



Wright Medical Technology, Inc.
5677 Airline Road Arlington, TN 38002
www.wmt.com

510(K) SUMMARY

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807.92, this information serves as a Summary of Safety and Effectiveness for the use of the CHARLOTTE® CLAW® Plate System.

- 1. Submitted By:** Wright Medical Technology, Inc.
5677 Airline Road
Arlington, TN 38002
- Date:** February 27, 2014
- Contact Person:** Leslie Fitch
Senior Regulatory Affairs Specialist
(901) 867-4120
- 2. Proprietary Name:** CHARLOTTE® CLAW® Plate System
- Common Name:** Bone Plate System
Screw, Fixation, Bone
- Classification Name and Reference:** 21 CFR 888.3030 – Class II
21 CFR 888.3040 – Class II
- Device Product Code, Device Panel:** HRS: Orthopedic
HWC: Orthopedic
- 3. Predicate Devices:** K051908 – CHARLOTTE® CLAW® Plate System
K080295 – CHARLOTTE® CLAW® 3.5
K113014 – CLAW® II Polyaxial Compression Plating System
K043059 – Compression Staple and Simple Staple

4. Device Description

The CHARLOTTE® CLAW® Plate System consists of plates and screws of various anatomic configurations and lengths. All plates are manufactured from implant grade stainless steel and are available in lengths of 15-30 mm. The plates accept 2.7 mm (12-30 mm long) and 3.5 mm (14-40 mm long) locking screws. The locking thread feature of the screws engages the plate holes to prevent screw back-out.

5. Intended Use

The CHARLOTTE® CLAW® Plate System is intended to be used for fixation such as:

- Midfoot and hindfoot arthrodeses or osteotomies
- Tarsometatarsal arthrodeses (metatarsocuneiform, metatarsocuboid, and Lapidus arthrodeses)
- Intercuneiform arthrodeses
- Naviculocuneiform arthrodeses
- Talonavicular arthrodeses
- Calcaneocuboid arthrodeses
- Lisfranc arthrodeses
- Mono- or bi-cortical osteotomies in the forefoot, midfoot and hindfoot
- Fixation of osteotomies for hallux valgus treatment (Scarf and Chevron)
- Akin osteotomies
- First metatarsophalangeal arthrodeses

6. Technological Characteristics Comparison

The CHARLOTTE® CLAW® Plate System was cleared through K051908 and K080295 and previously compared to K043059. The technological features are identical to the systems previously cleared.

7. Substantial Equivalence – Non-Clinical Evidence

The purpose of this submission is to clarify the indication statement to be the same as the indications cleared in K113014 for CLAW® II Polyaxial Compression Plating System by adding specific joint arthrodesis that fall within the scope of the indications cleared through K051908 and K080295. Both the CHARLOTTE® CLAW® Plate System and the CLAW® II Polyaxial Compression Plating System share similar technical features and were found to be substantially equivalent in K113014, therefore we aim to consolidate the indication of both device systems. Performance testing and engineering rationales related to ultimate torque testing (lock and unlock), congruency analysis, pullout testing, four-point bending testing and brace expansion testing support the equivalence of the subject device.

8. Substantial Equivalence – Clinical Evidence

N/A

9. Substantial Equivalence – Conclusions

The design characteristics of the subject system do not raise any new types of questions of safety or effectiveness. From the evidence submitted in this 510(k), the subject devices can be expected to perform at least as well as the predicate systems.



February 28, 2014

Wright Medical Technology, Inc.
Ms. Leslie Fitch
Senior Regulatory Affairs Specialist
5677 Airline Road
Arlington, Tennessee 38002

Re: K133715

Trade/Device Name: CHARLOTTE® CLAW® Plate System

Regulation Number: 21 CFR 888.3030

Regulation Name: Single/multiple component metallic bone fixation appliances and accessories

Regulatory Class: Class II

Product Code: HRS, HWC

Dated: November 19, 2013

Received: December 6, 2013

Dear Ms. Fitch:

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

Page 2 – Ms. Leslie Fitch

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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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

Sincerely yours,

Vincent J. Devlin -S

for

Mark N. Melkerson

Director

Division of Orthopedic Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K133715

Device Name

CHARLOTTE® CLAW® Plate System

Indications for Use (Describe)

The CHARLOTTE® CLAW® Plate System is intended to be used for fixation such as:

- Midfoot and hindfoot arthrodeses or osteotomies
- Tarsometatarsal arthrodeses (metatarsocuneiform, metatarsocuboid, and Lapidus arthrodeses)
- Intercuneiform arthrodeses
- Naviculocuneiform arthrodeses
- Talonavicular arthrodeses
- Calcaneocuboid arthrodeses
- Lisfranc arthrodeses
- Mono- or bi-cortical osteotomies in the forefoot, midfoot and hindfoot
- Fixation of osteotomies for hallux valgus treatment (Scarf and Chevron)
- Akin osteotomies
- First metatarsophalangeal arthrodeses

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)

Elizabeth L. Frank -S

Division of Orthopedic Devices



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - W066-G609
Silver Spring, MD 20993-0002

February 28, 2014

Wright Medical Technology, Inc.
Ms. Leslie Fitch
Senior Regulatory Affairs Specialist
5677 Airline Road
Arlington, Tennessee 38002

Re: K133715

Trade/Device Name: CHARLOTTE® CLAW® Plate System

Regulation Number: 21 CFR 888.3030

Regulation Name: Single/multiple component metallic bone fixation appliances and accessories

Regulatory Class: Class II

Product Code: HRS, HWC

Dated: November 19, 2013

Received: December 6, 2013

Dear Ms. Fitch:

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Sincerely yours,

Vincent J. Devlin -S

for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Concurrence & Template History Page

[THIS PAGE IS INCLUDED IN IMAGE COPY ONLY]

Full Submission Number: K133715

For Office of Compliance Contact Information:

http://insideportlets.fda.gov:9010/portal/page?_pageid=197.415881&_dad=portal&_schema=PORTAL&org=318

For Office of Surveillance and Biometrics Contact Information:

http://insideportlets.fda.gov:9010/portal/page?_pageid=197.415881&_dad=portal&_schema=PORTAL&org=423

Digital Signature Concurrence Table	
Reviewer Sign-Off	Krutanjali Shah
Branch Chief Sign-Off	Elizabeth Frank Kunkoski
Division Sign-Off	Vincent J. Devlin 2014.02.28 09:32:41 -05'00'

f/t:

Template Name: K1(A) – SE after 1996

Template History:

Date of Update	By	Description of Update
7/27/09	Brandi Stuart	Added Updates to Boiler Table
8/7/09	Brandi Stuart	Updated HFZ Table
1/11/10	Diane Garcia	Liability/Warranty sentence added at bottom of 1 st page
10/4/11	M. McCabe Janicki	Removed IFU sheet and placed in Forms
9/25/12	Edwena Jones	Added digital signature format
12/12/12	M. McCabe Janicki	Added an extra line between letter signature block and the word "Enclosure". Also, added a missing digit in 4-digit extension on letterhead zip code: "002" should be "0002".
4/2/2013	M. McCabe Janicki	Edited sentence that starts "If you desire specific advice for your device on our labeling regulation (21 CFR Part 801)..." Replaced broken Compliance link with general link to DSMICA.
4/12/2013	Margaret McCabe Janicki	Fixed a typo: Paragraph 1, final sentence, "We remind you, however; that device labeling must be truthful..." Replaced incorrect semicolon with a comma.

Indications for Use

510(k) Number (if known)

K133715

Device Name

CHARLOTTE® CLAW® Plate System

Indications for Use (Describe)

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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)

Elizabeth L. Frank -S

Division of Orthopedic Devices



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5677 Airline Road Arlington, TN 38002
www.wmt.com

November 19, 2013

FDA CDRH DMC

DEC 05 2013

Received

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

RE: **Traditional 510(k) Premarket Notification**
CHARLOTTE® CLAW® Plate System

Dear Sir or Madam:

Pursuant to 21 CFR Part 807, Wright Medical Technology, Inc. is submitting this Traditional 510(k) Premarket Notification of its intent to market the CHARLOTTE® CLAW® Plate System.

The following regulatory declaration is stated:

CHARLOTTE® CLAW® Plate System	
Common Name:	Plate, Fixation, Bone
Classification:	888.3030
Device Class:	II
Device Panel:	Orthopedics
Product Codes:	HRS
Subsequent Code:	HWC

The subject device is currently marketed in the US with the indications cleared through K051908 and K080295. The purpose of this submission is the clarify the indication statement to be the same as the indications cleared in K113014 for CLAW® II Polyaxial Compression Plating System by adding specific joint arthrodesis that fall within the scope of the indications cleared through K051908 and K080295. Both the CHARLOTTE® CLAW® Plate System and the CLAW® II Polyaxial Compression Plating System were found to be substantially equivalent in K113014, therefore we aim to consolidate the indication of both device systems.

Additionally, this submission is intended to inform FDA of minor modifications that were implemented to the subject device system and did not necessitate a 510k submission according to the guidance "Deciding When to Submit a 510k for a Change to an Existing Device". These device changes are reported in this submission to ensure the reviewer is fully aware of the design features of the subject device and can accurately compare the subject and predicate device systems.

23

The design and use for this device include:

Design and Use of the Device

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

An original paper copy and identical electronic copy of this 510(k) Premarket Notification are enclosed. The electronic copy is provided on CD as an Acrobat Portable Document file (pdf). Additionally, for your convenience, a table of contents for this submission immediately follows this cover letter.

Wright Medical Technology, Inc. hereby requests that this submission and its contents be held as confidential, commercial information and, therefore, exempt from public disclosure. Please do not hesitate to contact me by phone at (901) 867-4120, by email at leslie.fitch@wmt.com, or by fax at (901) 867-4190 should you have any questions regarding this submission.

Kind Regards,



Leslie Fitch
 Senior Regulatory Affairs Specialist
 Wright Medical Technology, Inc.
 5677 Airline Road
 Arlington, TN 38002



Wright Medical Technology, Inc.
 5677 Airline Road Arlington, TN 38002
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November 19, 2013

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

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The design and use for this device include:

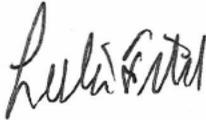
Design and Use of the Device

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

An original paper copy and identical electronic copy of this 510(k) Premarket Notification are enclosed. The electronic copy is provided on CD as an Acrobat Portable Document file (pdf). Additionally, for your convenience, a table of contents for this submission immediately follows this cover letter.

Wright Medical Technology, Inc. hereby requests that this submission and its contents be held as confidential, commercial information and, therefore, exempt from public disclosure. Please do not hesitate to contact me by phone at (901) 867-4120, by email at leslie.fitch@wmt.com, or by fax at (901) 867-4190 should you have any questions regarding this submission.

Kind Regards,



Leslie Fitch
Senior Regulatory Affairs Specialist
Wright Medical Technology, Inc.
5677 Airline Road
Arlington, TN 38002

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Contains Nonbinding Recommendations

Print Form

Acceptance Checklist for Traditional 510(k)s

(Should be completed within 15 days of DCC receipt)

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

510(k) #: 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 RTA and the element will be assessed during the substantive review.

Preliminary Questions		
Answers in the shaded blocks indicate consultations with Center advisor is needed	Yes	No
<p>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)?</p> <p>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 Office Jurisdiction Liaison to determine the appropriate action, and inform division management. <i>Provide a summary of the Jurisdictional Officer's/Liaison's determination.</i> If the product does not appear to be a device or such a combination product, mark "No."</p>	×	
Comments?		
<p>2. Is the application with the appropriate Center?</p> <p>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 application is not with the appropriate Center or you are unsure, consult with the CDRH Jurisdictional Officer or CBER Office Jurisdiction Liaison to determine the appropriate action and inform your division management. <i>Provide a summary of the Jurisdictional Officer's/Liaison's determination.</i> If application should not be reviewed by your Center mark "No."</p>	×	
Comments?		
<p>3) If a Request for Designation 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:</p> <p>a) Is the device or combination product the same (e.g., design, formulation) as that presented in the RFD submission?</p> <p>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 ?</p> <p>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 appropriate CBER Jurisdiction Liaison to determine the appropriate action and inform your division management. <i>Provide summary of Jurisdictional Officer's/Liaison's determination.</i> If the answer to either question is no, mark "No." If there was no RFD, skip this question.</p>		
Comments?		
<p>4) Is this device type eligible for a 510(k) submission?</p> <p>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."</p>	×	
Comments?		

<p>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.</p>		×
<p>Comments?</p>		
<p>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 - BIMO) 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</p>		×
<p>Comments?</p>		

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-BIMO or CBER/OCBQ/DIS/BMB, provide a summary of the discussion with the BIMO Staff, and indicate BIMO's recommendation/action.

Organizational Elements

Failure to include these items alone generally should not result in an RTA designation.

	Yes	No
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? Traditional 510(k)		

Elements of a Complete Submission (RTA Items)
(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision.
 - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.

