



**510(K) SUMMARY
OF SAFETY AND EFFECTIVENESS**

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, this information serves as a Summary of Safety and Effectiveness for the use of the CHARLOTTE™ CLAW 3.5.

Submitted By: Wright Medical Technology, Inc.
Date: January 23, 2005
Contact Person: Sarah Holtgrewe
Regulatory Affairs Specialist
Proprietary Name: CHARLOTTE™ CLAW 3.5
Common Name: Compression Plate
Classification Name and Reference: 21 CFR 888.3030 Plate, Fixation, Bone – Class II
Device Product Code and Panel Code: Orthpedics/87/HRS

DEVICE INFORMATION

A. INTENDED USE

The CHARLOTTE™ CLAW® 3.5 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.

B. DEVICE DESCRIPTION

The CHARLOTTE™ CLAW® 3.5 consists of curved 4-hole plates and locking screws of various lengths. All plates and screws are manufactured from stainless steel.

C. SUBSTANTIAL EQUIVALENCE INFORMATION

The design features of the CHARLOTTE™ CLAW® 3.5 system are substantially equivalent to the design features of the predicates identified in this 510(k) submission. The safety and effectiveness of the CHARLOTTE™ CLAW® 3.5 is adequately supported by the substantial equivalence information, materials information, and analysis data provided within this premarket notification.



FEB 27 2008

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Wright Medical Technology, Inc.
% Ms. Sarah Holtgrewe
Regulatory Affairs Specialist
5677 Airline Road
Arlington, TN 38002

Re: K080295
Trade/Device Name: Charlotte™ Claw® 3.5
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation
appliances and accessories
Regulatory Class: Class II
Product Code: HRS
Dated: January 24, 2008
Received: February 4, 2008

Dear Ms. Holtgrewe:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 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 (21CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: CHARLOTTE™ CLAW 3.5

Indications For Use:

The CHARLOTTE™ CLAW® 3.5 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.

Prescription Use xxx
(Part 21 CFR 801 Subpart D)

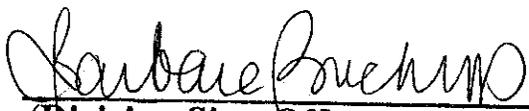
AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

1 of 1


(Division Sign-Off)
**Division of General, Restorative,
and Neurological Devices**

510(k) Number K080295



FEB 27 2008

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Wright Medical Technology, Inc.
% Ms. Sarah Holtgrewe
Regulatory Affairs Specialist
5677 Airline Road
Arlington, TN 38002

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Page 2 – Ms. Sarah Holtgrewe

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Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: CHARLOTTE™ CLAW 3.5

Indications For Use:

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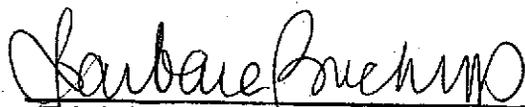
AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

1 of 1



(Division Sign-Off)

Division of General, Restorative,
and Neurological Devices

510(k) Number K080295

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

February 05, 2008

WRIGHT MEDICAL TECHNOLOGY, INC.
5677 AIRLINE RD.
ARLINGTON, TN 38002
ATTN: SARAH HOLTGREWE

510(k) Number: K080295
Received: 04-FEB-2008
Product: CHARLOTTE CLAW 3.5

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

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC) (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 510(k) submission.

On September 27, 2007, the President signed an act reauthorizing medical device user fees for fiscal years 2008 - 2012. The legislation - the Medical Device User Fee Amendments of 2007 is part of a larger bill, the Food and Drug Amendments Act of 2007. Please visit our website at <http://www.fda.gov/cdrh/mdufma/index.html> for more information regarding fees and FDA review goals. In addition, effective January 2, 2008, any firm that chooses to use a standard in the review of ANY new 510(k) needs to fill out the new standards form (Form 3654) and submit it with their 510(k). The form may be found at <http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf>.

A new provision of the Food and Drug Administration Amendments Act of 2007, 42 U.S.C. 282(j)(5)(B), requires that a certification form (<http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3674.pdf>) accompany all 510(k)/HDE/PMA submissions on or after December 26, 2007. You are responsible for registering certain device clinical trials in the Clinical Trials Data Bank (<http://prsinfo.clinicaltrials.gov>). If your submission does not include FDA Form 3674, please send 2 hardcopies of the completed certification form referencing the submission number identified above. Additional information about the new certification

form may be found at the following link to the Federal Register Notice (<http://www.fda.gov/OHRMS/DOCKETS/98fr/07-6023.htm>).

Please note the following documents as they relate to 510(k) review:

- 1) Guidance for Industry and FDA Staff entitled, "Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements". This guidance can be found at <http://www.fda.gov/cdrh/ode/guidance/1655.pdf>. Please refer to this guidance for information on a formalized interactive review process.
- 2) Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at www.fda.gov/cdrh/ode/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at www.fda.gov/cdrh/electsub.html.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice www.fda.gov/cdrh/devadvice/. If you have questions on the status of your submission, please contact DSMICA at (240) 276-3150 or the toll-free number (800) 638-2041, or at their Internet address <http://www.fda.gov/cdrh/dsma/dsmastaf.html>. If you have procedural questions, please contact the 510(k) Staff at (240) 276-4040.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Office of Device Evaluation
Center for Devices and Radiological Health



January 24, 2008

Office of Device Evaluation
Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Blvd.
Rockville, MD 20850

FDA CDRH DMC

FEB 4 2008

Received

RE: **Special 510(k) Premarket Notification**
CHARLOTTE™ CLAW® 3.5

Dear Sir or Madam:

The purpose of this letter is to notify FDA of our intent to market the CHARLOTTE™ CLAW® 3.5. The CHARLOTTE™ CLAW® 3.5 consists of a compression plate and screws. The compression plate is a modified version of our previously cleared CHARLOTTE™ Compression Plate, 510(k) K051908. The screws are modified versions of our CHARLOTTE™ Compression Plate screws (K051908) and our DARCO® 3.5 screws cleared under 510(k) K061808. Wright Medical acquired DARCO® and all of its assets (including the DARCO® 3.5 screws and its 510(k) clearance). Hence, Wright Medical is the manufacturer and owns the 510(k) for the original unmodified DARCO® device¹.

The modifications for both the plate and screws are limited to dimensional and material changes (i.e. addition of new type of stainless steel), with no change in fundamental scientific technology. Wright concludes that this submission meets the eligibility requirements for a Special 510(k) based on the criteria included in the March 1998 FDA guidance document "The New 510(k) Paradigm: Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications." Also, in accordance with this referenced document, a declaration of conformity with design control requirements is included in this submission along with other content requirements.

Please find attached immediately following this cover letter a copy of a letter from Health Policy Associates Inc. which certifies that the data and information contained within this 510(k) is accurate, complete, and reliable.

¹ A letter summarizing the acquisition of DARCO® is included in Exhibit 2.

K17
OR
II



We consider our intent to market CHARLOTTE™ CLAW® 3.5 to be confidential commercial information, and therefore exempt from public disclosure. Please do not hesitate to contact me by phone at (901) 867-4476, by email at sholtgrewe@wmt.com, or by fax at (901) 867-4190 should you have any questions regarding this submission. Thank you in advance for your review and support.

Best Regards,

A handwritten signature in cursive script that reads "Sarah Holtgrewe".

Sarah Holtgrewe
Regulatory Affairs Specialist
Wright Medical Technology, Inc.

**SCREENING CHECKLIST
FOR ALL PREMARKET NOTIFICATION [510(k)] SUBMISSIONS**

510(k) Number: _____

The cover letter clearly identifies the type of 510(k) submission as **(Check the appropriate box):**

- Special 510(k) - Do Sections 1 and 2
- Abbreviated 510(k) - Do Sections 1, 3, and 4
- Traditional 510(k) or no identification provided - Do Sections 1 and 4

Section 1: Required Elements for All Types of 510(k) Submissions

| | Present or Adequate | Missing or Inadequate |
|--|---|------------------------------|
| Cover letter, containing the elements listed on page 3-2 of the Premarket Notification [510(k)] Manual. | Before 1 st tab & PMN ¹ pg. 1 | |
| Table of Contents. | PMN | |
| Truthful and Accurate Statement. | Exhibit 3 | |
| Device's Trade Name, Device's Classification Name and Establishment Registration Number. | PMN pg.1 | |
| Device Classification, Regulation Number and Regulatory Status (Class I, Class II, Class III, or Unclassified.) | PMN pg.1 | |
| Proposed Labeling including the material listed on page 3-4 of the Premarket Notification [510(k)] Manual. | Exhibit 12 | |
| Statement of Indications for Use that is on a separate page in the premarket submission. | Exhibit 4 | |
| Substantial Equivalence Comparison, including comparisons of the new device with the predicate in areas that are listed on page 3-4 of the Premarket Notification [510(k)] Manual. | PMN pg. 2 & 15 | |
| 510(k) Summary or 510(k) Statement. | Exhibit 4 | |
| Description of the device (or modification of the device) including diagrams, engineering drawings, photographs, or service manuals. | PMN pg. 2 & Exhibit 6 | |
| Identification of legally marketed predicate device.* | PMN pg 2 | |
| Compliance with performance standards* [See Section 514 of the Act and 21 CFR 807.87(d)]. | N/A | |
| Class III Certification and Summary.** | N/A | |
| Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study.* | N/A | |
| 510(k) Kit Certification.*** | N/A | |

* May not be applicable for Special 510(k)s.

