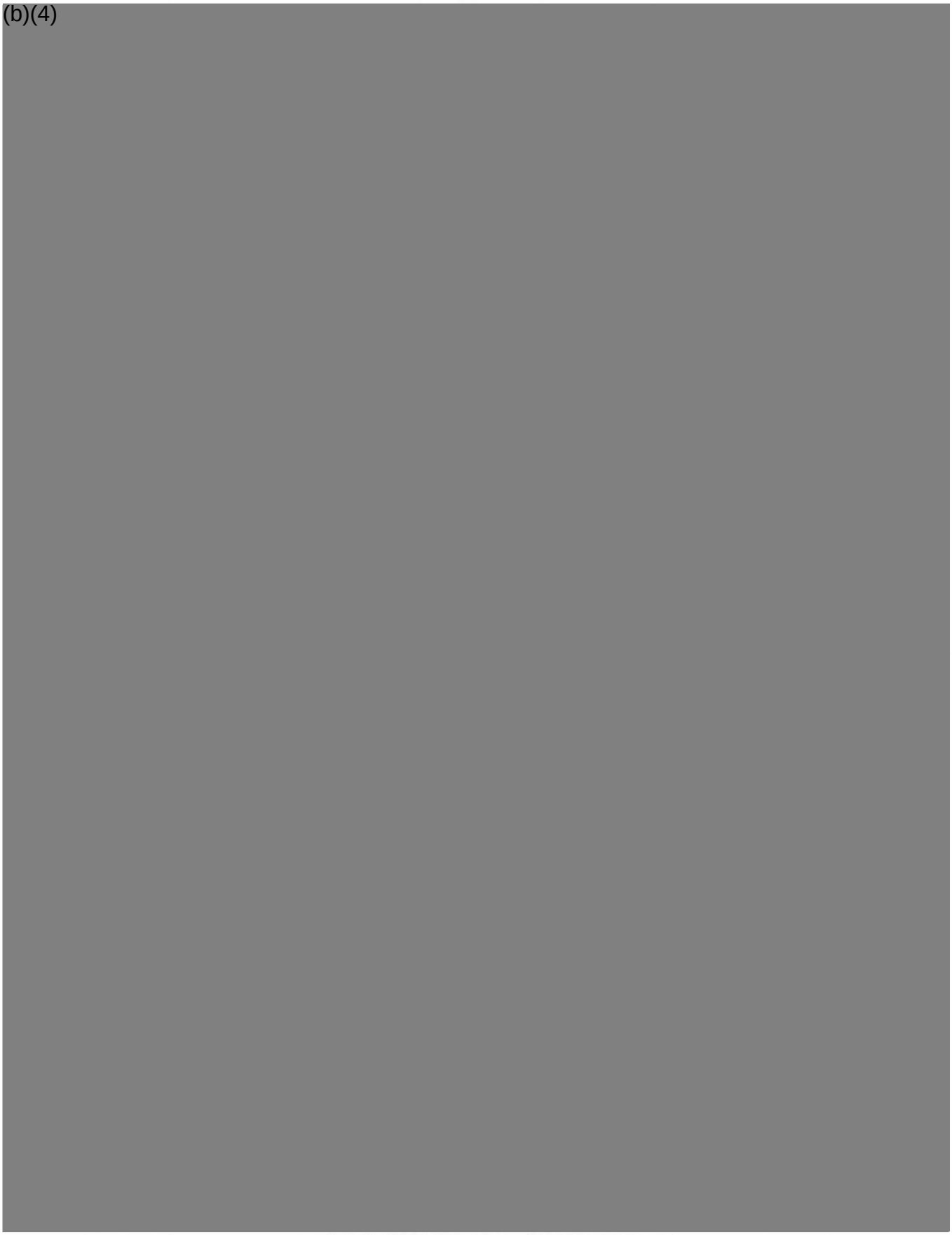

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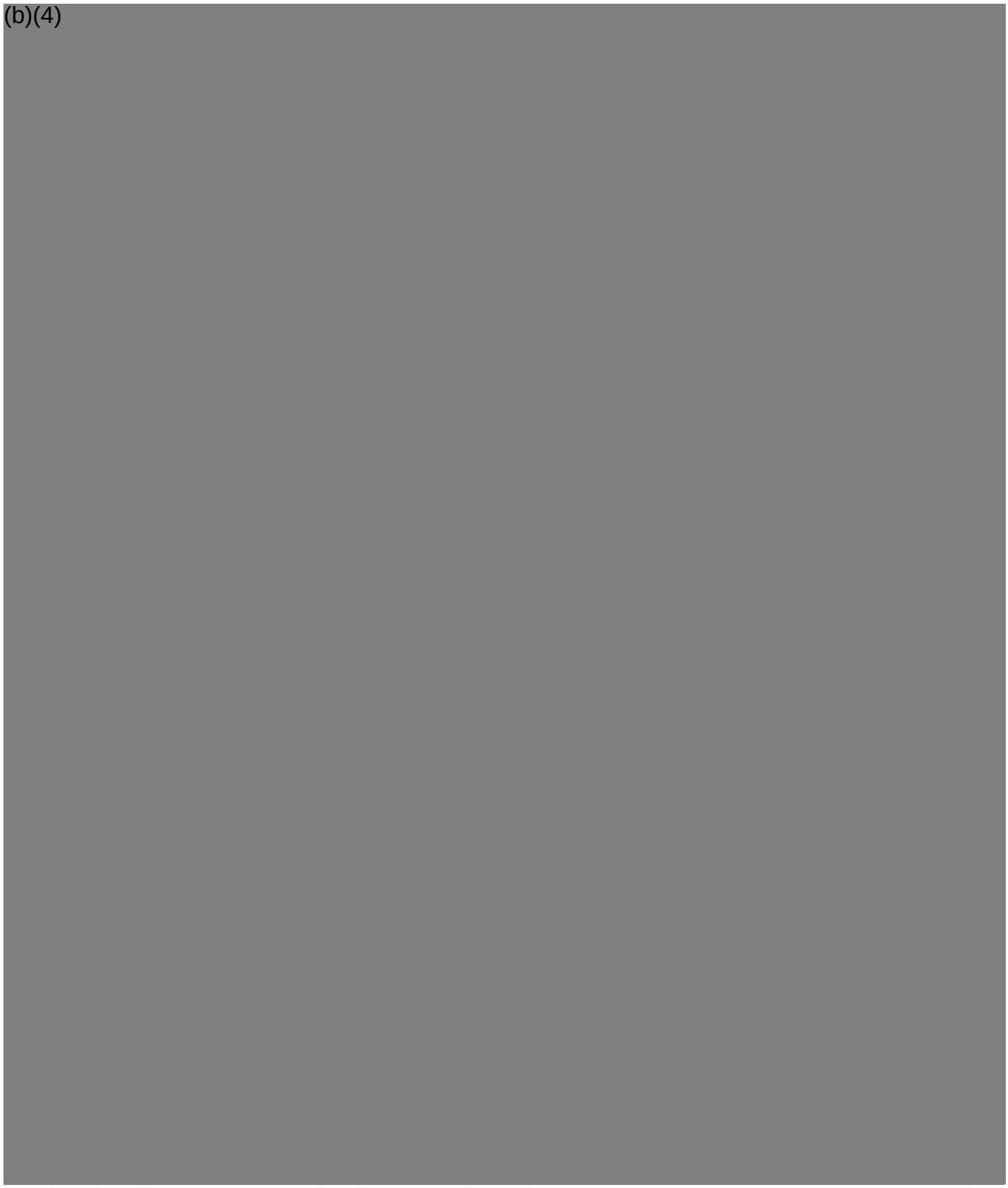