	Yes	No	N/A	Comment
A. Administrative				
1) All content used to support the submission is written in English (including translations of test reports, literature articles, etc.)	X			
Comments?				
2) Submission identifies the following (such as in CDRH Premarket Review Submission Cover Sheet (Form 3514) or 510(k) cover letter):	X			
a) Device trade name or proprietary name	X			
b) Device common name	X			
c) Device class and panel or Classification regulation or Statement that device has not been classified with rationale for that conclusion	X			
Comments? See Tab 5 Section 3				
3) Submission contains Indications for Use Statement with Rx and/or OTC designation (see also 21 CFR 801.109).	X			
Comments? See Exhibit 1				
4) Submission contains 510(k) Summary or 510(k) Statement	X			
a) Summary contains all elements per 21 CFR 807.92 (See also 510(k) Summary Checklist)	X			
b) Statement contains all elements per 21 CFR 807.93			X	
Comments? See Exhibit 2				
5) Submission contains Truthful and Accuracy Statement per 21 CFR 807.87(k) See recommended format.	X			
Comments? See Exhibit 3				
6) Submission contains Class III Summary and Certification. See recommended content.			X	
Comments? Class II Device				
7) Submission contains clinical data			X	
Comments?				
8) If submission references use of a national or international standard as part of demonstration of substantial equivalence, submission contains Standards Data Report for 510(k)s (Form 3654) or includes detailed information about how and the extent to which the standard has been followed.	X			
Comments? See Tab 4				

Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision.
 - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.

Yes	No	N/A	Comment
-----	----	-----	---------

9) The submission identifies prior submissions for the same device for which FDA provided feedback related to the data or information needed to support substantial equivalence (e.g., submission numbers for Pre-Submission, IDE, prior not substantially equivalent (NSE) determination, prior 510(k) that was deleted or withdrawn) or states that there were no prior submissions for the subject device.

X			
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a) If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence outlined in prior communications are addressed. For additional information regarding the Pre-Submission process, please refer to the Draft Guidance "[Medical Devices: The Pre-Submission Program and Meetings with FDA Staff](#)." Once finalized, this guidance will represent the Agency's current thinking on this topic.

		X	
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Comments? Statement is located in Tab 5 at the end of section 9.

B. Device Description

10)

a) If there are requirements regarding the device description, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes device description information to establish that the submitter has followed the device-specific requirement.

		X	
--	--	---	--

b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes device description information to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.

		X	
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Comments?

11) Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling), including:

a) A description of the principle of operation and mechanism of action for achieving the intended effect.

X			
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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			
---	--	--	--

Comments? See Exhibit 5, Surgical Technique

12) Submission contains representative engineering drawing(s), schematics, illustrations and/or figures of the device that are clear, legible, labeled, and include dimensions.

X			
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Comments? See Exhibit 4, Engineering Drawings

13) If device is intended to be marketed with multiple components, accessories, and/or as part of a system

a) Submission includes a list of all components and accessories to be marketed with the subject device.

X			
---	--	--	--

Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision.
 - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.

	Yes	No	N/A	Comment
b) Submission includes a description (as detailed in item 11(a) and (b) and 12 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.	X			

C. Substantial Equivalence Discussion

14) Submitter has identified a predicate device.	X			
a) Predicate's 510(k) number, trade name, and model number (if applicable) provided. For predicates that are preamendments devices, information is provided to document preamendments status. <i>Information regarding documenting preamendment status is available online.</i>	X			
b) The identified predicate(s) is consistent throughout the submission (i.e., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing.	X			

Comments? See Tab 5 Section 3. K051908, K080295 and K113014

15) Submission includes a comparison of the following for the predicate(s) and subject device				
a) Indications for Use	X			
b) Technology, including features, materials, and principles of operation	X			

Comments? a) See Tab 5 Section 11

16) Submission includes an analysis of why any differences between the subject device and predicate(s) do not render the device NSE (e.g., does not constitute a new intended use; and any differences in technological characteristics are accompanied by information that demonstrates the device is as safe and effective as the predicate and do not raise different questions of safety and effectiveness than the predicate), affect safety or effectiveness, or raise different questions of safety and effectiveness (see section 513(i)(1)(A) of the FD&C Act and <u>21 CFR 807.87(f)</u>)	X			
--	---	--	--	--

Comments? See Tab 5 Section 11

D. Proposed Labeling (see also 21 CFR part 801)

If *in vitro* diagnostic (IVD) device, criteria 17, 18, & 19 may be omitted.

17) Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual) that include a description of the device, its intended use, and the directions for use.	X			
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) Submission includes directions for use that - include statements of all conditions, purposes or uses for which the device is intended (e.g., hazards, warnings, precautions, contraindications) AND - includes directions for layperson (see <u>21 CFR 801.5</u>) OR submission states that device qualifies for exemption per <u>21 CFR 801 Subpart D</u>	X			

Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision.
 - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.

Comments? See Exhibits 5, 6, and 7

	Yes	No	N/A	Comment
18) If indicated for prescription use, labeling includes the prescription use statement (see <u>21 CFR 801.109(b)(1)</u>) or "Rx only" symbol [See also <u>Alternative to Certain Prescription Device Labeling Requirements</u>]	X			

Comments? See Exhibit 7

19) General labeling provisions

a) Labeling includes name and place of business of the manufacturer, packer, or distributor (<u>21 CFR 801.1</u>).	X			
--	---	--	--	--

b) Labeling includes device common or usual name. (<u>21 CFR 801.61</u>)	X			
--	---	--	--	--

Comments? See Exhibit 7

20)

a) If there are requirements regarding labeling, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes labeling to establish that the submitter has followed the device-specific requirement.			X	
--	--	--	---	--

b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes labeling to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.			X	
--	--	--	---	--

c) If there is a special controls document applicable to the device, the submission includes labeling to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness.			X	
---	--	--	---	--

Comments?

21) If the device is an in vitro diagnostic device, provided labeling includes all applicable information required per <u>21 CFR 809.10</u> .			X	
---	--	--	---	--

Comments?

E. Sterilization

If IVD device and sterilization is not applicable, select "N/A" and criteria below will be omitted from checklist.				X
--	--	--	--	---

Submission states that the device and/or accessories are: (one of the below must be checked)

<input checked="" type="checkbox"/> provided sterile				
--	--	--	--	--

<input checked="" type="checkbox"/> provided non-sterile but sterilized by the end user				
---	--	--	--	--

<input type="checkbox"/> non-sterile when used				
--	--	--	--	--

<input type="checkbox"/> Information regarding the sterility status of the device is not provided.				
--	--	--	--	--

Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision.
 - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.

Yes No N/A Comment

This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.

Comments? See Tab 5 Section 13 and Exhibit 8

22) Assessment of the need for sterilization information

a) Identification of device, and/or accessories, and/or components that are provided sterile.

×

b) Identification of device, and/or accessories, and/or components that are end user sterilized.

×

c) Identification of device, and/or accessories, and/or components that are reusable and cleaning /disinfection instructions are provided.

×

23) If the device, and/or accessory, and/or a component is provided sterile:

a) Sterilization method is stated for each component (including parameters such as dry time for steam sterilization, radiation dose, etc.).

×

b) A description of method to validate the sterilization parameters (e.g., half-cycle method and full citation of FDA-recognized standard, including date) is provided for each proposed sterilization method. *Note, the sterilization validation report is not required.*

×

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.

×

d) Submission includes description of packaging and packaging contents (e.g., if multiple devices are included within the same package, Tyvek packaging, etc.)

×

e) Sterility Assurance Level (SAL) is stated.

×

24) If the device, and/or accessory, and/or a component is end user sterilized:

a) Sterilization method is stated for each component (including parameters such as dry time for steam sterilization, radiation dose, etc.).

×

b) A description of method to validate the sterilization parameters (e.g., half-cycle method and full citation of FDA-recognized standard, including date) is provided for each proposed sterilization method. *Note, the sterilization validation report is not required.*

×

c) Submission includes description of packaging and packaging contents (e.g., if multiple devices are included within the same package, Tyvek packaging, etc.).

×

d) Submission includes sterilization instructions for end user.

×

25)

a) If there are requirements regarding sterility, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes sterility information to establish that the submitter has followed the device-specific requirement.

×

Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision.
 - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.

Yes	No	N/A	Comment
		×	
		×	

b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes sterility information to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.

c) If there is a special controls document applicable to the device, the submission includes sterility information to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness.

F. Shelf Life

26) Proposed shelf life/expiration date stated

×			
---	--	--	--

Comments? See Exhibit 7, Labels. Expiration date is 8 years from the time of manufacture.

27) For sterile device, submission includes summary of methods used to establish that device will remain sterile through the proposed shelf life or a rationale for why testing to establish shelf life is not applicable.

×			
---	--	--	--

Comments? See Exhibit 9

28) Submission includes summary of methods used to establish that device performance is not adversely affected by aging or includes a rationale for why the storage conditions are not expected to affect device safety or effectiveness.

×			
---	--	--	--

Comments? See Tab 5 Section 13

G. Biocompatibility

If IVD device, select "N/A" and the below criteria will be omitted from checklist.

--	--	--	--

Submission states that there: (one of the below must be checked)

× are direct or indirect (e.g., through fluid infusion) patient-contacting components.

are no direct or indirect (e.g., through fluid infusion) patient-contacting components.

Information regarding the patient contact status of the device is not provided.

This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.

Comments? See Tab 5 Section 10

29) Submission includes list of patient-contacting device components and associated materials of construction, including identification of color additives, if present

×			
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Comments? All Charlotte Claw components are patient contacting. See Exhibit 5 and Tab 5 Sections 10 & 11

30) Submission identifies contact classification (e.g., surface-contacting, less than 24 hour duration, etc.)

×			
---	--	--	--

Comments? See Tab 5 Section 10, implanted for durations greater than 30 days

Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision.
 - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.

	Yes	No	N/A	Comment
31) 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			

Comments? See Tab 5 Section 14

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 regarding whether the device contains software is not provided.

This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.

Comments? See Tab 5 Section 14

I. EMC and Electrical Safety

Submission states that the device: (one of the below must be checked)

does require EMC and Electrical Safety evaluation.

X does not require EMC and Electrical Safety evaluation.

Information regarding whether the device requires EMC and Electrical Safety evaluation is not provided.

This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.

Comments? See Tab 5 Section 15

J. Performance Data - General

If IVD device, select "N/A" and the below criteria will be omitted from checklist. Performance data criteria relating to IVD devices will be addressed in Section K.

36) 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, and an explanation of how the data generated from the test supports a finding of substantial equivalence.	X			
--	---	--	--	--

Comments? See Exhibits 10 & 11

37)

Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision.
 - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.

Yes	No	N/A	Comment
		X	
		X	
		X	

- a) If there are requirements regarding performance data, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes performance data to establish that the submitter has followed the device-specific requirement.
- b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes performance data to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.
- c) If there is a special controls document applicable to the device, the submission includes performance data to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness.

Comments?

38) If literature is referenced in the submission, submission includes:

39) For each completed nonclinical (i.e., animal) study conducted

Comments? See Exhibit 10 and Tab 5 Section 10

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.

Comments? See Tab 5 end of Section 10

Decision: Accept Refuse to Accept

If Accept, notify applicant.

If Refuse to Accept, notify applicant in writing 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.

CLAW - Matt Paul

Form Approved: OMB No. 0910-511 Expiration Date: February 28, 2013. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION MEDICAL DEVICE USER FEE COVER SHEET		PAYMENT IDENTIFICATION NUMBER: (b)(4)Trade Secret Write the Payment Identification number on your check.	
A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/cover sheet.html			
1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code) WRIGHT MEDICAL TECHNOLOGIES INC 5677 AIRLINE ROAD ARLINGTON TN 38002 US		2. CONTACT NAME Gloria Grandberry 2.1 E-MAIL ADDRESS gloria.grandberry@wmt.com 2.2 TELEPHONE NUMBER (include Area code) 901-867-4582 2.3 FACSIMILE (FAX) NUMBER (Include Area code) 901-867-4190	
1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) (b)(4)Trade Secret			
3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/oc/mdufma Select an application type:			
<input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party <input type="checkbox"/> 513(g) Request for Information <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR) <input type="checkbox"/> Annual Fee for Periodic Reporting (APR) <input type="checkbox"/> 30-Day Notice		3.1 Select a center <input checked="" type="checkbox"/> CDRH <input type="checkbox"/> CBER 3.2 Select one of the types below <input checked="" type="checkbox"/> Original Application Supplement Types: <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP)	
4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)			
<input type="checkbox"/> YES, I meet the small business criteria and have submitted the required qualifying documents to FDA		<input checked="" type="checkbox"/> NO, I am not a small business	
4.1 If Yes, please enter your Small Business Decision Number:			
5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?			
<input checked="" type="checkbox"/> YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.)			
<input type="checkbox"/> NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/oc/mdufma for additional information)			
6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.			
<input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates		<input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population	
<input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only		<input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially	
7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).)			
<input type="checkbox"/> YES		<input checked="" type="checkbox"/> NO	
PAPERWORK REDUCTION ACT STATEMENT Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below. Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 1350 Piccard Drive, 4th Floor Rockville, MD 20850 [Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]			
8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION			
(b)(4)Trade Secret		05-Nov-2012	

(b)(4)Trade Secret
Form FDA 3601 (01/2007)

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Chaw-Christine / MAT-T Paul

Form Approved: OMB No. 0910-0511 Expiration Date: April 30, 2016. See Instructions for OMB Statement