** Required for Class III devices, only.

*** See pages 3-12 and 3-13 in the Premarket Notification [510(k)] Manual and the Convenience Kits Interim Regulatory Guidance

¹ PMN refers to the tab labeled Premarket Notification

Section 2: Required Elements for a SPECIAL 510(k) Submissions

| | Present or Adequate | Missing or Inadequate |
|--|----------------------------|------------------------------|
| Name and 510(k) number of the submitter's own, unmodified predicate device. | PMN pg 2 & Exhibit 1 | |
| A description of the modified device and a comparison to the sponsor's predicate device. | PMN pg 3 | |
| A statement that the intended use(s) and indications of the modified device, as described in its labeling, are the same as the intended uses and indications for the submitter's unmodified predicate device. | PMN pg 2 | |
| Reviewer's confirmation that the modification has not altered the fundamental scientific technology of the submitter's predicate device. | | |
| A Design Control Activities Summary that includes the following elements (a-c): | | |
| a. Identification of the Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and results of the analysis. | PMN pg 6 | |
| b. Based on the Risk Analysis, an identification of the required verification and validation activities, including the methods or tests used and the acceptance criteria to be applied. | PMN pg 6 | |
| c. A Declaration of Conformity with design controls that includes the following statements: | Exhibit 5 | |
| A statement that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results of the activities demonstrated that the predetermined acceptance criteria were met. This statement is signed by the individual responsible for those particular activities | Exhibit 5 | |
| A statement that the manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review. This statement is signed by the individual responsible for those particular activities. | Exhibit 5 | |

Section 3: Required Elements for an ABBREVIATED 510(k)* Submissions

| | Present or Adequate | Missing or Inadequate |
|--|----------------------------|------------------------------|
| For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type. (If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.) | N/A | |
| For a submission, which relies on a recognized standard, a declaration of conformity is required. [For a listing of the required elements of a declaration of conformity, SEE Required Elements for a Declaration of Conformity to a Recognized Standard , which is posted with the 510(k) boilers on the H drive .] | N/A | |
| For a submission, which relies on a recognized standard without a declaration of conformity, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device. | N/A | |
| For a submission, which relies on a non-recognized standard that has been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device. | N/A | |
| For a submission, which relies on a non-recognized standard that has <u>not</u> been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device <u>and</u> any additional information requested by the reviewer in order to determine substantial equivalence. | N/A | |
| Any additional information, which is not covered by the guidance document, special control, recognized standard and/or non-recognized standard, in order to determine substantial equivalence. | N/A | |

* When completing the review of an abbreviated 510(k), please fill out an Abbreviated Standards Data Form (located on the H drive) and list all the guidance documents, special controls, recognized standards and/or non-recognized standards, which were noted by the sponsor.

Section 4: Additional Requirements for ABBREVIATED and TRADITIONAL 510(k) Submissions (If applicable)

| | | Present or Adequate | Missing or Inadequate |
|----|---|----------------------------|------------------------------|
| a) | Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation: | N/A | |
| b) | Sterilization and expiration dating information: | N/A | |
| | i) sterilization process | N/A | |
| | ii) validation method of sterilization process | N/A | |
| | iii) SAL | N/A | |
| | iv) packaging | N/A | |
| | v) specify pyrogen free | N/A | |
| | vi) ETO residues | N/A | |
| | vii) radiation dose | N/A | |
| | viii) Traditional Method or Non-Traditional Method | N/A | |
| c) | Software Documentation | N/A | |

Items with checks in the “Present or Adequate” column do not require additional information from the sponsor. Items with checks in the “Missing or Inadequate” column must be submitted before substantive review of the document.

Passed Screening ___Yes ___No

Reviewer: _____

Concurrence by Review Branch: _____

Date: _____

The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(I) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If however, you believe that the information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the “A Suggested Approach to Resolving Least Burdensome Issues” document. It is available on our Center web page at: <http://www.fda.gov/cdrh/modact/leastburdensome.html>

CharlotteTM CLaw[®] 35- Sarah Holtgraw

Form Approved: OMB No. 0910-511 Expiration Date: January 31, 2010. 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 Write the Payment Identification number on your check. | |
| A completed Cover Sheet must accompany each original application or supplement subject to fees. The following actions must be taken to properly submit your application and fee payment: | | | |
| 1. Electronically submits the completed Cover Sheet to the Food and Drug Administration (FDA) before payment is sent. 2. Include printed copy of this completed Cover Sheet with a check made payable to the Food and Drug Administration. Remember that the Payment Identification Number must be written on the check. 3. Mail Check and Cover Sheet to the US Bank Lock Box, FDA Account, P.O. Box 956733, St. Louis, MO 63195-6733. (Note: In no case should payment be submitted with the application.) 4. If you prefer to send a check by a courier, the courier may deliver the check and Cover Sheet to: US Bank, Attn: Government Lockbox 956733, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. Contact the US Bank at 314-418-4821 if you have any questions concerning courier delivery.) 5. For Wire Transfer Payment Procedures, please refer to the MDUFMA Fee Payment Instructions at the following URL: http://www.fda.gov/cdrh/mdufma/faqs.htm#3a . You are responsible for paying all fees associated with wire transfer. 6. Include a copy of the complete Cover Sheet in volume one of the application when submitting to the FDA at either the CBER or CDRH Document Mail Center. | | | |
| 1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code) WRIGHT MEDICAL TECHNOLOGY INC 5677 AIRLINE ROAD ARLINGTON TN 38002 US 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) (b)(4) | | 2. CONTACT NAME Angela Smith 2.1 E-MAIL ADDRESS asmith@wmt.com 2.2 TELEPHONE NUMBER (include Area code) 901-8679971 4582 2.3 FACSIMILE (FAX) NUMBER (Include Area code) 901-8674190 | |
| 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/dc/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 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. 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, parents, and partner firms <input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only | | <input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population <input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially | |
| 6. 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 | | | |
| 7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (b)(4) 0 | | | |

15-Jan-2008

FEB 4 2008

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Date of Submission
 1/21/2008

User Fee Payment ID Number

(b)(4) Trade

Received

FDA Submission Document Number (if known)

SECTION A

TYPE OF SUBMISSION

| | | | | |
|--|--|---|--|--|
| <p>PMA</p> <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 | <p>PMA & HDE Supplement</p> <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 | <p>PDP</p> <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP | <p>510(k)</p> <input checked="" type="checkbox"/> Original Submission: <input type="checkbox"/> Traditional <input checked="" type="checkbox"/> Special <input type="checkbox"/> Abbreviated (Complete section I, Page 5) <input type="checkbox"/> Additional Information <input type="checkbox"/> Third Party | <p>Meeting</p> <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): |
| <p>IDE</p> <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement | <p>Humanitarian Device Exemption (HDE)</p> <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment | <p>Class II Exemption Petition</p> <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information | <p>Evaluation of Automatic Class III Designation (De Novo)</p> <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information | <p>Other Submission</p> <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) 867-4476 | | |
| Street Address 5677 Airline Rd. | FAX Number (including area code) (901) 867-4190 | | |
| City Arlington | State / Province TN | ZIP/Postal Code 38002 | Country USA |
| Contact Name Sarah Holtgrewe | | | |
| Contact Title Regulatory Affairs Specialist | | Contact E-mail Address sholtgrewe@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/Postal Code | Country |
| Contact Name | | | |
| Contact Title | | Contact E-mail Address | |

SECTION D1

REASON FOR APPLICATION - PMA, PDP, OR HDE

| | | |
|---|--|---|
| <input type="checkbox"/> Withdrawal <input type="checkbox"/> Additional or Expanded Indications 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"/> Sterilization <input type="checkbox"/> Packaging <input type="checkbox"/> Other (specify below) | <input type="checkbox"/> Labeling change: <input type="checkbox"/> Indications, <input type="checkbox"/> Instructions <input type="checkbox"/> Performance <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 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"/> 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"/> Repose 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"/> Other Reason (specify): | | |

SECTION D3

REASON FOR SUBMISSION - 510(k)

| | | |
|--|---|---|
| <input checked="" type="checkbox"/> New Device | <input type="checkbox"/> Additional or Expanded Indications | <input type="checkbox"/> Change in Technology |
| <input type="checkbox"/> Other Reason (specify): | | |

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

| | | | | | | | | |
|--|-----|---|--|---|--|---|--|---|
| Product codes of devices to which substantial equivalence is claimed | | | | | | | | Summary of, or statement concerning, safety and effectiveness information <input checked="" type="checkbox"/> 510 (k) summary attached <input type="checkbox"/> 510 (k) statement |
| 1 | HRS | 2 | | 3 | | 4 | | |
| 5 | | 6 | | 7 | | 8 | | |

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

| | 510(k) Number | | Trade or Proprietary or Model Name | | Manufacturer |
|---|---------------|---|---|---|---------------------------------|
| 1 | K051908 | 1 | CHARLOTTE™ Compression Plate | 1 | Wright Medical Technology, Inc. |
| 2 | K061808 | 2 | DARCO Locking Locking Bone Plate System | 2 | Wright Medical Technology, Inc. |
| 3 | | 3 | | 3 | |
| 4 | | 4 | | 4 | |
| 5 | | 5 | | 5 | |
| 6 | | 6 | | 6 | |

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification
 Compression Plate

| | Trade or Proprietary or Model Name for This Device | | Model Number |
|---|--|---|--------------|
| 1 | CHARLOTTE™ CLAW® 3.5 | 1 | Assorted |
| 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)

The CHARLOTTE™ CLAW® 3.5 is intended to be used for fixation such as: LisFranc arthrodesis, mono or bi-cortical osteotomies in the forefoot, first tarsophalangeal-arthrodesis, Akin osteotomy, midfoot and hindfoot arthrodeses or osteotomies, fixation of osteotomies for hallux valgus treatment (arf and Chevron), and arthrodesis of the metatarsocuneiform joint to reposition and stabilize metatarsus primus varus.