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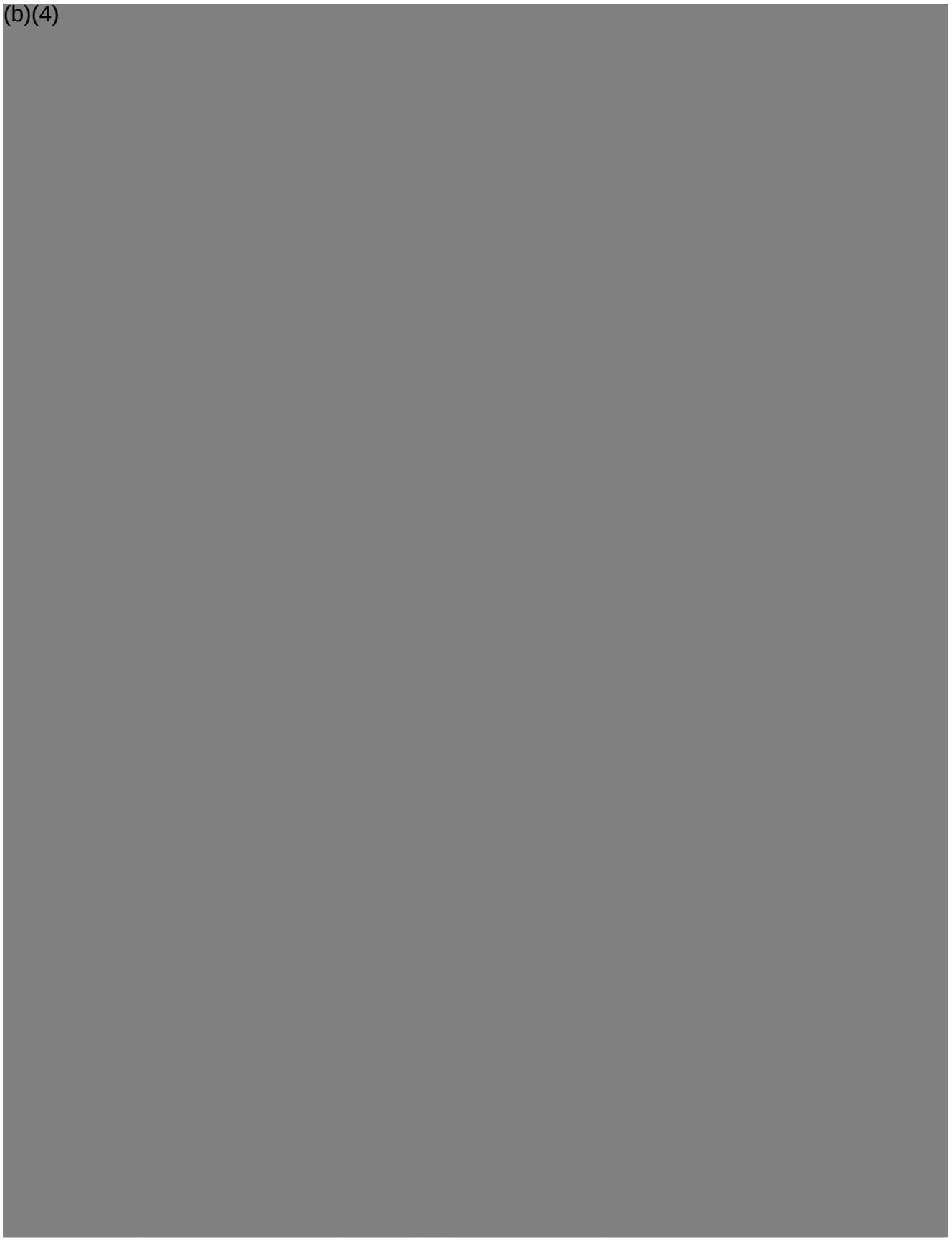

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