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION MEDICAL DEVICE USER FEE COVER SHEET		PAYMENT IDENTIFICATION NUMBER: (b)(4)Trade Secret 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) WRIGHT MEDICAL TECHNOLOGIES INC 5677 AIRLINE ROAD ARLINGTON TN 38002 US		2. CONTACT NAME Gloria Grandberry 2.1 E-MAIL ADDRESS gloria.grandberry@wmt.com 2.2 TELEPHONE NUMBER (include Area code) 901-867-4582 2.3 FACSIMILE (FAX) NUMBER (Include Area code) 901-867-4190	
1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) (b)(4)Trade Secret			
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) <u>Select an application type:</u> <input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party <input type="checkbox"/> 513(g) Request for Information <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR) <input type="checkbox"/> 30-Day Notice			
3.1 Select a center <input checked="" type="checkbox"/> CDRH <input type="checkbox"/> CBER 3.2 Select one of the types below <input checked="" type="checkbox"/> Original Application <u>Supplement Types:</u> <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP)			
4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status) <input type="checkbox"/> YES, I meet the small business criteria and have submitted the required qualifying documents to FDA <input checked="" type="checkbox"/> NO, I am not a small business 4.1 If Yes, please enter your Small Business Decision Number:			
5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA? <input checked="" type="checkbox"/> YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.) <input type="checkbox"/> NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053165.htm for additional information)			
6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION. <input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates <input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population <input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only <input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially			
7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA)). <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO			
PAPERWORK REDUCTION ACT STATEMENT Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below. Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 1350 Piccard Drive, 4th Floor Rockville, MD 20850 [Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]			
8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (b)			29-Oct-2013

Form FDA 3601 (01/2007)

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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 OMB Statement on page 5.
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Date of Submission 11/19/2013	User Fee Payment ID Number (b)(4)Trade	FDA Submission Document Number (if known)
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SECTION A TYPE OF SUBMISSION

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

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

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name Wright Medical Technology, Inc.	Establishment Registration Number (if known) 1043534		
Division Name (if applicable)	Phone Number (including area code) 901.867.4120		
Street Address 5677 Airline Road	FAX Number (including area code) 901.867.4190		
City Arlington	State / Province TN	ZIP/Postal Code 38002	Country USA
Contact Name Leslie Fitch			
Contact Title Senior Regulatory Affairs Specialist		Contact E-mail Address leslie.fitch@wmt.com	

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name			
Division Name (if applicable)		Phone Number (including area code)	
Street Address		FAX Number (including area code)	
City	State / Province	ZIP Code	Country
Contact Name			
Contact Title		Contact E-mail Address	

SECTION D1			REASON FOR APPLICATION - PMA, PDP, OR HDE		
<input type="checkbox"/> New Device <input type="checkbox"/> Withdrawal <input type="checkbox"/> Additional or Expanded Indications <input type="checkbox"/> Request for Extension <input type="checkbox"/> Post-approval Study Protocol <input type="checkbox"/> Request for Applicant Hold <input type="checkbox"/> Request for Removal of Applicant Hold <input type="checkbox"/> Request to Remove or Add Manufacturing Site	<input type="checkbox"/> Change in design, component, or specification: <input type="checkbox"/> Software / Hardware <input type="checkbox"/> Color Additive <input type="checkbox"/> Material <input type="checkbox"/> Specifications <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Location change: <input type="checkbox"/> Manufacturer <input type="checkbox"/> Sterilizer <input type="checkbox"/> Packager			
<input type="checkbox"/> Process change: <input type="checkbox"/> Manufacturing <input type="checkbox"/> Packaging <input type="checkbox"/> Sterilization <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Labeling change: <input type="checkbox"/> Indications <input type="checkbox"/> Instructions <input type="checkbox"/> Performance Characteristics <input type="checkbox"/> Shelf Life <input type="checkbox"/> Trade Name <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Report Submission: <input type="checkbox"/> Annual or Periodic <input type="checkbox"/> Post-approval Study <input type="checkbox"/> Adverse Reaction <input type="checkbox"/> Device Defect <input type="checkbox"/> Amendment			
<input type="checkbox"/> Response to FDA correspondence:		<input type="checkbox"/> Change in Ownership <input type="checkbox"/> Change in Correspondent <input type="checkbox"/> Change of Applicant Address			
<input type="checkbox"/> Other Reason (specify):					
SECTION D2			REASON FOR APPLICATION - IDE		
<input type="checkbox"/> New Device <input type="checkbox"/> New Indication <input type="checkbox"/> Addition of Institution <input type="checkbox"/> Expansion / Extension of Study <input type="checkbox"/> IRB Certification <input type="checkbox"/> Termination of Study <input type="checkbox"/> Withdrawal of Application <input type="checkbox"/> Unanticipated Adverse Effect <input type="checkbox"/> Notification of Emergency Use <input type="checkbox"/> Compassionate Use Request <input type="checkbox"/> Treatment IDE <input type="checkbox"/> Continued Access	<input type="checkbox"/> Change in: <input type="checkbox"/> Correspondent / Applicant <input type="checkbox"/> Design / Device <input type="checkbox"/> Informed Consent <input type="checkbox"/> Manufacturer <input type="checkbox"/> Manufacturing Process <input type="checkbox"/> Protocol - Feasibility <input type="checkbox"/> Protocol - Other <input type="checkbox"/> Sponsor	<input type="checkbox"/> Response to FDA Letter Concerning: <input type="checkbox"/> Conditional Approval <input type="checkbox"/> Deemed Approved <input type="checkbox"/> Deficient Final Report <input type="checkbox"/> Deficient Progress Report <input type="checkbox"/> Deficient Investigator Report <input type="checkbox"/> Disapproval <input type="checkbox"/> Request Extension of Time to Respond to FDA <input type="checkbox"/> Request Meeting <input type="checkbox"/> Request Hearing			
<input type="checkbox"/> Report submission: <input type="checkbox"/> Current Investigator <input type="checkbox"/> Annual Progress Report <input type="checkbox"/> Site Waiver Report <input type="checkbox"/> Final					
<input type="checkbox"/> Other Reason (specify):					
SECTION D3			REASON FOR SUBMISSION - 510(k)		
<input type="checkbox"/> New Device	<input checked="" type="checkbox"/> Additional or Expanded Indications	<input type="checkbox"/> Change in Technology			
<input type="checkbox"/> Other Reason (specify):					

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed				Summary of, or statement concerning, safety and effectiveness information	
1	HRS	2		3	
5		6		7	
				<input checked="" type="checkbox"/> 510 (k) summary attached <input type="checkbox"/> 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	K113014	CLAW II Polyaxial Compression Plating System and ORTHOLOC 3DSi Locking Screws	1	Wright Medical Technology, Inc.
2	K080295	CHARLOTTE Claw 3.5	2	Wright Medical Technology, Inc.
3	K051908	CHARLOTTE Compression Plate	3	Wright Medical Technology, Inc.
4			4	
5			5	
6			6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name
 Plate, Fixation, Bone

	Trade or Proprietary or Model Name for This Device		Model Number
1	CHARLOTTE CLAW Plate System	1	Variable
2		2	
3		3	
4		4	
5		5	

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

1	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

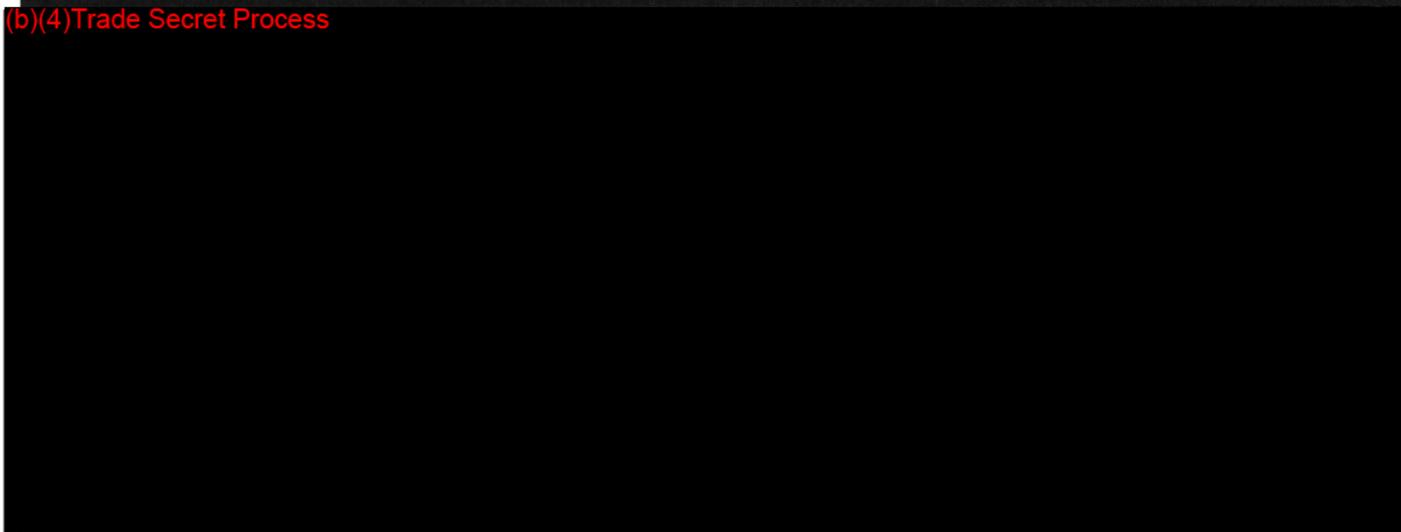
Laboratory Testing
 Animal Trials
 Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code HRS	C.F.R. Section (if applicable) 888.3030	Device Class <input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified
Classification Panel Orthopedics		
Indications (from labeling) See statement of Indications for Use		

Note: Submission of the information entered in Section H does not affect the need to submit device establishment registration.		FDA Document Number <i>(if known)</i>	
SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION			
<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	Facility Establishment Identifier (FEI) Number 1043534	<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Manufacturer	<input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Repackager / Relabeler
Company / Institution Name Wright Medical Technology		Establishment Registration Number 1043534	
Division Name <i>(if applicable)</i> Regulatory Affairs		Phone Number <i>(including area code)</i> 901.867.4120	
Street Address 5677 Airline Road		FAX Number <i>(including area code)</i> 901.867.4190	
City Arlington	State / Province TN	ZIP Code 38002	Country USA
Contact Name Leslie Fitch	Contact Title Senior Regulatory Affairs Specialist	Contact E-mail Address leslie.fitch@wmt.com	

(b)(4)Trade Secret Process



<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	Facility Establishment Identifier (FEI) Number	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Manufacturer	<input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name <i>(if applicable)</i>		Phone Number <i>(including area code)</i>	
Street Address		FAX Number <i>(including area code)</i>	
City	State / Province	ZIP Code	Country
Contact Name	Contact Title	Contact E-mail Address	

SECTION I UTILIZATION OF STANDARDS

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

	Standards No.	Standards Organization	Standards Title	Version	Date
1	F138	ASTM	Standard Specification for Wrought 18 Chromium-14 Nickel-2.5 Molybdenum Stainless Steel Bar and Wire for Surgical Implants	08	
2	F139	ASTM	Standard Specification for Wrought, Nitrogen Strengthened 23 Manganese-21 Chromium-1 Molybdenum Low-Nickle Stainless Steel Alloy Bar and Wire for Surgical Implants	08	
3	F543	ASTM	Standard Specification and Test Methods for Metallic Medical Bone Screws	02	
4	F382	ASTM	Standard Specification and Test Method for Metallic Bone Plates	2003	
5					
6					
7					

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

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

Department of Health and Human Services
 Food and Drug Administration
 Office of Chief Information Officer
 1350 Piccard Drive, Room 400
 Rockville, MD 20850

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

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

TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

ASTM F138 Standard Specification for Wrought 18 Chromium-14 Nickel-2.5 Molybdenum Stainless Steel Bar and Wire

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ #8-169

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: _____

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>

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

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

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

⁶ The online search for CDRH Guidance Documents can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>

**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
----------------	---------------	---

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
----------------	---------------	---

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
----------------	---------------	---

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

* 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.

† Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour 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:

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Rockville, MD 20850

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Department of Health and Human Services
Food and Drug Administration
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 F139 - Standard Specification for Wrought 18 Chromium-14 Nickel-2.5 Molybdenum Stainless Steel Sheet

Please answer the following questions

Yes No

Is this standard recognized by FDA ² ?

FDA Recognition number ³ #8-58

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: _____

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>

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

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

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

⁶ The online search for CDRH Guidance Documents can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>

**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

* 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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 Rockville, MD 20850

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Department of Health and Human Services
Food and Drug Administration
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 F 382 Standard Specification and Test Methods for Metallic Bone Plates

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ #11-214

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: _____

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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address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.
⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>
⁶ The online search for CDRH Guidance Documents can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>

**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE
ASTM F 382 Standard Specification and Test Methods for Metallic Bone Plates

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
----------------	---------------	---

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
----------------	---------------	---

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
----------------	---------------	---

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

* 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
(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

ASTM F 543 Standard Specification and Test Methods for Metallic Bone Screws

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ #11-210

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: _____

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

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

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

⁶ The online search for CDRH Guidance Documents can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE ASTM F 543 - 07 Standard Specification and Test Methods for Metallic Bone Screws		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
<p>* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.</p> <p>† Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.</p>		
Paperwork Reduction Act Statement		
<p>Public reporting burden for this collection of information is estimated to average 1 hour 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:</p> <p style="margin-left: 40px;">Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer 1350 Piccard Drive, Room 400 Rockville, MD 20850</p> <p style="margin-left: 40px;"><i>An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.</i></p>		

CHARLOTTE® CLAW® Plate
TRADITIONAL PREMARKET 510(k) NOTIFICATION

1. MANUFACTURER IDENTIFICATION

Date of Application: December 1, 2013

Manufacturer's Name: Wright Medical Technology, Inc.
5677 Airline Road
Arlington, TN 38002

Establishment Registration Number: 1043534

Primary Contact: Leslie Fitch
Senior Regulatory Affairs Specialist
Phone: 901-867-4120 Fax: 901-867-4190

Secondary Contact: Jeanine Redden
Director, Regulatory Affairs
Phone: 901-867-4522 Fax: 901-867-4190

2. EXECUTIVE SUMMARY**Device Description**

The CHARLOTTE™ CLAW® Compression Plate system was originally cleared through K051908 as a two-hole compression plate utilizing 2.7mm locking screws. The primary purpose of this 510(k) is to clear more specific indications to align the indications of the CHARLOTTE® CLAW® Plate System with the previously cleared indications of the CLAW® II Polyaxial Compression Plating System.