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form. FDA Document Number (if known)

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

| | | | |
|---|---|--|---|
| <input 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, Inc. | | Establishment Registration Number 1043534 | |
| Division Name (if applicable) N/A | | Phone Number (including area code) (901) 867-4476 | |
| Street Address 5677 Airline Rd | | FAX Number (including area code) (901) 867-4190 | |
| City Arlington | | State / Province TN | ZIP/Postal Code 38002 |
| Contact Name Sarah Holtgrewe | | Contact Title Regulatory Affairs Specialist | |
| | | Contact E-mail Address sholtgrewe@wmt.com | |

(b)(4) Trade Secret Process - Product Specs

| | | | |
|---|--|---|---|
| <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 (if applicable) | | Phone Number (including area code) () | |
| Street Address | | FAX Number (including area code) () | |
| City | | State / Province | ZIP/Postal Code |
| 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 | 03 | 06/10/2003 |
| 2 | F2229 | ASTM | Standard Specification for Wrought, Nitrogen Strengthened 23Manganese-21Chromium-1Molybdenum Low-Nickel Stainless Steel Alloy Bar and Wire for Surgical Implants | 02 | 12/10/2002 |
| 3 | F543 | ASTM | Standard Specification and Test Methods for Metallic Medical Bone Screws | 02 | 4/10/2002 |
| 4 | F382 | ASTM | Standard Specification and Test Method for Metallic Bone Plates | 03 | 4/10/2003 |
| | F1839 | ASTM | Standard Specification for Rigid Polyurethane Foam for Use as a Standard Material for Testing Orthopaedic Devices and Instruments | 01 | 2007 |
| 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:

Food and Drug Administration
CDRH (HFZ-342)
9200 Corporate Blvd.
Rockville, MD 20850

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



DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

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

Form Approved: OMB No. 0910-0616
Expiration Date: 06-30-2008
See OMB Statement on Reverse

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

SPONSOR/APPLICANT/SUBMITTER INFORMATION

| | |
|--|---|
| <p>1. NAME OF SPONSOR/APPLICANT/SUBMITTER</p> <p>Sarah Holtgrewe</p> | <p>2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES</p> <p>January 21, 2007</p> |
| <p>3. ADDRESS (Number, Street, State, and Zip Code)</p> <p>Wright Medical Technology, Inc. 5677 Airline Rd Arlington, TN 38002</p> | <p>4. TELEPHONE AND FAX NUMBER (Include Area Code)</p> <p>(T) +1 (901) 867-4476 (F) +1 (901) 867-4190</p> |

PRODUCT INFORMATION

5. FOR DRUGS/BIOLOGICS: Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s)
FOR DEVICES: Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s) (Attach extra pages as necessary)

| | |
|---|--|
| CHARLOTTE™ CLAW® 3.5--compression plate | |
| 21 CFR 888.3030--Class II Implant | |
| | |
| | |

APPLICATION/SUBMISSION INFORMATION

6. TYPE OF APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

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

7. INCLUDE IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/OTHER NUMBER (If number previously assigned)

| | | | | | |
|--|--|--|--|--|--|
| | | | | | |
|--|--|--|--|--|--|

8. SERIAL NUMBER ASSIGNED TO APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

CERTIFICATION STATEMENT/INFORMATION

9. CHECK ONLY ONE OF THE FOLLOWING BOXES (See instructions for additional information and explanation)

A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply because the application/submission which this certification accompanies does not reference any clinical trial.

B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply to any clinical trial referenced in the application/submission which this certification accompanies.

C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.

10. IF YOU CHECKED BOX C, IN # 9, PROVIDE THE NATIONAL CLINICAL TRIAL (NCT) NUMBER(S) FOR ANY "APPLICABLE CLINICAL TRIAL(S)," UNDER 42 U.S.C. § 282(j)(1)(A)(i), SECTION 402(j)(1)(A)(i) OF THE PUBLIC HEALTH SERVICE ACT, REFERENCED IN THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES (Attach extra pages as necessary)

NCT Number(s)

| | | | | |
|--|--|--|--|--|
| | | | | |
|--|--|--|--|--|

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

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

| | |
|--|---|
| <p>11. SIGNATURE OF SPONSOR/APPLICANT/SUBMITTER OR AN AUTHORIZED REPRESENTATIVE (SIGN)</p> <p><i>Sarah Holtgrewe</i></p> | <p>12. NAME AND TITLE OF THE PERSON WHO SIGNED IN #11</p> <p>Sarah Holtgrewe</p> <p>Regulatory Affairs Specialist</p> |
| <p>13. ADDRESS (Number, Street, State, and Zip Code) (of person identified in #11 & 12)</p> <p>5677 Airline Rd Arlington, TN 38002</p> | <p>14. TELEPHONE AND FAX NUMBER (Include Area Code)</p> <p>(T) +1 (901) 867-4476</p> <p>(F) +1 (901) 867-4190</p> |

15. DATE OF CERTIFICATION January 21, 2007

Paperwork Reduction Act Statement

Public Reporting Burden for this collection of information is estimated to average 15 minutes and 45 minutes (depending on the type of application/submission) per response, including time for reviewing instructions. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to the applicable address below.

| | | |
|---|---|---|
| Food and Drug Administration Center for Drug Evaluation and Research Central Document Room Form No. FDA 3674 5901-B Ammendale Road Beltsville, MD 20705-1266 | Food and Drug Administration Center for Biologics Evaluation and Research 1401 Rockville Pike Rockville, MD 20852-1448 | Food and Drug Administration Center for Devices and Radiological Health Program Operations Staff (HFZ-403) 9200 Corporate Blvd. Rockville, MD 20850 |
|---|---|---|

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information, unless it displays a currently valid OMB control number.

Department of Health and Human Services
 Food and Drug Administration
STANDARDS DATA REPORT FOR 510(K)
(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 TITLE¹
 ASTM F138-03 Standard Specification for Wrought 18Chromium-14Nickel-2.5Molybdenum Stainless Steel Bar and Wire for Surgical Implants

Please answer the following questions Yes No

Is this standard recognized by FDA²?

FDA Recognition number³ # 017

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

Is a summary report⁴ 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 the standard?
 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 guidance⁶ 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], www.fda.gov/cdrh/stdsprog.html

³ <http://www.accessdata.fda.gov/scripts/cdrh/odocs/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 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 of CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

Department of Health and Human Services
 Food and Drug Administration
STANDARDS DATA REPORT FOR 510(K)S
(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 F2229-02 Standard Specification for Wrought, Nitrogen Strengthened 23Manganese-21Chromium-1Molybdenum Low-Nickel Stainless Steel Alloy Bar and Wire for Surgical Implants

Please answer the following questions Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ # _____

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 the standard?
 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], www.fda.gov/cdrh/stdsprog.html
³ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>
⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name 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 of CDH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

Department of Health and Human Services
 Food and Drug Administration
STANDARDS DATA REPORT FOR 510(K)S
(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 TITLE¹

ASTM F1839-01 Standard Specification for Rigid Polyurethane Foam for Use as a Standard Material for Testing Orthopaedic Devices and Instruments

Please answer the following questions

Yes No

Is this standard recognized by FDA²?

FDA Recognition number³ # _____

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

Is a summary report⁴ 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 the standard?
 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 guidance⁶ 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], www.fda.gov/cdrh/stdsprog.html

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

⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name 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 of CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(K)S
(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 TITLE¹

ASTM F382-99(2003) Standard Specification and Test Method for Metallic Bone Plates

Please answer the following questions

Yes No

Is this standard recognized by FDA²?

FDA Recognition number³ # 016

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

Is a summary report⁴ 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 the standard?
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 guidance⁶ 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], www.fda.gov/cdrh/stdsprog.html

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

⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name 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 of CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE
ASTM F382-99(2003) STANDARD SPECIFICATION AND TEST METHOD FOR METALLIC BONE PLATES

CONFORMANCE WITH STANDARD SECTIONS*

| SECTION NUMBER | SECTION TITLE | CONFORMANCE? |
|----------------|--|--|
| A1 | Standard Test Method for Single Cycle Bend Testing of Metallic Bone Plates | <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A |

TYPE OF DEVIATION OR OPTION SELECTED*

(b)(4) Trade

DESCRIPTION

(b)(4) Trade Secret Process - Product Specs

JUSTIFICATION

(b)(4) Trade Secret Process - Product Specs

| SECTION NUMBER | SECTION TITLE | CONFORMANCE? |
|----------------|---|--|
| A2 | Standard Test Method for determining the Bending Fatigue Properties of Metallic Bone Plates | <input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A |

TYPE OF DEVIATION OR OPTION SELECTED*

Exclusion of this section of the standard

DESCRIPTION

No fatigue testing completed

JUSTIFICATION

Testing not required for predicate 510(k)

| 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)
(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 F543-02 Standard Specification and Test Methods for Metallic Medical Bone Screws

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ # 017

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?

as 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 the standard?
 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], www.fda.gov/cdrh/stdsprog.html

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

⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name 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 of CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE
ASTM F543-02 STANDARD SPECIFICATION AND TEST METHODS FOR METALLIC MEDICAL BONE SCREWS

CONFORMANCE WITH STANDARD SECTIONS*

| SECTION NUMBER | SECTION TITLE | CONFORMANCE? |
|----------------|--|--|
| A1 | Test Method for Determining Torsional Properties of Metallic Bone Screws | <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A |

TYPE OF DEVIATION OR OPTION SELECTED*
Adaptation of a section

DESCRIPTION
Data recorded only peak torque as measured by an electronic meter of insertion, removal and ultimate torque

JUSTIFICATION
Peak torque is necessary for insertion and removal and ultimate torque. This is of primary importance of the intended device

| SECTION NUMBER | SECTION TITLE | CONFORMANCE? |
|----------------|---|--|
| A2 | Test Method for Driving Torque of Medical Bone Screws | <input checked="" 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? |
|----------------|--|--|
| | Test Method for Determining the Axial Pull Out Strength of Medical Bone Screws | <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A |

TYPE OF DEVIATION OR OPTION SELECTED*
Adaption of section

DESCRIPTION
The distal threads were inserted into the foam bone to the neck of the screw.