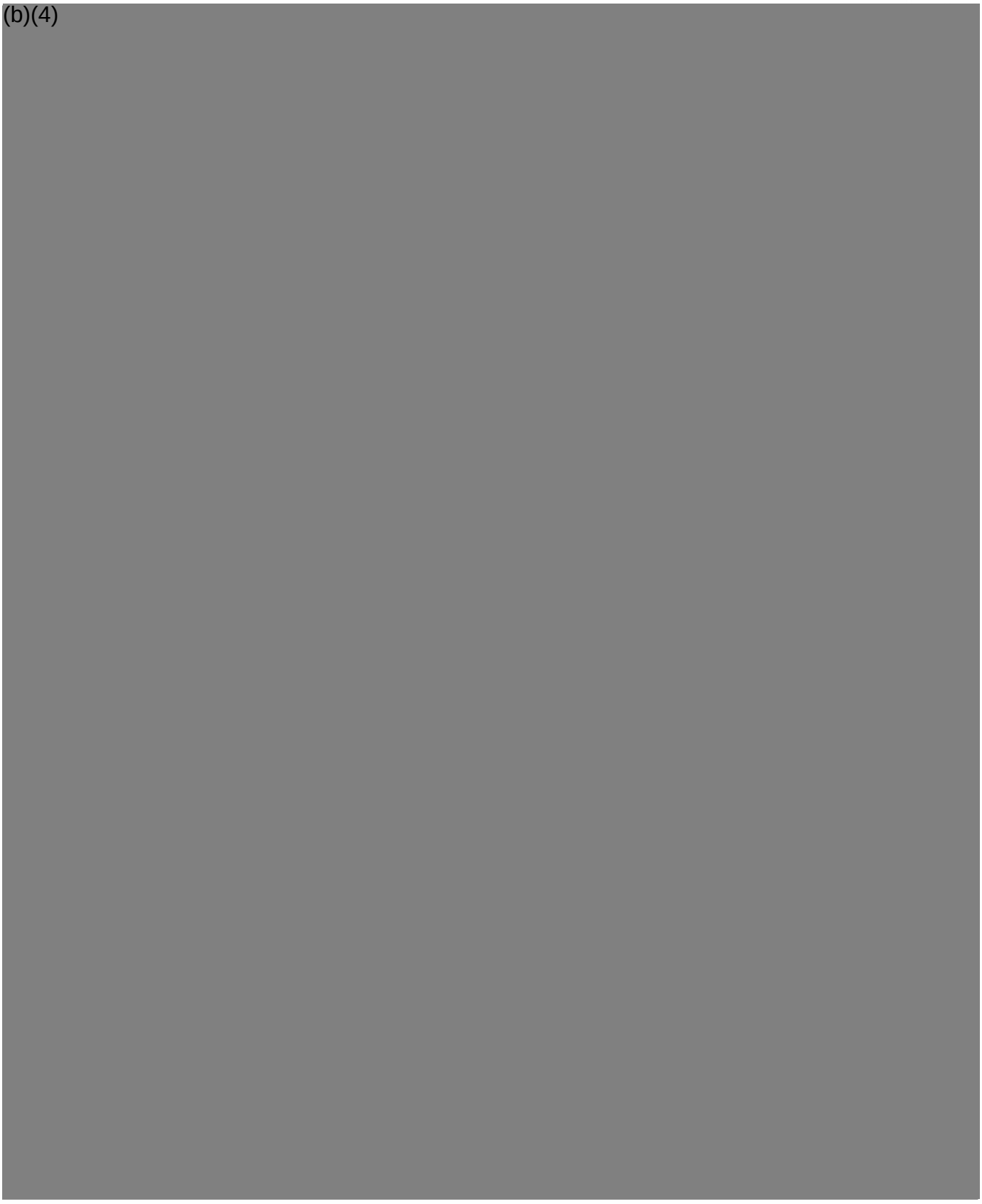

(b)(4)

XV. Contact History

Digital Signature Concurrence Table	
Reviewer Sign-Off	Ian P. Broverman -A Digitally signed by Ian P. Broverman -A DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=2000792945, cn=Ian P. Broverman -A Date: 2016.11.23 20:44:20 -05'00'