(b)(4)Trade Secret Process

These design changes include:

- Modifying the screw locking feature (b)(4)Trade Secret Process
- Updating the driver/screw interface from a cruciform driver/screw interface to a hex interface
- Adding additional screw lengths to the system (b)(4)Trade Secret Process

A four-hole plate design that utilized 3.5mm locking screws was then added to this system through K080295 (b)(4)Trade Secret Process

This design change is also included in the scope of this submission:

- A two-hole plate design was designed that used the same 3.5mm locking screws that were cleared in K080295. A two-hole plate had previously been cleared in K051908, so this update provides a full offering of products in 2 and 4 hole configurations for the previously cleared 3.5mm locking screw.

The indications below are the updated indications for Use.

Indications for Use

The CHARLOTTE® CLAW® Plate System is intended to be used for fixation such as:

- Midfoot and hindfoot arthrodeses or osteotomies
- Tarsometatarsal arthrodeses (metatarsocuneiform, metatarsocuboid, and Lapidus arthrodeses)
- Intercuneiform arthrodeses
- Naviculocuneiform arthrodeses
- Talonavicular arthrodeses
- Calcaneocuboid arthrodeses
- Lisfranc arthrodeses
- Mono- or bi-cortical osteotomies in the forefoot, midfoot and hindfoot
- Fixation of osteotomies for hallux valgus treatment (Scarf and Chevron)
- Akin osteotomies
- First metatarsophalangeal arthrodeses

Substantial Equivalence

The subject components were demonstrated to be substantially equivalent to CHARLOTTE® CLAW® system components manufactured by Wright Medical Technology, Inc. and cleared by the FDA in K051908 (S.E. 08/10/2005) and K080295 (S.E. 02/27/2008) as well as CLAW® II system components manufactured by Wright Medical Technology, Inc. and cleared by the FDA in K113014 (S.E. 01/31/2012).

Performance Testing

Mechanical testing, including torsion, pullout, four-point bending, and brace expansion have been performed on the subject CHARLOTTE® CLAW® Plate and the results have shown them to be substantially equivalent to the predicate plate systems. (b)(4)Trade Secret Process were utilized for the torsion, pullout and four-point bending testing.

3. DEVICE IDENTIFICATION

	Subject Device	Predicate Devices	
Proprietary Names:	CHARLOTTE® CLAW® Plate System	CHARLOTTE® CLAW® Plate System (K051908 and K080295)	CLAW® II Polyaxial Compression Plating System (K113014)
Common Name:	Plate, Fixation, Bone	Plate, Fixation, Bone	Plate, Fixation, Bone
Classification:	Class II	Class II	Class II
Reference:	21 CFR 888.3030– Single/Multiple component metallic bone fixation appliances and accessories.	21 CFR 888.3030– Single/Multiple component metallic bone fixation appliances and accessories.	21 CFR 888.3030– Single/Multiple component metallic bone fixation appliances and accessories.
Device Panel:	Orthopedic	Orthopedic	Orthopedic
Product Code:	HRS	HRS	HRS
Subsequent Product Code:	HWC	HWC	HWC

4. **INDICATION STATEMENT**

The indications for use statements of the subject device is provided in **Exhibit 1** and reiterated below for your convenience:

The CHARLOTTE® CLAW® Plate System is intended to be used for fixation such as:

- Midfoot and hindfoot arthrodeses or osteotomies
- Tarsometatarsal arthrodeses (metatarsocuneiform, metatarsocuboid, and Lapidus arthrodeses)
- Intercuneiform arthrodeses
- Naviculocuneiform arthrodeses
- Talonavicular arthrodeses
- Calcaneocuboid arthrodeses
- Lisfranc arthrodeses
- Mono- or bi-cortical osteotomies in the forefoot, midfoot and hindfoot
- Fixation of osteotomies for hallux valgus treatment (Scarf and Chevron)
- Akin osteotomies
- First metatarsophalangeal arthrodeses

5. **510(k) SUMMARY**

A 510(k) Summary is included in **Exhibit 2**.

6. **TRUTHFUL AND ACCURACY STATEMENT**

A Truthful and Accuracy Statement is included in **Exhibit 3**.

7. **CLASS III SUMMARY AND CERTIFICATION**

Not Applicable. This device is not a Class III product.

8. **FINANCIAL CERTIFICATION OR DISCLOSURE STATEMENT**

Not Applicable. Clinical trials were not performed.

9. **DECLARATION OF CONFORMITY AND SUMMARY REPORT**

Not Applicable. This is a Traditional Premarket Notification.

10. DEVICE DESCRIPTION

The CHARLOTTE™ CLAW® Compression Plate system was originally cleared through K051908 as a two-hole compression plate utilizing 2.7mm locking screws. Minor design modifications were made to this device system based on surgeon feedback (b)(4)Trade Secret Process. These design changes include modifying the screw locking feature, updating the driver/screw interface, and adding larger screw sizes to the system. A four-hole plate design that utilized 3.5mm locking screws was then added to this system through K080295. A minor design modification was again made to the system based on surgeon feedback (b)(4)Trade Secret Process. This design change added a two-hole plate design that used the same 3.5mm locking screws. The entire subject device plate system in its current form is described below and engineering drawings of the subject and predicate systems are provided in **Exhibit 4**.

SUBJECT DEVICE - IMPLANTS

The current CHARLOTTE™ CLAW® Compression Plate is a highly versatile implant for osteotomies and arthrodeses of the foot. It is particularly useful for calcaneal-cuboid, talonavicular and midfoot arthrodesis as well as corrective osteotomies of the calcaneous, midfoot and forefoot. (b)(4)Trade Secret Process

The CHARLOTTE® CLAW® Plate System consists of plates and screws of various anatomic configurations and lengths. All plates are manufactured from stainless steel and are available in lengths of 15-30mm.

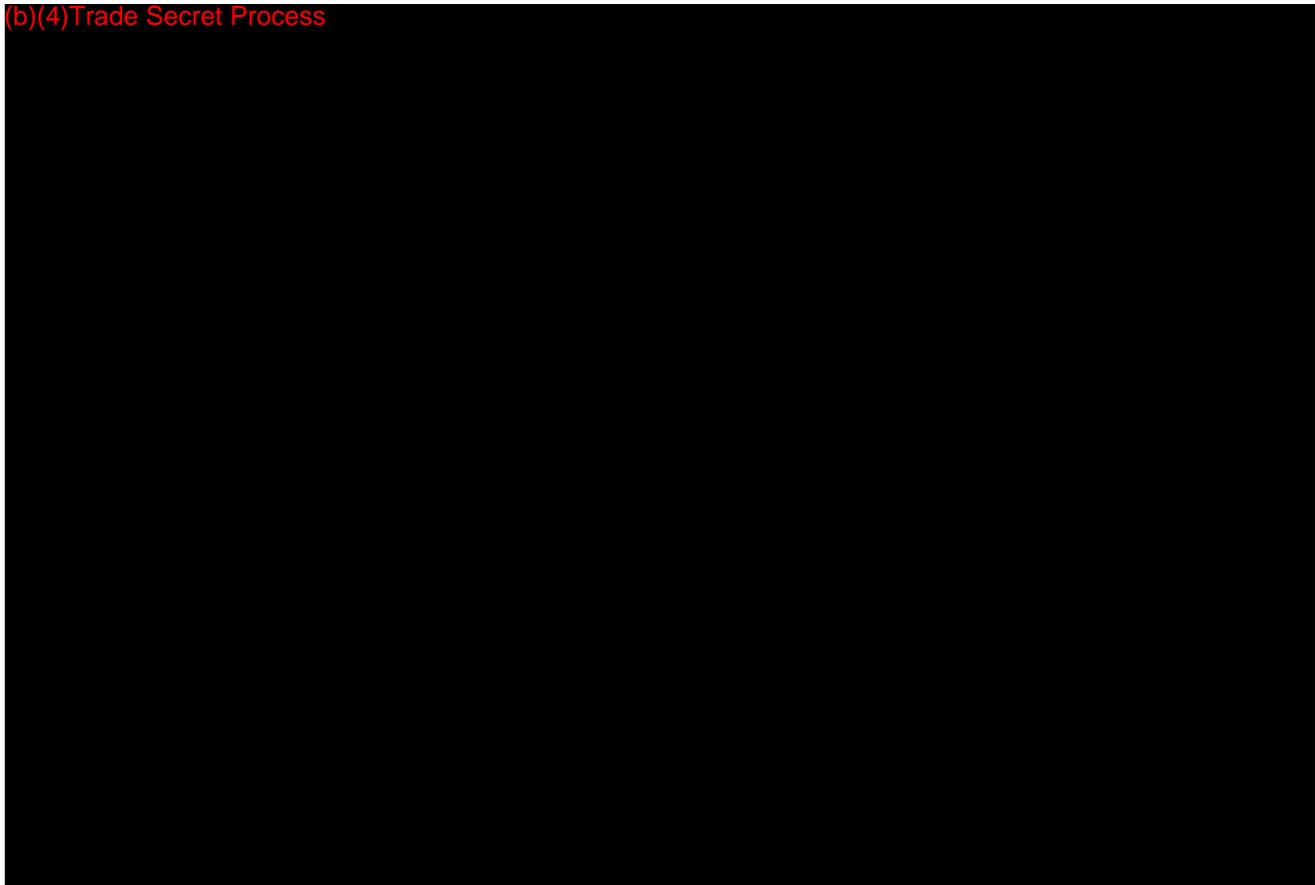
The plates accept 2.7mm (b)(4)Trade or 3.5mm (b)(4)Trade locking screws manufactured from stainless steel. The locking thread feature of the screws engages the plate holes to prevent screw back-out.

Table 1: CHARLOTTE® CLAW® Plate System Options

(b)(4)Trade Secret Process



(b)(4) Trade Secret Process



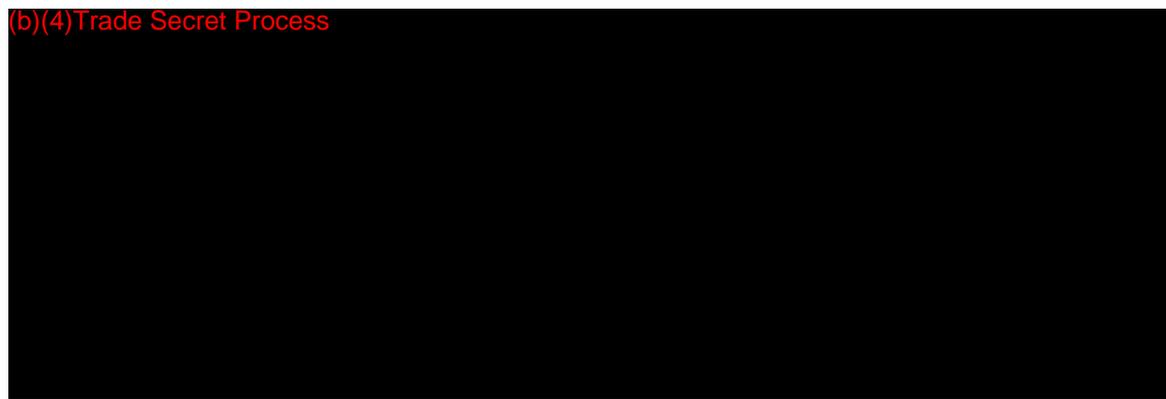
Minor Design Changes to the 2.7mm Plates

The following minor modifications to CLAW® system were implemented based on surgeon feedback.

Updated locking mechanism: (b)(4) Trade Secret Process



(b)(4) Trade Secret Process



(b)(4)Trade Secret Process [REDACTED] The plate dimensions were increased slightly to accommodate a slightly larger diameter screw head. (b)(4)Trade Secret Process [REDACTED]

Change in driver/screw interface: The cruciform driver/screw interface of the cleared design was replaced with a hex interface.