JUSTIFICATION
Worst case condition for the subject screw is a 14 mm screw as measured from the tip of the screw to the top of the head with about 5 distal threads. Worst case condition for the predicate screw is a 12mm screw as measured from the tip of the screw to the top of the head with about 7 distal threads. The section states 60% of the threads for a fully threaded screw under 20 mm be inserted into the foam bone material. For the subject device, only 3 threads would be inserted. The peak force is necessary for the axial pull out strength. To insure consistent data, the screw was inserted into the foam bone to the neck of the screw, 5 and 7 threads respectively

* 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.

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**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE
TM F543-02 STANDARD SPECIFICATION AND TEST METHODS FOR METALLIC MEDICAL BONE SCREWS

CONFORMANCE WITH STANDARD SECTIONS*

| | | |
|----------------------|--|--|
| SECTION NUMBER A4 | SECTION TITLE Specifications for HA and HB Metallic Medical Bone Screws | CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A |
|----------------------|--|--|

TYPE OF DEVIATION OR OPTION SELECTED*

DESCRIPTION

JUSTIFICATION

Device is a locking plate screw, not an HA or HB metallic medical bone screw

| | | |
|----------------------|---|--|
| SECTION NUMBER A5 | SECTION TITLE Specification for HC and HD Metallic Medical Bone Screws | CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A |
|----------------------|---|--|

TYPE OF DEVIATION OR OPTION SELECTED*

DESCRIPTION

JUSTIFICATION

Device is a locking plate screw, not an HC or HD metallic medical bone screw

| | | |
|----------------|--|--|
| SECTION NUMBER | SECTION TITLE Specification for Metallic Bone Screw Drive Connections | CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A |
|----------------|--|--|

TYPE OF DEVIATION OR OPTION SELECTED*

option selected: A6.2.1.6 Hexagonal

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.

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| <i>Establishment Registration Number</i> | 1 |
| <i>Primary Contact</i> | 1 |
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CHARLOTTE™ CLAW® 3.5 SPECIAL 510(k) PREMARKET NOTIFICATION

I. ADMINISTRATIVE INFORMATION

- A.** The **TRUTHFUL AND ACCURATE STATEMENT** is provided as **Exhibit 3**.
- B.** The **510(k) SUMMARY** and **INDICATIONS STATEMENT** are provided as **Exhibit 4**.

C. MANUFACTURER IDENTIFICATION

| | |
|------------------------------------|--|
| Manufacturer's Name: | Wright Medical Technology, Inc. 5677 Airline Road Arlington, TN 38002 |
| Establishment Registration Number: | 1043534 |
| Primary Contact: | Sarah Holtgrewe Regulatory Affairs Specialist sholtgrewe@wmt.com Phone: 901-867-4476 Fax: 901-867-4630 |
| Secondary Contact: | Brian Young Senior Director, Regulatory Affairs byoung@wmt.com Phone: 901-867-4120 Fax: 901-867 4630 |

D. DEVICE IDENTIFICATION

| | |
|--|---|
| Proprietary Name: | CHARLOTTE™ CLAW® 3.5 |
| Common Name: | Compression Plate |
| Classification Name and Reference: | 21 CFR 888.3030 Plate, Fixation, Bone – Class II |
| Device Classification for the Predicate Device | 21 CFR 888.3030 Plate, Fixation, Bone – Class II |
| Device Product Code and Panel Code: | Orthopedics/87/HRS |

II. DEVICE INFORMATION and SUBSTANTIAL EQUIVALENCE COMPARISON

A. SUBJECT AND PREDICATE DEVICE IDENTIFICATION

Subject Device: CHARLOTTE™ CLAW® 3.5

Predicate Devices: CHARLOTTE™ Compression Plate
510(k): K051908
Exhibit 1

DARCO® 3.5 screws¹
510(k): K061808
Exhibit 1 & Exhibit 2

B. INTENDED USES/ INDICATIONS

The indications for use for the CHARLOTTE™ CLAW® 3.5 are identical to the indications for use for the previously cleared CHARLOTTE™ Compression Plate, 510(k) K051908 (**Exhibit 1**), and are stated below.

The CHARLOTTE™ CLAW® 3.5 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.

C. DEVICE DESCRIPTION

The CHARLOTTE™ CLAW® 3.5 (Figure 1) consists of curved 4-hole plates and locking screws of various lengths. The screws are available in two material types: ASTM F138 CW stainless steel (standard) and ASTM F2229 stainless steel (BIODUR).

The design features of the CHARLOTTE™ CLAW® 3.5 plates (**Exhibit 6: Drawings**) are substantially equivalent to the design features of the 2-hole CHARLOTTE™ Compression Plate (**Exhibit 7: Drawings**). The design features of the CHARLOTTE™ CLAW® 3.5 screws are substantially equivalent to the design features of the CHARLOTTE™ Compression Plate screws and Wright Medical Technology's DARCO® 3.5 screws cleared under 510(k) K061808 (**Exhibit 8: Drawings**). The CHARLOTTE™ CLAW® 3.5 and the CHARLOTTE™ Compression Plate have the same intended use.

¹ Wright Medical acquired DARCO and its assets, (including the DARCO PIA screws and the original 510(k) clearance). Hence Wright Medical is the manufacturer and owns the 510(k) for the original, unmodified device. A letter summarizing the acquisition is in **Exhibit 2**.

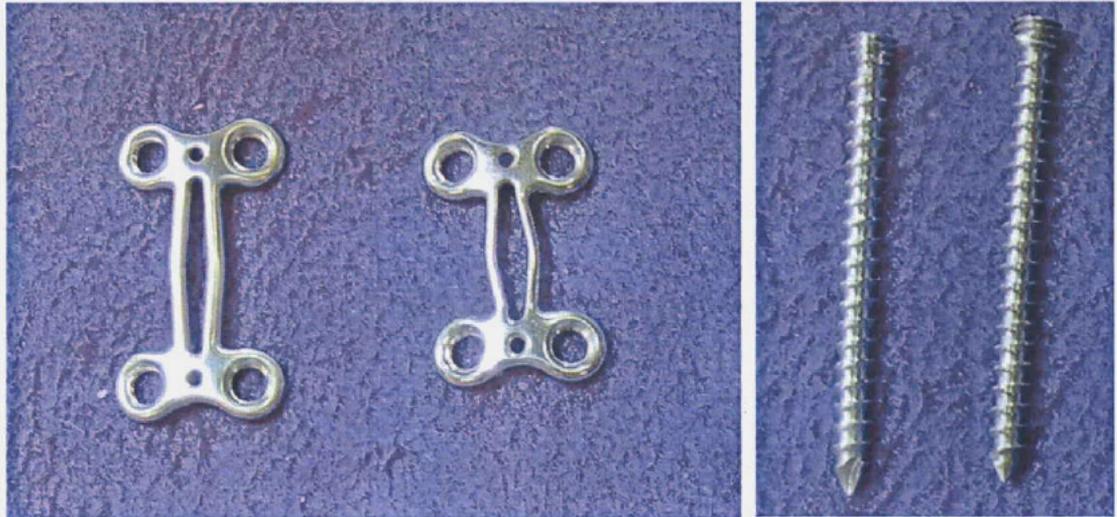


Figure 1 Wright Medical Technology's CHARLOTTE™ CLAW® 3.5
(from left to right):

(b)(4) Trade Secret Process - Product Specs

The design features of the CHARLOTTE™ CLAW® 3.5 are summarized below:

Plate

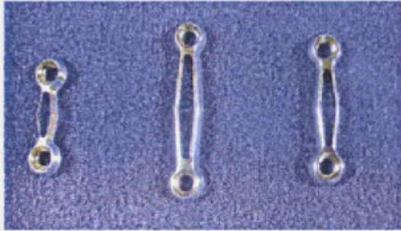
- Manufactured from ASTM F138 Type 316L stainless steel, cold worked
- 4 screw holes
- 2 K-wire holes for 1.6mm k-wire (Wright Medical k-wires are not used as implants)
- 3 sizes available: (b)(4) Trade Secret
- Diamond shape slot compression feature
- Curved plate to generally fit bones in midfoot and hindfoot
- Locking detail to prevent screw back-out
- Packaged sterile or non-sterile

Screws

- Manufactured from ASTM F138 Type 316L stainless steel, cold worked or ASTM F2229 stainless steel
- 3.5mm threaded diameter
- 6 lengths available: (b)(4) Trade Secret
- 4.5mm threaded tapered locking head to engage plate
- Self tapping feature
- 2.5 mm hex head drive
- Packaged sterile or non-sterile

Table 1 compares the design features of the CHARLOTTE™ CLAW® 3.5 plate to the design features of the predicate CHARLOTTE™ Compression Plate. Table 2 compares the design features of the CHARLOTTE™ CLAW® 3.5 screws to the design features of the predicates CHARLOTTE™ Compression Plate screws and DARCO® 3.5 screws.