Additional screw lengths: Additional length screws were added to the system to better meet anatomic variability among patients. The CLAW® system cleared through K051908 included 2.7mm diameter screws offered in lengths ranging from 12-24mm. This submission is adding 3 longer screws (b)(4)Trade [REDACTED]

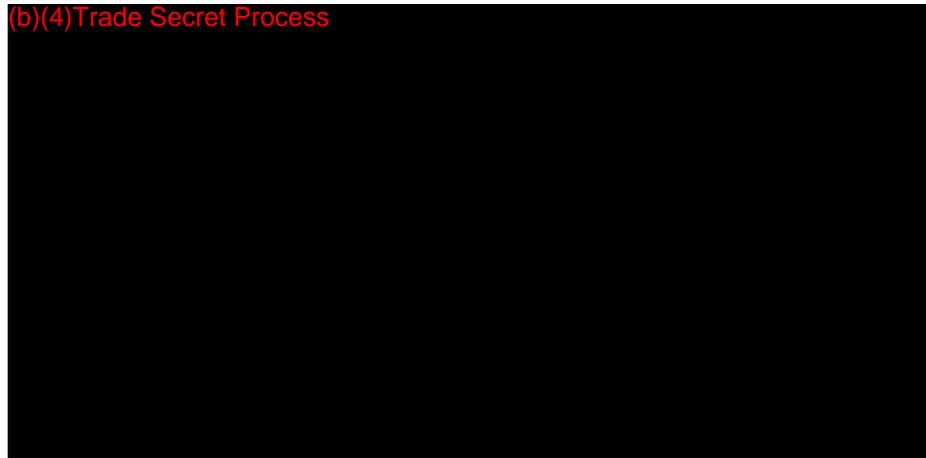
K080295

Through the clearance of K080295 (i.e., CHARLOTTE™ CLAW® 3.5), the CHARLOTTE® CLAW® Plate System was expanded to include four-hole plates that were (b)(4)Trade Secret long and accepted 3.5mm diameter locking screws (14-40mm long). All the plates and screws in the system are composed of stainless steel (b)(4)Trade Secret Process [REDACTED]

(b)(4)Trade Secret Process [REDACTED]

(b)(4)Trade Secret Process [REDACTED]

feature is provided in **Figure 5**.



Minor Design Changes to the 3.5mm Plates

A 2-hole version of the CHARLOTTE™ CLAW® plate that accepted 3.5mm diameter locking screws was added to the CHARLOTTE™ CLAW® product line (b)(4)Trade Secret Process. This 2-hole CHARLOTTE™ CLAW® plate for 3.5mm diameter locking screws was determined to be equivalent to the 510(k)-cleared 4-hole CHARLOTTE™ CLAW® Plate (K080295) and 2-hole CHARLOTTE™ CLAW® Plate (K051908). The 2-hole plate shares the same indications for use, material composition, and basic design features as both predicates. In addition, the subject 2-hole CLAW® plate shares the same size ranges, sterilization process, and tapered locking mechanism with the 4-hole CLAW® plate that accepts a 3.5mm diameter locking screw and was cleared in K080295. Therefore the subject 2-hole CHARLOTTE™ CLAW® Plate is a combination of features that have previously been cleared in K051908 and K080295.

Table 2 compares the subject 2-hole CLAW® that accepts a 3.5mm locking screw to the predicate devices cleared through K080295 and K051908. **Figures 6 and 7** illustrate the location of each dimension on the plate. All the dimensions for the subject 2-hole CLAW® plate that accepts a 3.5mm locking screw are between the predicate 510(k) cleared devices.

Table 2 CHARLOTTE® CLAW® Plate Comparison.

Description	CHARLOTTE® CLAW® Plate System 3.5mm Screws 2-hole Configuration (subject device)		CHARLOTTE® CLAW® Plate System 3.5mm Screws 4-hole Configuration (K080295)		CHARLOTTE® CLAW® Plate System 2.7mm Screws 2-hole Configuration (K051908)	
	20mm	30mm	20mm	30mm	15mm	25mm
Plate Size (shortest and longest)	20mm	30mm	20mm	30mm	15mm	25mm
510(k) Number	Subject		K080295		K051908	
Materials	Stainless Steel (b)(4)Tra		Stainless Steel (b)(4)Tra		Stainless Steel (b)(4)Tra	
Locking Mechanism	(b)(4)Trade		(b)(4)Trade		(b)(4)Trade Secret	
Locking Screw Type	3.5mm		3.5mm		2.7 mm	

	14 – 40mm long	14 – 40mm long	12 – 24 mm long
# of Locking Screw Holes	(b)(4)Trade Secret Process		
Brace Thickness (in)			
Brace Width (in)			
Interaxis Length - (in)			
Olive Length - (in)			
Sterility	Sterile or sterilized by end user	Sterile or sterilized by end user	Sterilized by end user

(b)(4)Trade Secret Process

K113014

The CHARLOTTE® CLAW® Plate System was proven to be substantially equivalent to CLAW® II Polyaxial Compression Plating System through K113014. The indications of the CLAW® II Polyaxial Compression Plating System were expanded in K113014.

The subject device is currently marketed in the US with the cleared indications shown in **Table 3**. These indications include midfoot and hindfoot arthrodesis osteotomies. This submission is also to add more specific arthrodeses into the indication statement for the CHARLOTTE® CLAW® Plate System that fall within the more general indications cleared previously in K051908 and K080295. The CLAW® II Polyaxial Compression Plating System (K113014) is already cleared with these more specific arthrodesis indications and possesses similar design features to the CHARLOTTE® CLAW® Plate System. The indications for use of both the subject and predicate devices are shown below in **Table 3**. The indications highlighted in yellow are the more specific arthrodeses indications for the CHARLOTTE® CLAW® Plate System that differ from the indications cleared through K051908 and K080295. These indications fall within the cleared “midfoot and hindfoot arthrodeses or osteotomies” indications of K051908 and K080295 highlighted in red and are identical to the indications for the CLAW® II Polyaxial Compression Plating System, K113014.

Table 3: Indications of the Predicate Plating Systems

	Subject Device	Predicate Devices	
Proprietary Names:	CHARLOTTE® CLAW® Plate System	CHARLOTTE® CLAW® Plate System (K051908 and K080295)	CLAW® II Polyaxial Compression Plating System (K113014)
Indication for Use Statement:	<p>The CHARLOTTE® CLAW® Plate System is intended to be used for fixation such as:</p> <ul style="list-style-type: none"> • Midfoot and hindfoot arthrodeses or osteotomies • Tarsometatarsal arthrodeses (metatarsocuneiform, metatarsocuboid, and Lapidus arthrodeses) • Intercuneiform arthrodeses • Naviculocuneiform arthrodeses • Talonavicular arthrodeses • Calcaneocuboid arthrodeses • Lisfranc arthrodeses • Mono- or bi-cortical osteotomies in the forefoot, midfoot and hindfoot • Fixation of osteotomies for hallux valgus treatment (Scarf and Chevron) • Akin osteotomies • First metatarsophalangeal arthrodeses 	<p>The CHARLOTTE™ CLAW® Plate is intended to be used for fixation such as: Lisfranc arthrodesis, mono or bi-cortical osteotomies in the forefoot, first metatarsophalangeal arthrodesis, Akin osteotomy, midfoot and hindfoot arthrodeses or osteotomies, fixation of osteotomies for hallux valgus treatment (Scarf and Chevron), and arthrodesis of the metatarsocuneiform joint to reposition and stabilize metatarsus primus varus.</p>	<p>The CLAW® II Polyaxial Compression Plating System is intended to be used for fixation such as:</p> <ul style="list-style-type: none"> • Midfoot and hindfoot arthrodeses or osteotomies • Tarsometatarsal arthrodeses (metatarsocuneiform, metatarsocuboid, and Lapidus arthrodeses) • Intercuneiform arthrodeses • Naviculocuneiform arthrodeses • Talonavicular arthrodeses • Calcaneocuboid arthrodeses • Lisfranc arthrodeses • Mono- or bi-cortical osteotomies in the forefoot, midfoot and hindfoot • Fixation of osteotomies for hallux valgus treatment (Scarf and Chevron) • Akin osteotomies • First metatarsophalangeal arthrodeses

In addition, the critical design features of both the CHARLOTTE® CLAW® Plate System and the CLAW® II Polyaxial Compression Plating System are compared in **Table 4** below.

Table 4: Technical Comparison between CHARLOTTE® CLAW® Plate System and the CLAW® II Polyaxial Compression Plating System

	Subject Device	Predicate Device	Differences
Proprietary Names:	CHARLOTTE® CLAW® Plate System	CLAW® II Polyaxial Compression Plating System (K113014)	
(b)(4)Trade Secret Process			

	Subject Device	Predicate Device	
Proprietary Names:	CHARLOTTE® CLAW® Plate System	CLAW® II Polyaxial Compression Plating System (K113014)	Differences

(b)(4)Trade Secret Process



	Subject Device	Predicate Device	
Proprietary Names:	CHARLOTTE® CLAW® Plate System	CLAW® II Polyaxial Compression Plating System (K113014)	Differences
(b)(4)Trade Secret Process			

Substantial Equivalence Flow Chart

The following are responses to FDA’s 510(k) Substantial Equivalence Decision-Making Process Flow Chart.

Does the New Device Have the Same Indication Statement? Yes

The subject device is currently marketed in the US with the indications cleared through K051908 and K080295. The purpose of this submission is the clarify the indication statement to be the same as the indications cleared in K113014 for CLAW® II Polyaxial Compression Plating System by adding specific joint arthrodesis that fall within the scope of the indications cleared through K051908 and K080295. Both the CHARLOTTE® CLAW® Plate System and the CLAW® II Polyaxial Compression Plating System were found to be substantially equivalent in K113014, therefore we aim to consolidate the indication of both device systems.

Does the New Device Have the Same Technological Characteristics? Yes

The new device has the same technological characteristics as the predicate. It features a similar design as well as identical materials. The technical features of the subject device are identical to the CHARLOTTE® CLAW® Plate System currently marketed in the US that was cleared through K051908 and K080295. The subject device also has similar technical features as the CLAW® II Polyaxial Compression Plating System and the substantial equivalence between these devices was established in K113014.

Are the Descriptive Characteristics Precise Enough to Ensure Equivalence? Yes

The descriptive characteristics outlined in the substantial equivalence section outlined in **Section 10** are precise enough to ensure equivalence.

Are Performance Data Available and Demonstrate Equivalence? Yes

The design of this system was (b)(4)Trade Secret Process proven to be equivalent to the cleared system through verification testing described in **Section 16** of this submission.

Conclusion

Based on the above responses to the questions provided in the 510(k) “Substantial Equivalence” Decision-Making Process and data presented within this Premarket Notification, Wright Medical Technology’s CHARLOTTE® CLAW® Plate System is substantially equivalent to the two predicate devices identified in **Section 2** of this submission.

12. PROPOSED LABELING

Important medical information is contained in the package insert provided in **Exhibit 6**. Samples of the package labels are provided in **Exhibit 7**. Per FDA’s requirement that symbols be defined, a symbol definition label is provided in **Exhibit 7**. This label will be applied to the outer carton or packaging near the product label. All carton labels have the same general design and follow the same format. A surgical technique is also provided as **Exhibit 5**.

13. STERILIZATION AND SHELF-LIFE

STERILIZATION

The subject CHARLOTTE® CLAW® Plate System presents no change in sterilization or packaging from the predicates. The subject CHARLOTTE® CLAW® Plate System are provided sterile or non-sterile. Parts provided sterile are sterilized by gamma radiation; a gamma sterilization process summary is provided in **Exhibit 8**. Sterilization instructions for parts provided non-sterile can be found in the package insert (**Exhibit 6**) and a summary is also provided in **Exhibit 8**.

SHELF-LIFE

The sterile devices are labeled with an 8 year shelf life. Wright Medical’s sterile packaging configuration has been validated to an 8 year shelf life (**Exhibit 9**). This is identical to the Shelf-Life of the predicate devices, as no change has been made to affect the shelf life.

14. BIOCOMPATIBILITY

There has been no change in the materials used in the CHARLOTTE® CLAW® Plating System, and thus, no change in Biocompatibility. The CHARLOTTE® CLAW® Plate System implants are manufactured from (b)(4)Trade Secret Stainless Steel. (b)(4)Trade Secret Process

(b)(4) Trade Secret Process

The instruments are composed of biocompatible materials that meet the requirements of the following standards:

- (b)(4) Trade Secret Process

Wright Medical has a long history of using instruments composed of materials conforming to the standards listed above. Instruments composed of these materials are an integral part of our cleared devices, including CHARLOTTE® CLAW® Plate System (K051908 and K080295) and CLAW® II Polyaxial Compression Plating System (K113014).

15. SOFTWARE

Not applicable. This product does not contain software.

16. ELECTROMAGNETIC COMPATIBILITY AND ELECTRICAL SAFETY

Not applicable. This product does not contain electrical components.

17. PERFORMANCE TESTING – BENCH

Verification of Minor Design Changes to the 2.7mm Plates

(b)(4) Trade Design Verification of the CHARLOTTE™ Foot and Ankle System CLAW™ Plate and Screws (Exhibit 10)

Change in locking mechanism- (b)(4) Trade Secret Process

- [Redacted]

(b)(4)Trade Secret Process
[Redacted]

Change in driver/screw interface- (b)(4)Trade Secret Process
[Redacted]

[Redacted]

Additional screw lengths- (b)(4)Trade Secret Process
[Redacted]

[Redacted]

(b)(4)Trade Secret Process

[Redacted]	[Redacted]	[Redacted]

Verification of Minor Design Changes to the 3.5mm Plates

(b)(4)Trade Design Verification of the CHARLOTTE™ Foot and Ankle System WMT
CLAW® 3.5 – 2 Hole Plate

Modified Plate Design- (b)(4)Trade Secret Process [Redacted]
[Redacted]

- [Redacted]
[Redacted]
[Redacted]
[Redacted]
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18. PERFORMANCE TESTING – ANIMAL

No animal testing was performed.

19. PERFORMANCE TESTING – CLINICAL

No clinical testing was performed.

Indications for Use

510(k) Number (if known)

Device Name

CHARLOTTE® CLAW® Plate System

Indications for Use (Describe)

The CHARLOTTE® CLAW® Plate System is intended to be used for fixation such as:

- Midfoot and hindfoot arthrodeses or osteotomies
- Tarsometatarsal arthrodeses (metatarsocuneiform, metatarsocuboid, and Lapidus arthrodeses)
- Intercuneiform arthrodeses
- Naviculocuneiform arthrodeses
- Talonavicular arthrodeses
- Calcaneocuboid arthrodeses
- Lisfranc arthrodeses
- Mono- or bi-cortical osteotomies in the forefoot, midfoot and hindfoot
- Fixation of osteotomies for hallux valgus treatment (Scarf and Chevron)
- Akin osteotomies
- First metatarsophalangeal arthrodeses

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)

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Wright Medical Technology, Inc.
 5677 Airline Road Arlington, TN 38002
www.wmt.com

510(K) SUMMARY

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807.92, this information serves as a Summary of Safety and Effectiveness for the use of the CHARLOTTE® CLAW® Plate System.

- 1. Submitted By:** Wright Medical Technology, Inc.
 5677 Airline Road
 Arlington, TN 38002
- Date:** November 19, 2013
- Contact Person:** Leslie Fitch
 Senior Regulatory Affairs Specialist
 (901) 867-4120
- 2. Proprietary Name:** CHARLOTTE® CLAW® Plate System
- Common Name:** Bone Plate System
 Screw, Fixation, Bone
- Classification Name and Reference:** 21 CFR 888.3030 – Class II
 21 CFR 888.3040 – Class II
- Device Product Code, Device Panel:** HRS: Orthopedic
 HWC: Orthopedic
- 3. Predicate Devices:** K051908 – CHARLOTTE® CLAW® Plate System
 K080295 – CHARLOTTE® CLAW® 3.5
 K113014 – CLAW® II Polyaxial Compression Plating System

4. Device Description

The CHARLOTTE® CLAW® Plate System consists of plates and screws of various anatomic configurations and lengths. All plates are manufactured from implant grade stainless steel and are available in lengths of 15-30mm. The plates accept 2.7mm (12-30mm long) and 3.5mm (14-40mm long) locking screws. The locking thread feature of the screws engages the plate holes to prevent screw back-out.

5. Intended Use

The CHARLOTTE® CLAW® Plate System is intended to be used for fixation such as:

- Midfoot and hindfoot arthrodeses or osteotomies
- Tarsometatarsal arthrodeses (metatarsocuneiform, metatarsocuboid, and Lapidus arthrodeses)
- Intercuneiform arthrodeses
- Naviculocuneiform arthrodeses
- Talonavicular arthrodeses
- Calcaneocuboid arthrodeses
- Lisfranc arthrodeses
- Mono- or bi-cortical osteotomies in the forefoot, midfoot and hindfoot
- Fixation of osteotomies for hallux valgus treatment (Scarf and Chevron)
- Akin osteotomies
- First metatarsophalangeal arthrodeses

6. Technological Characteristics Comparison

The CHARLOTTE® CLAW® Plate System was cleared through K051908 and K080295. The technological features are identical to the systems previously cleared.

7. Substantial Equivalence – Non-Clinical Evidence

The purpose of this submission is to clarify the indication statement to be the same as the indications cleared in K113014 for CLAW® II Polyaxial Compression Plating System by adding specific joint arthrodesis that fall within the scope of the indications cleared through K051908 and K080295. Both the CHARLOTTE® CLAW® Plate System and the CLAW® II Polyaxial Compression Plating System share similar technical features and were found to be substantially equivalent in K113014, therefore we aim to consolidate the indication of both device systems.

8. Substantial Equivalence – Clinical Evidence

N/A

9. Substantial Equivalence – Conclusions

The design characteristics of the subject system do not raise any new types of questions of safety or effectiveness. From the evidence submitted in this 510(k), the subject devices can be expected to perform at least as well as the predicate systems.

TRUTHFUL AND ACCURATE STATEMENT

AS REQUIRED BY 21 CFR 807.87(k)

I certify that, in my capacity as Regulatory Affairs Specialist of Wright Medical Technology, Inc., I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

Leslie Fitch

Leslie Fitch
Senior Regulatory Affairs Specialist

12-3-13

Date

CHARLOTTE™

CLAW® Compression Plates

SURGICAL TECHNIQUE



The Leader in
Foot & Ankle Surgery.

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Contents

Chapter 1	1	Preoperative Planning
Chapter 2	2	Surgical Technique
	2	Calcaneal-Cuboid Arthrodesis
	2	Plate Sizing
	3	Surface Preparation
	4	Hole Preparation & Screw Placement
	6	Plate Compression
Appendix A	7	Ordering Information

Proper surgical procedures and techniques are the responsibility of the medical professional. The following guidelines are furnished for information purposes only. Each surgeon must evaluate the appropriateness of the procedures based on his or her personal medical training and experience. Prior to use of the system, the surgeon should refer to the product package insert for complete warnings, precautions, indications, contraindications and adverse effects. Package inserts are also available by contacting Wright Medical Technology, Inc.

Preoperative Planning

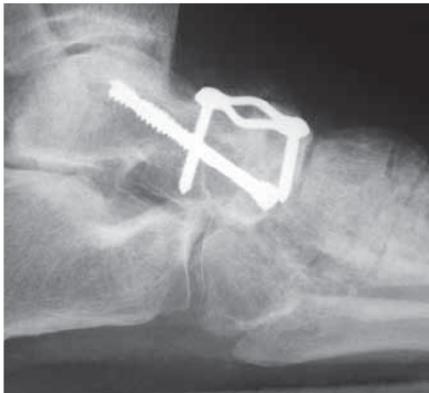


Introduction

The CHARLOTTE™ CLAW® Compression Plate is a highly versatile implant for osteotomies and arthrodeses of the foot. It is particularly useful for calcaneal-cuboid, talonavicular and midfoot arthrodesis as well as corrective osteotomies of the calcaneus, midfoot and forefoot. The CLAW® Plate is a unique, low-profile, fixed-angle device that delivers a high level of stability across a joint or osteotomy.

Surgical Goals

- To provide maximum stability across the fusion site.
- To ensure maximum stiffness of the fusion construct while minimizing device profile.
- To utilize a device highly resistant to pullout and bending.
- To provide surgical flexibility by implant size and geometry to patient anatomy.



CHARLOTTE™ CLAW® Plate X-ray

System Basics

- All CLAW® Plates are manufactured from surgical grade stainless steel for maximum strength and stiffness.
- Plate lengths are measured between the holes, center to center.
- Compression plates are available in lengths from 15 to 30mm with 2.7 or 3.5mm screw fixation **Table 1**
- Locking bone screws are available in 2.7mm (12-30mm long) or 3.5mm (14-40mm long).

	Screw Size	Available Lengths (mm)			
		15	20	25	30
	2.7mm	•	•	•	
	3.5mm		•	•	•
	3.5mm		•	•	•

Table 1

Surgical Technique

chapter 2

Calcaneal-Cuboid Arthrodesis

Expose the calcaneal-cuboid joint through a lateral (Ollier) incision. Distract the joint with a lamina spreader, and sharply debride the articular cartilage to expose bleeding subchondral bone. A powered drill may be used to create holes in the subchondral bone to promote vascular ingrowth and provide local bone grafting.

Plate Sizing

Use the measurement guide to determine the appropriate plate size. **Figure 1** Interaxis distance is chosen so that the plate will span the fusion site and leave an adequate bony bridge between the plate screws.



Figure 1

Surface Preparation

Assess the surface upon which the plate will sit. If the surface is uneven or irregularly contoured, the plate may not sit flush after application. Because of the locked screw construct, the screws will not contour the plate to the bone. Using the plate benders, the plate can be contoured to the bone. Care should be taken to protect the screw holes when bending. **Figure 2** The plate should only be bent in one direction and cannot exceed 10° of bending. Do not use drill guides to contour the plate. If necessary, bone may be removed with rongeurs or a powered burr prior to plate placement. Leave as much cortical bone intact as possible, particularly in the regions that will support the screws. Provisional fixation of the CLAW® Plate can be achieved using a 1.2mm temporary fixation wire.



Figure 2

Hole Preparation & Screw Placement

Thread the locking drill guides into plate holes. **Figure 3**
 Referring to **Table 2** use the appropriate drill size to prepare the first hole. **Figure 4**
 Read the screw length from the window in the locking drill guide. **Figure 5**
 Release the drill leaving it in the hole and then use a second drill to prepare for a screw that spans the osteotomy. Read the screw length on the drill guide, then remove the drill and drill guide. **Figure 6**

Screw Size	Pilot Drill	Hex
2.7mm	2.0mm	2.0mm
3.5mm	2.5mm	2.5mm

Table 2

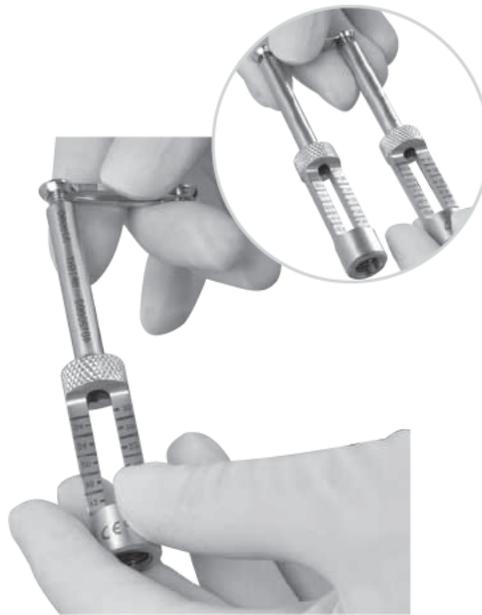


Figure 3

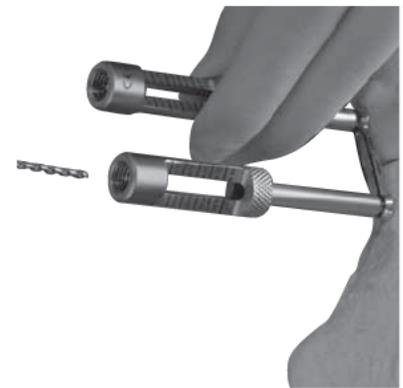


Figure 4

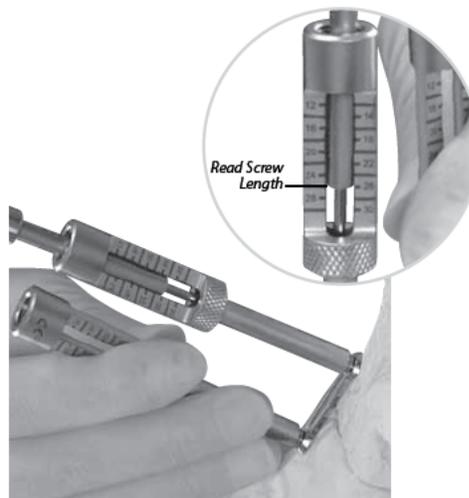


Figure 5



Figure 6

Referring to **Table 2**, use the appropriate size hex driver for the screw being used. If a self-retaining driver is used press the driver tip firmly into the head of the correct screw while it is still in the tray; this engages the driver into the screw and provides retention. **Figure 7** The driver may then be used to deliver the screw to the surgical site and place it in the hole. Alternatively, if a non-retaining driver is utilized, the screw gripper can be used to retain the screw. **Figure 8** The screw should be tightened until it locks securely into the plate; “two-finger” tightness on the driver should suffice. Remove the remaining drill bit and locking drill guide, and repeat the process. **Figure 9 and 10**

If a four hole plate is used, repeat the *Hole Preparation and Screw Placement* process.