Table 1 Comparison of the CHARLOTTE™ CLAW® 3.5 plate and the predicate plates.

| | CHARLOTTE™ CLAW® 3.5 | CHARLOTTE™ Compression Plate |
|------------------------|---|--|
| Device | Subject Device | Predicate (K051908) |
| Picture |  |  |
| Materials | ASTM F138 Stainless Steel, Cold Worked | ASTM F139 ² Stainless Steel, Cold Worked |
| Number of Holes | 4 | 2 |
| Size Range (Interaxis) | (b)(4) | (b)(4) |
| Plate Thickness | (b)(4) | (b)(4) |
| Plate Curvature | curved | flat |
| Compression Feature | Diamond shaped slot compression | Diamond shaped slot compression |
| Locking Detail | (b)(4) Trade Secret | (b)(4) Trade Secret Process - Product |
| Sterility | Performed by end user or Gamma sterilized | Gamma sterilized |
| Intended Use | Same as CHARLOTTE™ Compression Plate | The CHARLOTTE™ Compression 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. |

(b)(4) Trade Secret Process - Product Specs

Table 2 Comparison of the CHARLOTTE™ CLAW® 3.5 screws and the predicate screws.

| | CHARLOTTE™ CLAW® 3.5 | | DARCO® 3.5 | CHARLOTTE™ Compression Plate |
|--------------------------|---|---|--|---|
| Device | Subject Device | | Predicate (K061808) | Predicate (K051908) |
| Picture |  |  |  |  |
| Materials | ASTM F138 Stainless Steel, Cold Worked (standard) | ASTM F2229 Stainless Steel (BIODUR) | ISO 5832-3 Titanium Alloy | ASTM F138 Stainless Steel, Cold Worked |
| Screw Diameter | (b)(4) | | (b)(4) | (b)(4) |
| Screw Lengths | (b)(4) Trade Secret Process - Product Specs | | (b)(4) Trade Secret Process - Product Specs | |
| Thread Details | 3.5mm threaded diameter 4.5mm threaded locking head | | 3.5mm threaded diameter 4.5mm threaded locking head | 2.7mm threaded diameter 4.1mm locking head |
| Locking Drive Connection | 2.5mm hex head drive | | 2.5mm hex head drive | Cruciform drive connection |
| Sterility | Performed by end user or Gamma sterilized | | Performed by end user | Gamma sterilized |

D. MATERIALS

The CHARLOTTE™ CLAW® 3.5 system and the CHARLOTTE™ Compression Plate system are both manufactured from stainless steel.

- **CHARLOTTE™ CLAW® 3.5 Plate (subject)**
 ASTM F138 Standard Specification for Wrought 18 Chromium-14 Nickel-2.5 Molybdenum Stainless Steel Bar and Wire for Surgical Implants
- **CHARLOTTE™ Compression Plate (predicate)**
 ASTM F139 Standard Specification for Wrought 18 Chromium-14 Nickel-2.5 Molybdenum Stainless Steel Sheet and Strip for Surgical Implants
- **CHARLOTTE™ CLAW® 3.5 Screws (subject)**
 - ASTM F138 Standard Specification for Wrought 18 Chromium-14 Nickel-2.5 Molybdenum Stainless Steel Bar and Wire for Surgical Implants
 - ASTM F2229 Standard Specification for Wrought, Nitrogen Strengthened 23Manganese-21Chromium-1Molybdenum Low Nickel Stainless Steel Alloy Bar and Wire for Surgical Implants

- **CHARLOTTE™ Compression Plate Screws (predicate)**
ASTM F138 Standard Specification for Wrought 18 Chromium-14 Nickel-2.5 Molybdenum Stainless Steel Bar and Wire for Surgical Implants

III. DESIGN CONTROL ACTIVITIES

A. DECLARATION OF CONFORMITY

The signed declaration of conformity with design controls is provided in **Exhibit 5**.

B. RISK ANALYSIS METHOD

(b)(4) Trade Secret Process - Product Specs

A large black rectangular redaction box covers the content of this section.

C. DESIGN VERIFICATION TESTING

(b)(4) Trade Secret Process - Product Specs

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Table 3 Design Verification Tests.

(b)(4) Trade Secret Process - Product Specs

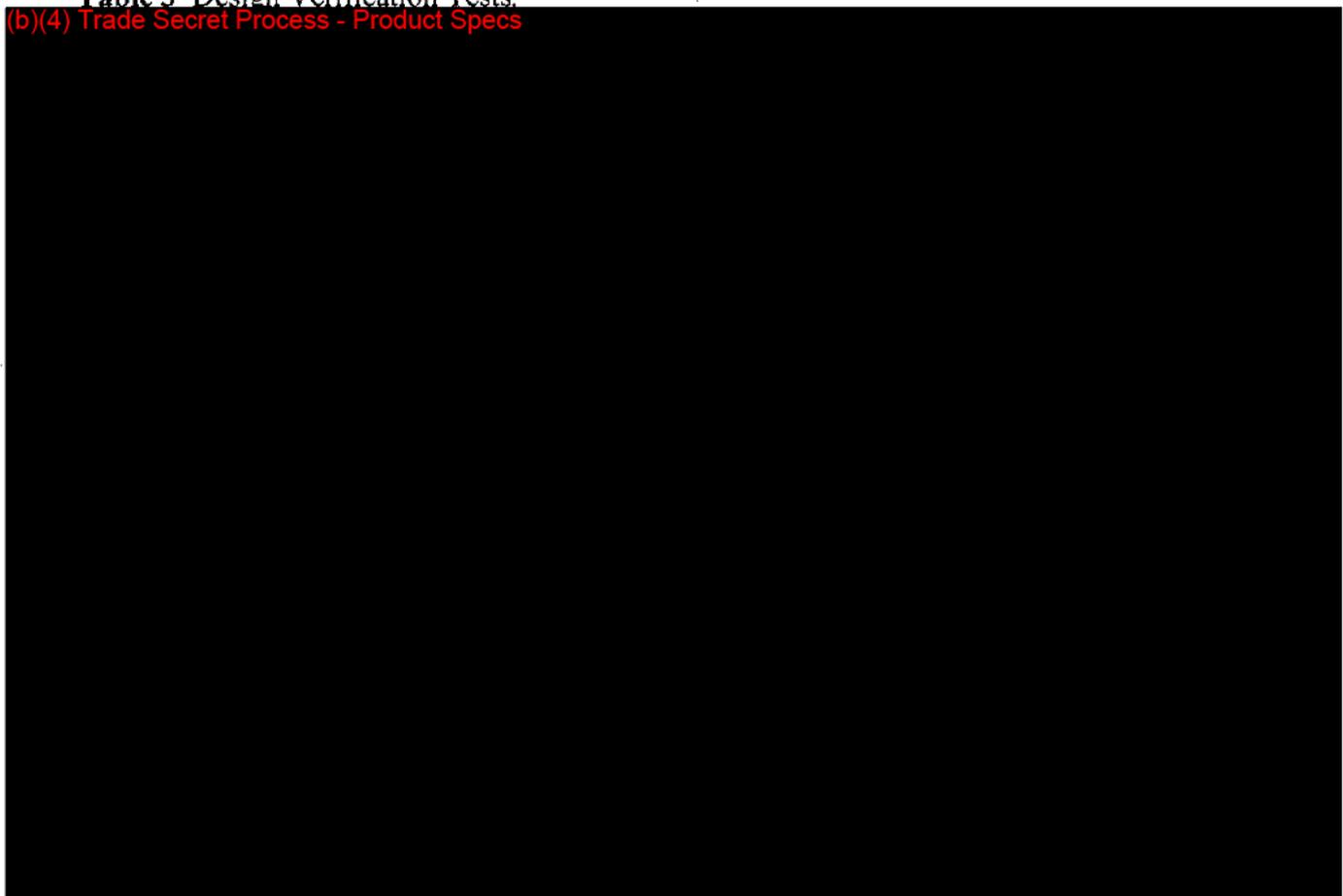
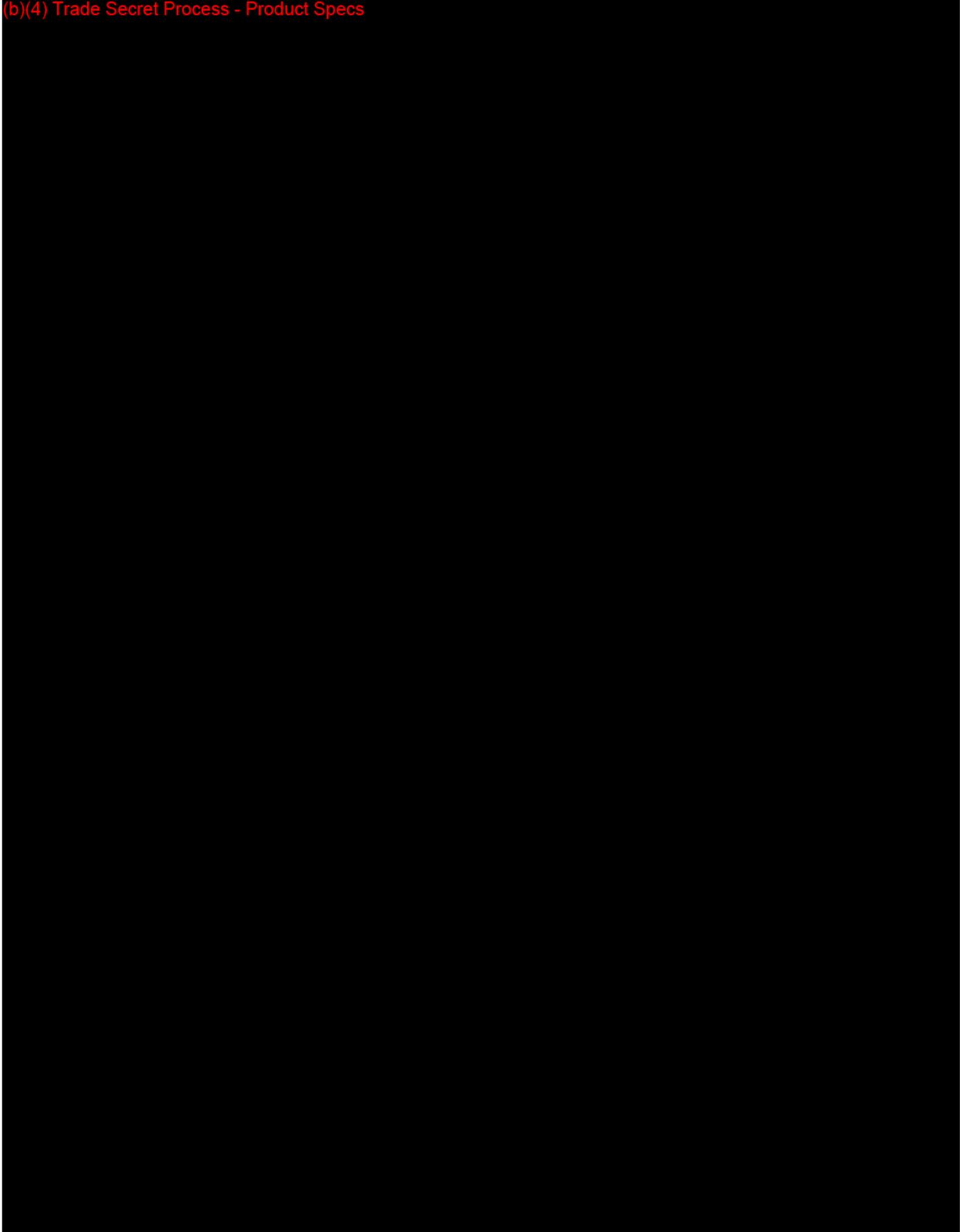
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Table 3 (cont'd)