Figure 7

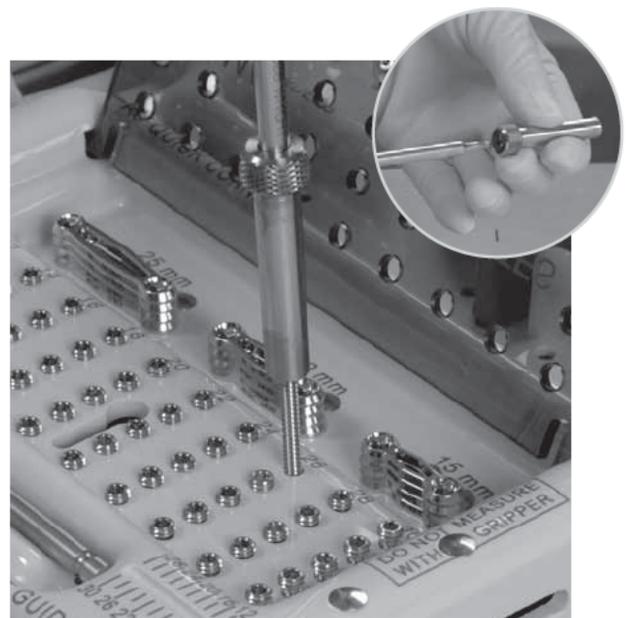


Figure 8

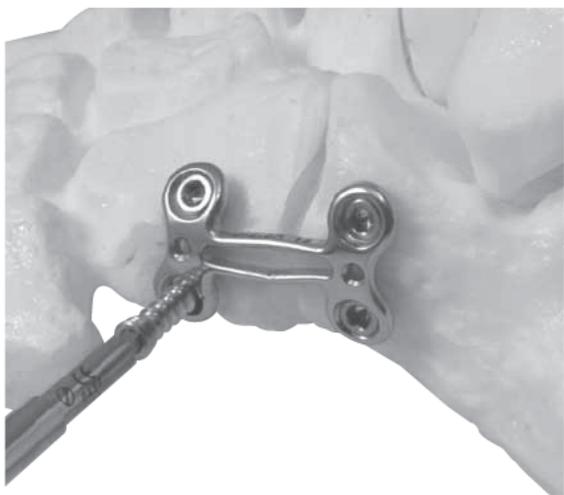


Figure 9

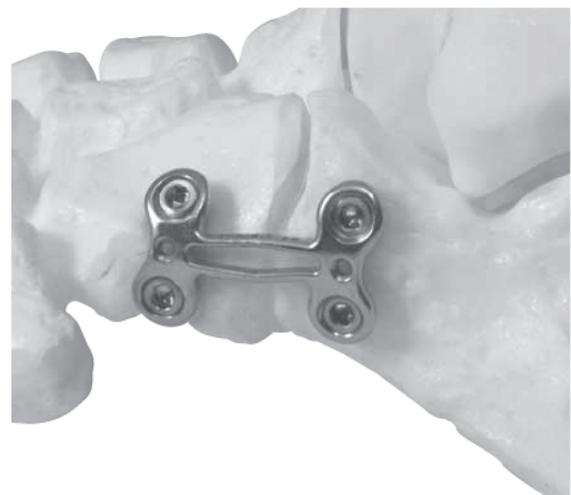


Figure 10

Plate Compression

To apply compression, use the Spreader by inserting the tips into the center “diamond” of the plate. Using firm pressure, squeeze the sides of the expansion mechanism outward, drawing the screws together. Be sure to insert the spreader completely into the center “diamond” of the plate before applying any force.

Figure 11, 12 and 13

Surgical closure is performed in the routine fashion.

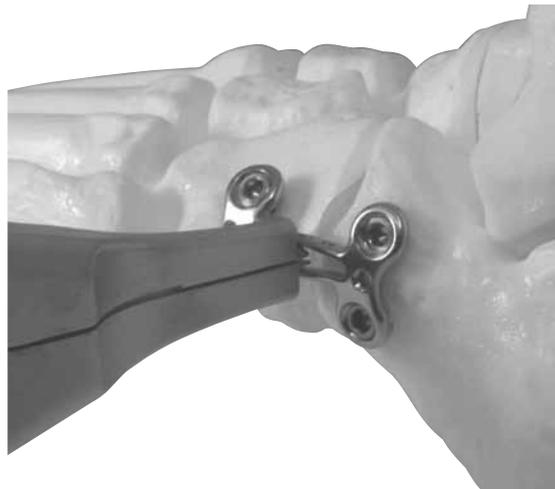


Figure 11

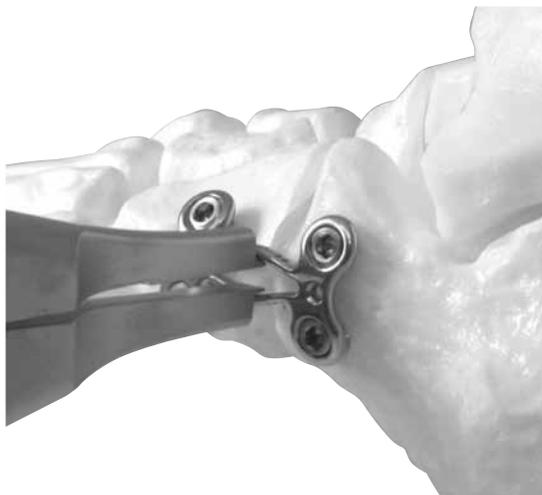


Figure 12

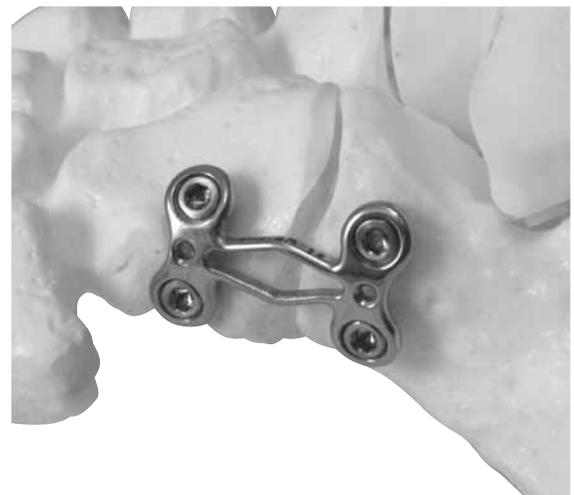
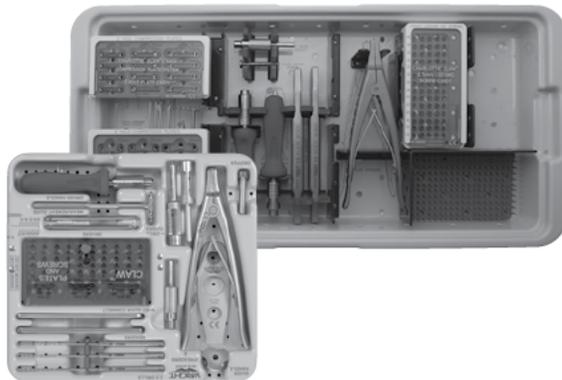


Figure 13

Ordering Information



CLAW® 2.7MM COMPRESSION PLATES

Part No.	Description
40120015	CLAW® PLATE 15MM INTERAXIS
40120020	CLAW® PLATE 20MM INTERAXIS
40120025	CLAW® PLATE 25MM INTERAXIS

CLAW® 2.7MM LOCKING SCREWS

Part No.	Description
40122712	CLAW® SCREW 2.7MM X 12MM
40122714	CLAW® SCREW 2.7MM X 14MM
40122716	CLAW® SCREW 2.7MM X 16MM
40122718	CLAW® SCREW 2.7MM X 18MM
40122720	CLAW® SCREW 2.7MM X 20MM
40122722	CLAW® SCREW 2.7MM X 22MM
40122724	CLAW® SCREW 2.7MM X 24MM
40122726	CLAW® SCREW 2.7MM X 26MM
40122728	CLAW® SCREW 2.7MM X 28MM
40122730	CLAW® SCREW 2.7MM X 30MM

CLAW® 2.7MM PLATE INSTRUMENTS

Part No.	Description
40122001	CLAW® DRILL BIT 2.0MM
40120002	CLAW® 2.0MM DRILL GUIDE
40120004	CLAW® GUIDE HANDLE
40120008	CLAW® HEX 2.0MM SCREWDRIVER
40120010	CLAW® 2.7MM MEASUREMENT GUIDE
40120014	CLAW® 2.7MM BENDER
41112017	AO QUICK CONNECT CANNULATED
40120024	CLAW® SCREW GRIPPER THREADED
44112009	AO CANNULATED DRIVER HANDLE
40120013	CLAW® 2.7MM PLATE SPREADER
40120016	CLAW® 2.7MM SURGICAL TRAY

CLAW® 3.5MM COMPRESSION PLATES

Part No.	Description
40130020	CLAW® 3.5MM PLATE 4 HOLE 20MM
40130025	CLAW® 3.5MM PLATE 4 HOLE 25MM
40130030	CLAW® 3.5MM PLATE 4 HOLE 30MM
40130120	CLAW® 3.5MM PLATE 2 HOLE 20MM
40130125	CLAW® 3.5MM PLATE 2 HOLE 25MM
40130130	CLAW® 3.5MM PLATE 2 HOLE 30MM

CLAW® 3.5MM LOCKING SCREWS

Part No.	Description
40133514	CLAW® HEX SCREW 3.5MM X 14MM
40133516	CLAW® HEX SCREW 3.5MM X 16MM
40133518	CLAW® HEX SCREW 3.5MM X 18MM
40133520	CLAW® HEX SCREW 3.5MM X 20MM
40133522	CLAW® HEX SCREW 3.5MM X 22MM
40133524	CLAW® HEX SCREW 3.5MM X 24MM
40133526	CLAW® HEX SCREW 3.5MM X 26MM
40133528	CLAW® HEX SCREW 3.5MM X 28MM
40133530	CLAW® HEX SCREW 3.5MM X 30MM
40133532	CLAW® HEX SCREW 3.5MM X 32MM
40133534	CLAW® HEX SCREW 3.5MM X 34MM
40133536	CLAW® HEX SCREW 3.5MM X 36MM
40133538	CLAW® HEX SCREW 3.5MM X 38MM
40133540	CLAW® HEX SCREW 3.5MM X 40MM

CLAW® 3.5MM PLATE INSTRUMENTS

Part No.	Description
40142500	CLAW® 2.5MM DRILL BIT
DC4212	TEMP FIXATION K-WIRE 1.2MM
44112008	SINGLE TROCAR WIRE 1.6 X 150MM
40140010	CLAW® 2.5MM DRILL GUIDE
40140015	CLAW® 3.5MM SCREW GRIPPER
40140020	CLAW® 3.5MM PLATE BENDER
40140025	CLAW® 3.5MM MEASUREMENT GUIDE
40120028	CLAW® RATCHETING DRIVER HANDLE
41112017	AO QUICK CONNECT CANNULATED
40140035	CLAW® 2.5MM HEX DRIVER
40140030	CLAW® 3.5MM PLATE SPREADER
40140040	CLAW® 3.5MM OUTER TRAY & LID
40140045	CLAW® 3.5MM SCREW CADDY
40140050	CLAW® 3.5MM 4-HOLE PLATE CADDY
40140055	CLAW® 3.5MM 2-HOLE PLATE CADDY



Wright Medical Technology, Inc.

5677 Airline Road
Arlington, TN USA 38002
901.867.9971
800.238.7117
www.wmt.com

Wright Medical EMEA

Hoogoorddreef 5
1101 BA Amsterdam
The Netherlands
011.31.20.545.0100
www.wmt-emea.com

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50277-905 R510



CHARLOTTE® CLAW® Plate System

138025-5

The following languages are included in this packet:

English (en)
Español (es)
Türkçe (tk)

Deutsch (de)
Italiano (it)

Nederlands (nl)
Português (pt)

Français (fr)
中文-Chinese (sch)

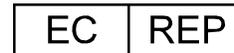
For additional languages, visit our website www.wmt.com

Then click on the **Prescribing Information** option.

For additional information and translations please contact the manufacturer or local distributor.



Wright Medical Technology, Inc.
5677 Airline Rd.
Arlington, TN 38002
U.S.A.



Wright Medical EMEA
Hoogoorddreef 5
1101 BA Amsterdam
The Netherlands

*** The CE-Marking of Conformity is applied per catalog number and appears on the outer label, if applicable.**

Rx ONLY
December 2012
Printed in U.S.A.

Attention Operating Surgeon
IMPORTANT MEDICAL INFORMATION

WRIGHT MEDICAL
CHARLOTTE® CLAW® PLATE SYSTEM
 (138025-5)

OUTLINE:

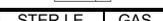
- I. GENERAL PRODUCT INFORMATION
 - A. PATIENT SELECTION
 - B. CONTRAINDICATIONS
 - C. POTENTIAL COMPLICATIONS AND ADVERSE REACTIONS
 - D. PRECAUTIONS
 - E. HANDLING AND STERILIZATION
 - F. STORAGE CONDITIONS

- II. SPECIFIC PRODUCT INFORMATION

DEFINITIONS

Symbols and abbreviations may be used on the package label. The following table provides the definition of these symbols and abbreviations.

Table 1. Definitions of Symbols and Abbreviations

Symbol	Definition
	Batch code
	Catalog number
	Do not re-use
	Caution, consult accompanying documents
	Consult operating instructions
	Use by
	Temperature limitation
	Keep dry
	Keep away from sunlight
	Date of manufacture
	Manufacturer
	Authorized EC Representative in the European Community
	Sterilized using ethylene oxide
	Sterilized using radiation
	Sterilized using gas plasma
	Sterilized using aseptic processing techniques
	For prescription use only

Abbreviation	Material
Ti	Titanium
Ti6Al4V	Titanium Alloy
CoCr	Cobalt Chrome Alloy
SS	Stainless Steel
UHMWPE	Ultra High Molecular Weight Polyethylene

I. GENERAL PRODUCT INFORMATION

Through the advancement of surgical fusion hardware, the surgeon has been provided a means of correcting deformity and reducing pain for many patients. While the implants used are largely successful in attaining these goals, it must be recognized that they are manufactured from metal, and that no implant can be expected to withstand the activity levels and loads as would normal, healthy bone after fusion occurs.

Each patient must be evaluated by the surgeon to determine the risk/benefit relationship.