(b)(4) Trade Secret Process - Product Specs



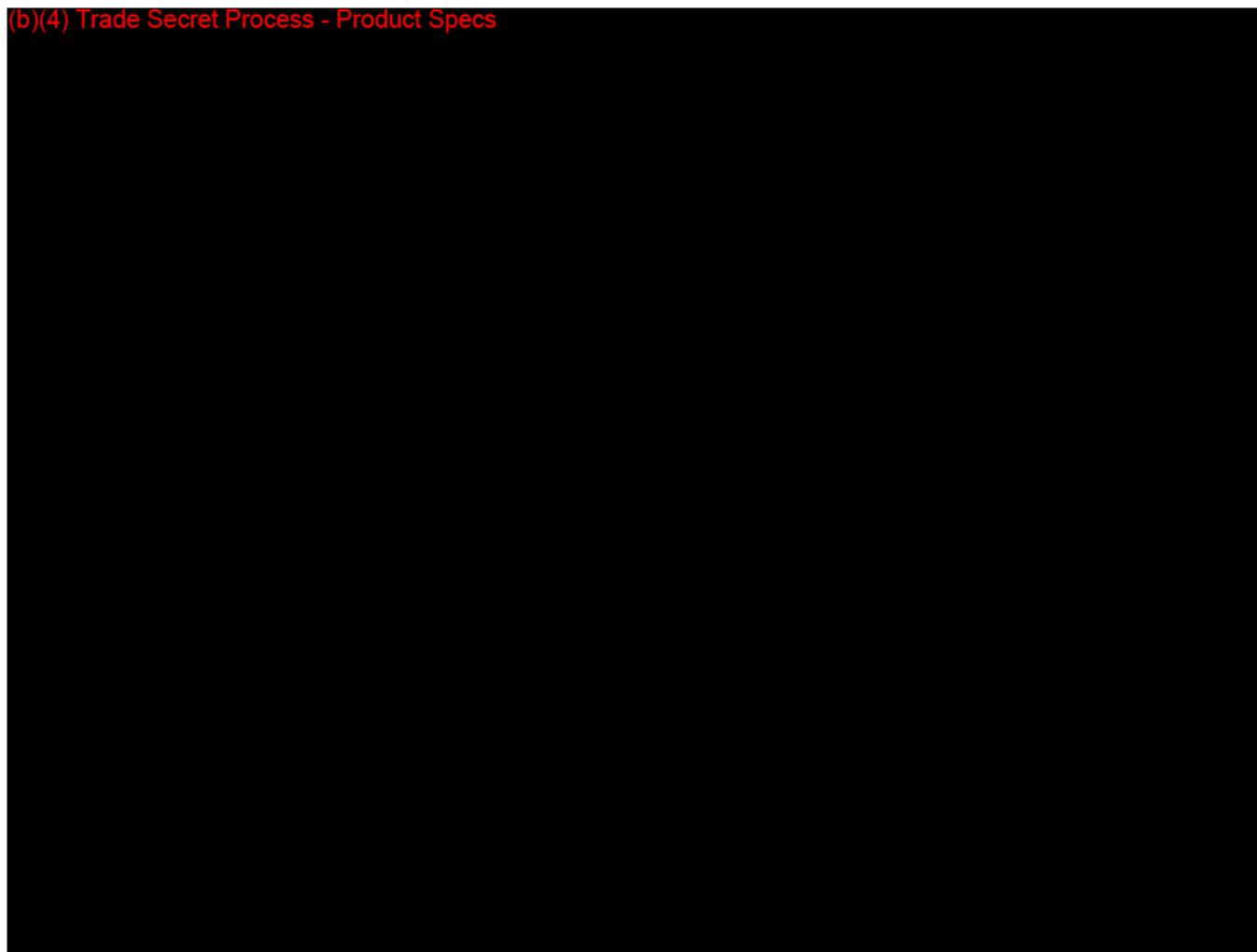
D. TESTING INFORMATION

(b)(4) Trade Secret Process - Product Specs

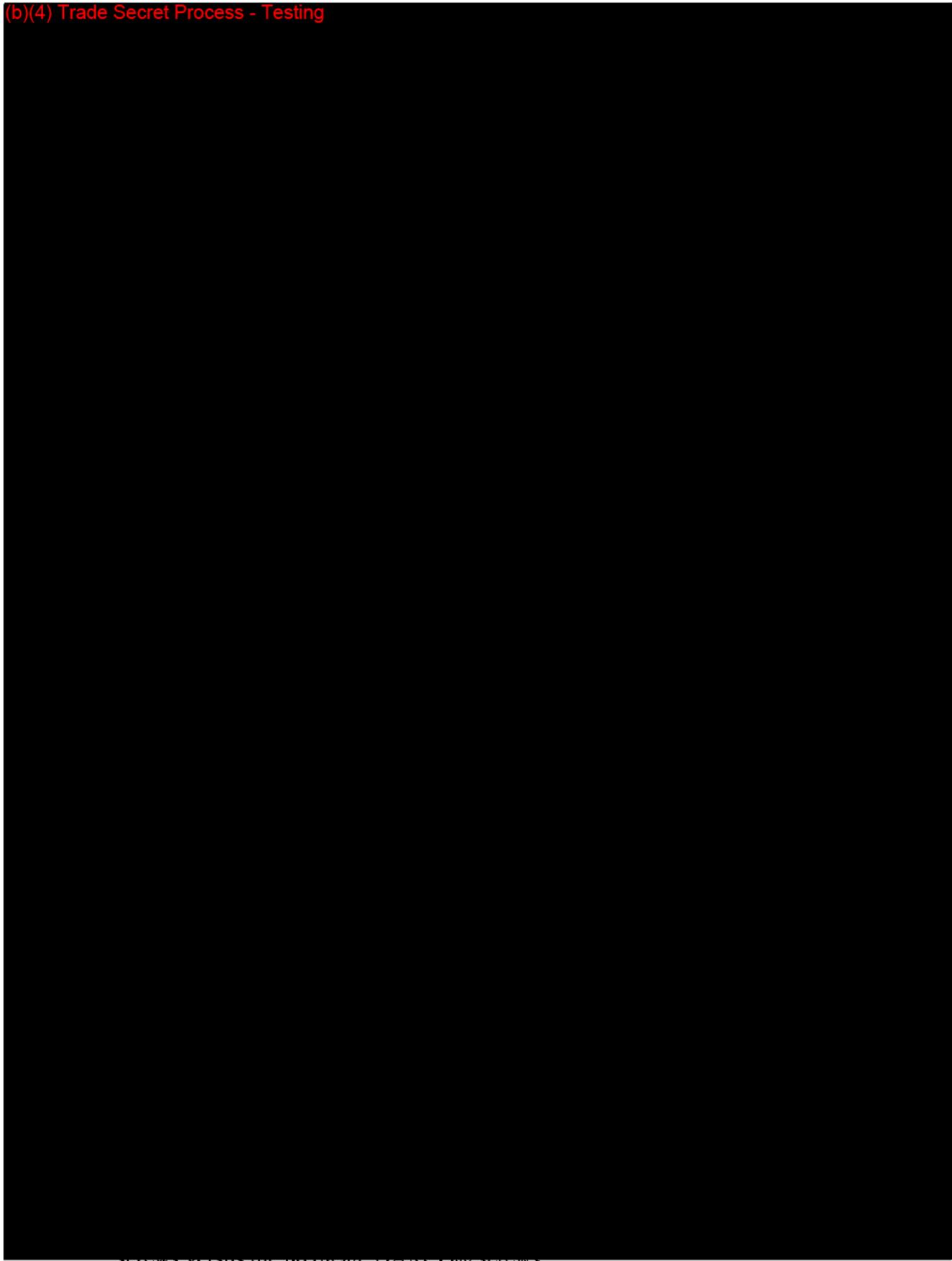


All tests are described below, and additional information can be located in the engineering report, **Exhibit 9**.

(b)(4) Trade Secret Process - Product Specs

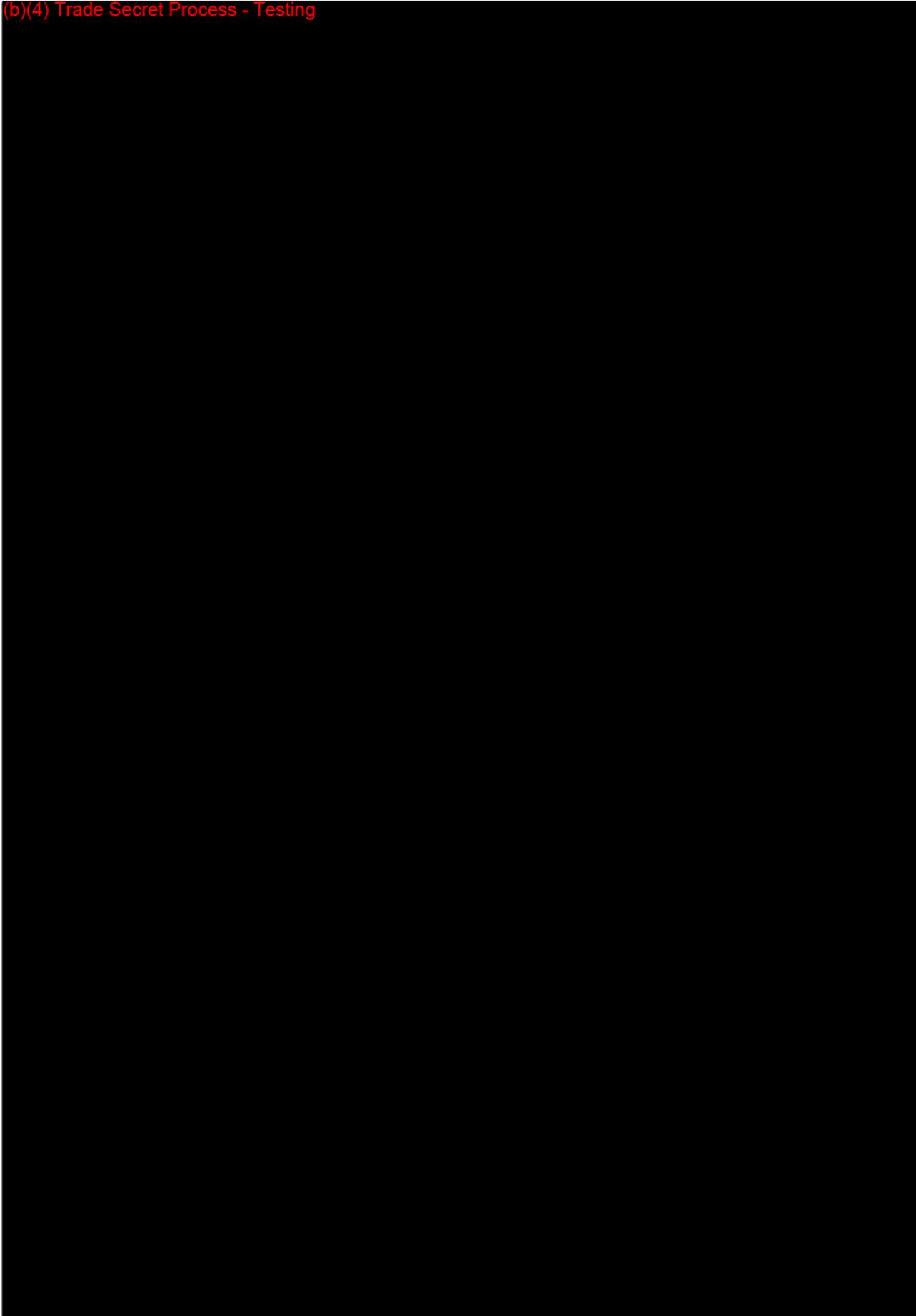


(b)(4) Trade Secret Process - Testing

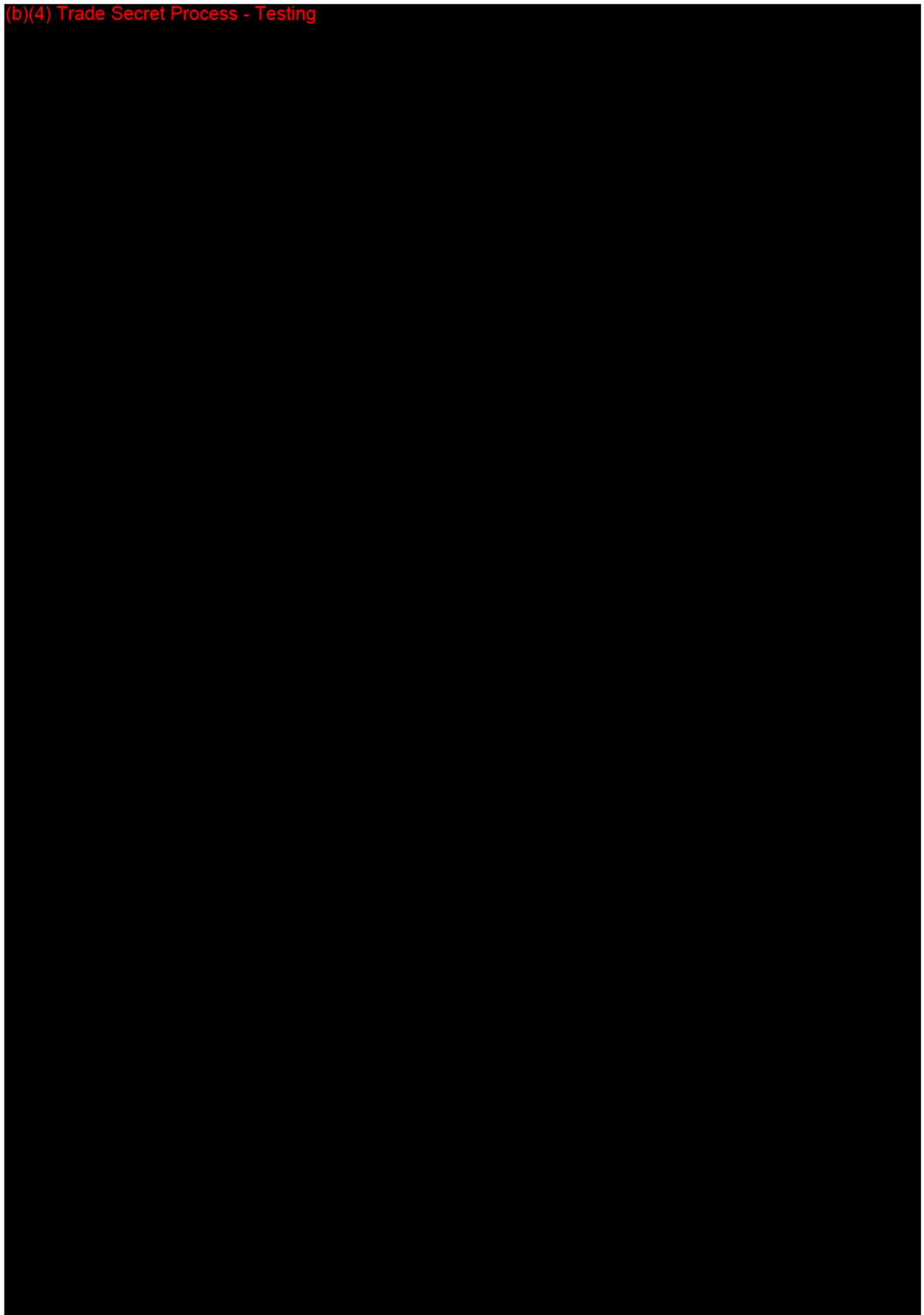


screws versus the predicate DAKCO® screws.