In using fusion implants, the surgeon should be aware of the following:

- **The correct selection and sizing of the implant is extremely important.** Selection of the proper size, shape, and design of the implant increases the potential for success. The implants require careful seating and adequate bone support.
- **In selecting patients for surgery, the following factors can be critical to the eventual success of the procedure:**
 1. **Patient's occupation or activity.** If the patient is involved in an occupation or activity which includes substantial lifting or muscle strain, the resultant forces can cause failure of the fixation, the device, or both. The implant will not restore function to the level expected with normal healthy bone, and the patient should not have unrealistic functional expectations.
 2. **Condition of senility, mental illness, or alcoholism.** These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the implant, leading to failure or other complications.
 3. **Foreign body sensitivity.** Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation.

A. PATIENT SELECTION

Use of surgical fusion hardware requires consideration of the following general indications:

- Good condition of the patient
- Good neurovascular status
- Adequate skin coverage
- Possibility of a functional musculotendinous system
- Adequate bone stock to receive implant

- Availability of post-operative therapy
- Cooperative patient

See Section II for specific product information.

B. CONTRAINDICATIONS

- Infection
- Physiologically or psychologically inadequate patient
- Inadequate skin, bone, or neurovascular status
- Irreparable tendon system
- Possibility for conservative treatment
- Growing patients with open epiphyses
- Patients with high levels of activity

C. POTENTIAL COMPLICATIONS AND ADVERSE REACTIONS

In any surgical procedure, the potential for complications exists. The risks and complications with these implants include:

- Infection or painful, swollen or inflamed implant site
- Fracture of the implant
- Loosening or dislocation of the implant requiring revision surgery
- Bone resorption or over-production
- Allergic reaction(s) to implant material(s)
- Untoward histological responses possibly involving macrophages and/or fibroblasts
- Migration of particle wear debris possibly resulting in a bodily response
- Embolism

See Section II for specific product information.

D. PRECAUTIONS

Following the instructions for use provided in product literature can minimize the potential for complications or adverse reactions with any implant.

It is the responsibility of each surgeon using implants to consider the clinical and medical status of each patient and to be knowledgeable about all aspects of implant procedure and the potential complications that may occur. The benefits derived from implant surgery may not meet the patient's expectations or may deteriorate with time, necessitating revision surgery to replace the implant or to carry out alternative procedures. Revision surgeries with implants are common. The patient's mental status must also be considered. Willingness and/or ability to follow post-operative instructions may also impact the surgical outcome. Surgeons must balance many considerations to achieve the best result in individual patients.

IF EXCESSIVE LOADING CANNOT BE PREVENTED, AN IMPLANT SHOULD NOT BE USED.

The main goal of surgery with this implant is to establish bony fusion. Abnormal or excessive forces could lead to delayed union, non-union, or failure of the implant.

Abnormal force loading and subsequent wear may be caused by:

- Uncorrected instability
- Improperly sized implant
- Inadequate soft tissue support
- Implant malposition
- Excessive motion
- Uncorrected or recurrent deformity
- Patient misuse or overactivity

Proper fixation at the time of surgery is critical to the success of the procedure. Bone stock must be adequate to support the device.

Some preventative measures to consider to minimize the potential for complications:

- Follow guidelines for indications and contraindications provided above
- Identify prior pathology
- Stabilize collapse deformities
- Bone graft pre-existing cysts
- Use a properly sized implant
- Avoid K-wires and sutures through the implant

Avoid flawing implant surfaces to minimize the potential for early fatigue failure.

If complications develop, possible corrective procedures include:

- Implant removal
- Synovectomy
- Bone grafting of cysts
- Replacement of the implant
- Removal of the implant with fusion of the joint

Over time, metallic implants may loosen, fracture, or cause pain after the bone fracture or osteotomy is healed. Removal of metallic implants is at the surgeon's discretion, and the appropriateness of the selected procedure will be based on the surgeon's personal medical training and experience. It is imperative that adequate post-operative care and protection be provided by the surgeon.

Recommendations Regarding Device Fragments

1. Use medical devices in accordance with their labeled indications and the manufacturer's instructions for use, especially during insertion and removal.
2. Inspect devices **prior to use** for damage during shipment or storage or any out-of-box defects that might increase the likelihood of fragmentation during a procedure.
3. Inspect devices **immediately upon removal from the patient** for any signs of breakage or fragmentation.
4. If the device is damaged, retain it to assist with the manufacturer's analysis of the event.
5. Carefully consider and discuss with the patient (if possible) the risks and benefits of retrieving vs. leaving the fragment in the patient.

6. Advise the patient of the nature and safety of unretrieved device fragments including the following information:
 - a. The material composition of the fragment (if known);
 - b. The size of the fragment (if known);
 - c. The location of the fragment;
 - d. The potential mechanisms for injury, e.g., migration, infection;
 - e. Procedures or treatments that should be avoided such as MRI exams in the case of metallic fragments. This may help to reduce the possibility of a serious injury from the fragment.

Clinical results depend on surgeon and technique, pre-operative and post-operative care, the implant, patient pathology and daily activity. It is important that surgeons obtain appropriate informed consent and discuss the potential for complications with each patient prior to surgery. This may include a review of alternative, non-implant procedures such as soft tissue reconstruction or arthrodesis.

Concerning Magnetic Resonance Environments

The devices described in this package insert have not been evaluated for safety and compatibility in the MR environment. The devices described in this package insert have not been tested for heating or migration in the MR environment.

See Section II for specific product information.

E. HANDLING AND STERILIZATION

IMPLANTS

The implants in this system are either provided sterile or non-sterile; the individual product's labeling will determine whether or not it is packaged sterile. Implants that are presented in instrument trays are provided non-sterile.

Implants in sterile packaging should be inspected to ensure that the packaging has not been damaged or previously opened. The implants should be opened using aseptic OR technique; they should only be opened after the correct size has been determined.

Implants provided non-sterile should be processed according to the recommended parameters for instruments (below).

An implant should never be re-sterilized after contact with body tissues or fluids.

Devices labeled for single-use only should never be reused. Reuse of these devices may potentially result in serious patient harm. Examples of hazards related to the reuse of these devices include, but are not limited to: significant degradation in device performance, cross-infection, and contamination

.INSTRUMENTS

Surgical instruments (and non-sterile implants) should be cleaned and sterilized according to the following parameters:

Cleaning & Disinfection

Clean to remove gross contamination and disinfect to reduce the number of viable microorganisms.

1. **Disassemble** as per manufacturer instructions (if appropriate).
2. **Rinse** with cold tap water to remove gross contamination.
3. **Bathe** in an enzymatic detergent solution prepared per manufacturer directions for 5 minutes.
4. **Scrub** thoroughly with a soft brush and/or pipe cleaner; repeatedly flush any very narrow lumens with enzymatic detergent solution using a syringe.
5. **Rinse** with cold tap water for a minimum of one minute; use a syringe to repeatedly flush any very narrow lumens.
6. **Bathe** in a detergent solution prepared per manufacturer directions for 5 minutes.
7. **Scrub** thoroughly with a soft brush and/or pipe cleaner; repeatedly flush any very narrow lumens with detergent solution using a syringe.
8. **Rinse** thoroughly /flush with deionized / reverse osmosis (RO/DI) water.
9. **Sonicate** for a minimum of 10 minutes in an enzymatic detergent solution prepared per manufacturer directions.
10. **Rinse** thoroughly /flush with RO/DI water.
11. **Dry** with a clean, soft, absorbent, disposable cloth.
12. **Visually inspect** for cleanliness. All visible surfaces, internal and external, should be visually inspected. If necessary re-clean until it is visibly clean.

Note: Brushes (i.e. pipe cleaners) could be used for cleaning most lumens, however, the use of a syringe to flush narrow lumens with diameters less than or equal to 0.041 inches is recommended.

Sterilization

1. Double wrap the component in CSR wrap or a similar type non-woven medical grade wrapping material.
2. Autoclave according to the following parameters:

Steam Sterilization		
Cycle Type	Parameter	Minimum Set Point
Prevacuum 270 °F (132 °C)	Exposure Temperature	270 °F (132 °C)
	Exposure Time	4 minutes
	Dry Time	20 minutes

3. After sterilization, remove the component from its wrapping using accepted sterile technique with powder-free gloves. Ensure that implants are at room temperature prior to implantation. Avoid contact with hard objects that may cause damage.

These recommendations are consistent with AAMI ST79 Table 5 guidelines and have been developed and tested using specific equipment. Due to variations in environment and equipment, it must be demonstrated that these recommendations produce sterility in your environment. If processing conditions, wrapping materials, or equipment changes occur, the effectiveness of the sterilization process must be demonstrated.

For additional information see Wright's "Cleaning and Handling of Wright Medical Instruments".

F. STORAGE CONDITIONS

All implants must be stored in a clean, dry environment and be protected from sunlight and extremes in temperature.

II. SPECIFIC PRODUCT INFORMATION

DESCRIPTION

The CHARLOTTE™ CLAW® Plate consists of plates and locking-screws in various lengths. All plates and screws are manufactured from stainless steel.

INDICATIONS

The CHARLOTTE® CLAW® Plate System is intended to be used for fixation such as:

- Midfoot and hindfoot arthrodeses or osteotomies
- Tarsometatarsal arthrodeses (metatarsocuneiform, metatarsocuboid, and Lapidus arthrodeses)
- Intercuneiform arthrodeses
- Naviculocuneiform arthrodeses
- Talonavicular arthrodeses
- Calcaneocuboid arthrodeses
- Lisfranc arthrodeses
- Mono- or bi-cortical osteotomies in the forefoot, midfoot and hindfoot
- Fixation of osteotomies for hallux valgus treatment (Scarf and Chevron)
- Akin osteotomies
- First metatarsophalangeal arthrodeses

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CLAWPLATE SCREW



4 142748 32 3520 17*



4 4991 6ABC 154V6*



146302 Rev 0

Symbol	Definition
	BATCH CODE
	CATALOG NUMBER
	DO NOT RE-USE
	CAUTION, CONSULT ACCOMPANYING DOCUMENTS
	CONSULT OPERATING INSTRUCTIONS
	USE BY DATE
	TEMPERATURE LIMITATION
	KEEP DRY
	KEEP AWAY FROM SUNLIGHT
	DATE OF MANUFACTURE
	MANUFACTURER

	AUTHORIZED EC REPRESENTATIVE IN THE EUROPEAN COMMUNITY
	STERILIZED USING ETHYLENE OXIDE
	STERILIZED USING RADIATION
	STERILIZED USING ASEPTIC PROCESSING TECHNIQUES
	STERILIZED USING GAS PLASMA
	CAUTION: U.S. FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN
	DO NOT USE IF PACKAGING IS DAMAGED
	NON STERILE
	DO NOT RESTERILIZE
	STERILE

Appendix C – Statistical Analysis

Appendix B
Statistical Analysis Calculations

Appendix B
Statistical Analysis Calculations

Appendix C
Test Report (b)(4)Trade Secret

Collins, Virginia *

From: Collins, Virginia *
Sent: Thursday, March 06, 2014 12:24 PM
To: 'leslie.fitch@wmt.com'
Cc: DCCLetters
Subject: K133715 SE Letter
Attachments: K133715.pdf

Tracking:	Recipient	Delivery
	'leslie.fitch@wmt.com'	
	DCCLetters	Delivered: 3/6/2014 12:24 PM



COVER SHEET MEMORANDUM

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

NOTE: This form is REQUIRED for holds and for final decisions.

Reviewer Name Krutanjali M. Shah

510(k) Number K133715

Please list CTS decision code: SE - Substantially Equivalent

Hold (Additional Information or Telephone Hold) Hold Date

Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.)

Incomplete Response - Convert Supplement to Amendment (attach email sent to firm)

Add to File

(review staff should follow the instructions and complete the memo/routing sheet at:
http://eroom.fda.gov/eRoom/CDRH3/CDRHPreMarketNotification510kProgram/0_3bba7. DCC should refer to that documentation for the close-out code and mail any provided letter.)

The remainder of this form must be filled out for close-outs only

Class: II
Regulation Number: 21 CFR 888.3030
Product Code: HRS
Additional Product Codes: HWC

Please complete the following for a final clearance decision (i.e. SE, SE with Limitations, etc.)	YES	NO
Indications for Use Page (Attach IFU)	X	
510(k) Summary or 510(k) Statement (Attach Summary)	X	
Truthful and Accurate Statement (Must be present for a Final Decision)	X	
Is the device Class III?		X
Is this a combination product?		X
Is this device intended for pediatric use only?		X
Is this a prescription device? (If both prescription & OTC, check both boxes.)	X	
Is clinical data necessary to support the review of this 510(k)?		X
For United States based clinical studies only, did the application include a completed Form FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank? (If study was conducted in the United States and Form FDA 3674 was not included or was incomplete, then applicant must be contacted to obtain completed form.)		X
Does this device include an Animal Tissue Source?		X
All Pediatric Patients age <= 21		X

Neonate/Newborn (Birth to 28 days)		X
Infant (29 days to < 2 years)		X
Child (2 years to <12 years)		X
Adolescent (12 years to <18 years)		X
Transitional Adolescent A (18 years to <21 years); Special considerations are being given to this group, different from adults age >= 21 (different device design or testing, different protocol procedures, etc.)		X
Transitional Adolescent B (18 years to <21 years); No special considerations compared to adults >= 21 years)		X
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance)		X

Digital Signature Concurrence Table

(Not all signatures may be required)

Branch Chief Sign-Off

Elizabeth L. Frank-S
2014.02.25 13:48:12 -05'00'

Division Sign-Off

Vincent J. Devlin-S
2014.02.28 09:27:27 -05'00'