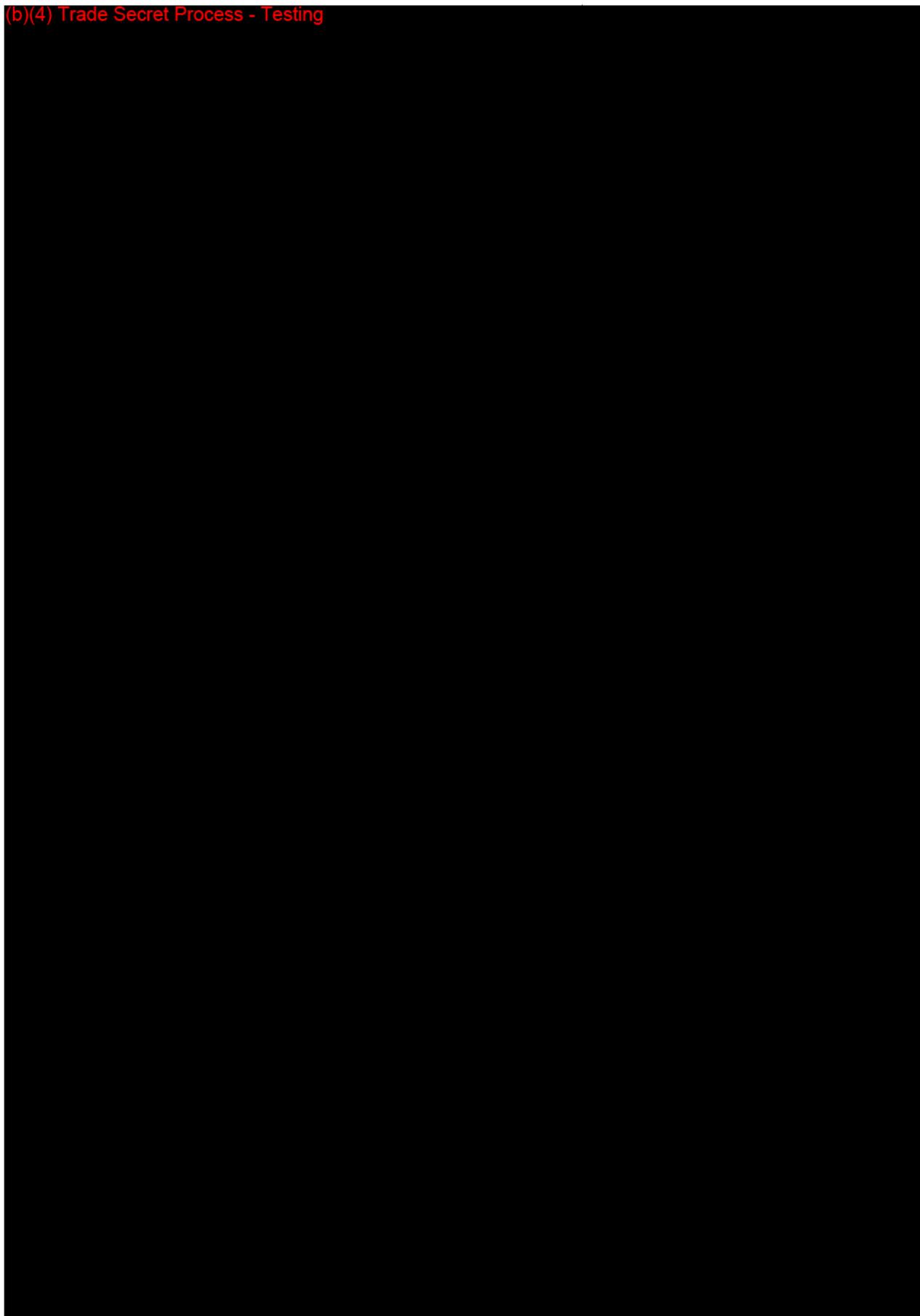
(b)(4) Trade Secret Process - Testing



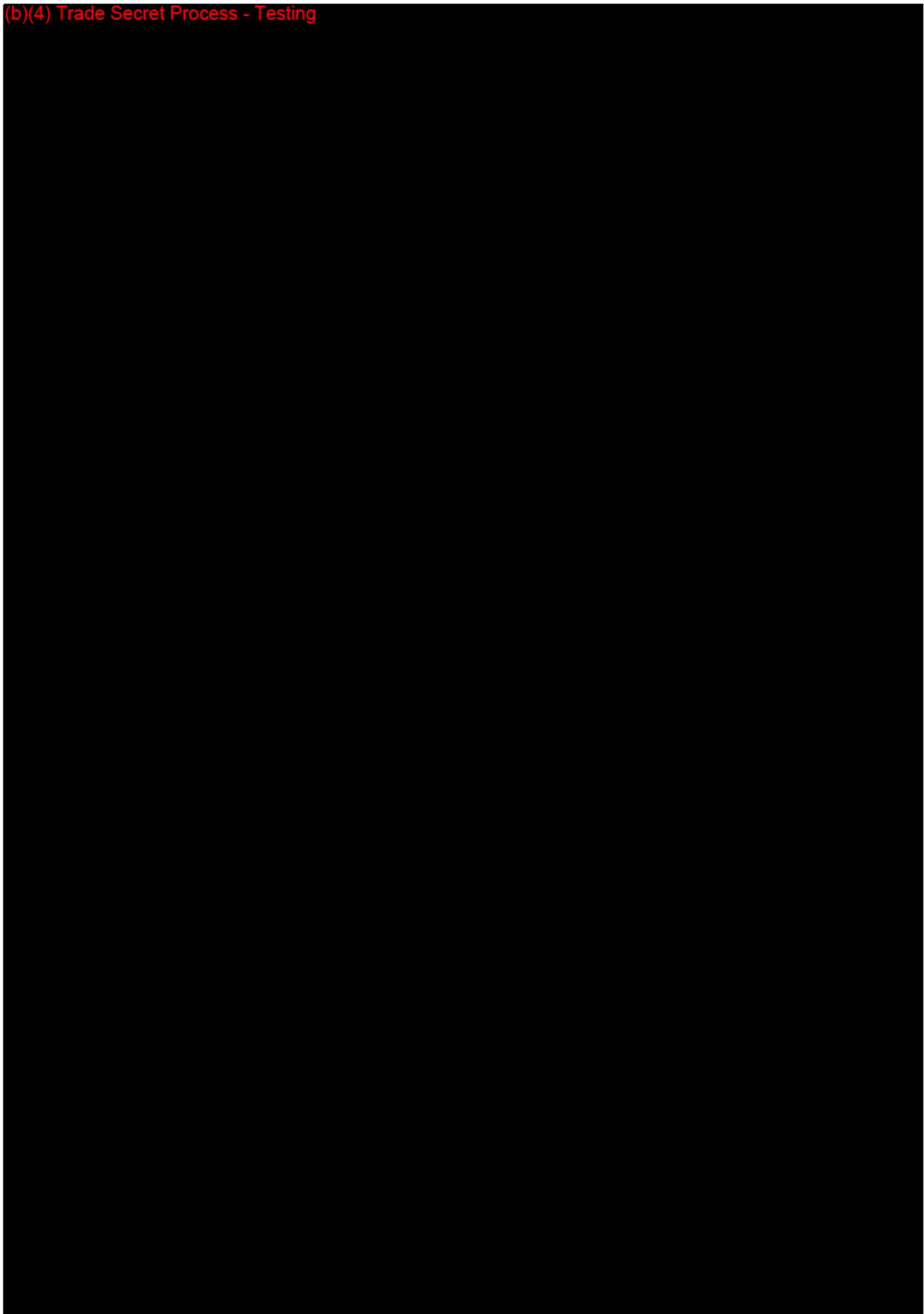
(b)(4) Trade Secret Process - Testing



(b)(4) Trade Secret Process - Testing



(b)(4) Trade Secret Process - Testing



(b)(4) Trade Secret Process - Testing

Based on the above testing analyses, the CHARLOTTE™ CLAW® 3.5 is expected to withstand typical physiological loading equivalent to the previously cleared CHARLOTTE™ Compression Plate and the DARCO® 3.5 screws. This testing supports the fact that the CHARLOTTE™ CLAW® 3.5 is substantially equivalent to its predicates.

E. STERILIZATION

The CHARLOTTE™ CLAW® 3.5 is provided either non-sterile or gamma sterilized. Sterilization parameters for parts provided sterile can be found in **Exhibit 10** and are identical to the sterilization parameters for the CHARLOTTE™ Compression Plate. Sterilization instructions for parts provided non-sterile can be found in the package insert (**Exhibit 11**).

F. LABELING

Important medical information is contained in the package insert provided as **Exhibit 11**. A sample of the package labeling is provided as **Exhibit 12**. All labels have the same general design and follow the same format. Advertising literature is not available at this time.

G. BIOCOMPATIBILITY

Both the subject CHARLOTTE™ CLAW® 3.5 plates and screws (standard type) and the predicate CHARLOTTE™ Compression Plate screws are manufactured from stainless steel conforming to ASTM F138. The BIODUR stainless steel screws for the subject CHARLOTTE™ CLAW® 3.5 conform to ASTM F2229. Both ASTM standards F138 and F2229 state, "an acceptable level of biological response can be expected, if the material is used in appropriate applications."

H. EXPIRATION

These devices are labeled with an 8 year expiration date.

I. SUBSTANTIAL EQUIVALENCE DECISION MAKING PROCESS

Following are responses to FDA's 510(k) "Substantial Equivalence" Decision-Making Process (Overview) flow chart.

Does the New Device Have Same Intended Use?

The indications for use for the CHARLOTTE™ CLAW® 3.5 are identical to the indications for use for the previously cleared CHARLOTTE™ Compression Plate (Exhibit 1: 510(k) K051908).

Does New Device Have Technological Characteristics That Raise New Types of Safety and Effectiveness Questions?

The CHARLOTTE™ CLAW® 3.5 incorporates 4-screw holes for added stability after compression loading as opposed to 2-screw holes in the CHARLOTTE™ Compression Plate. The subject plates are slightly thicker, curved, and (b)(4) Trade Secret Process to the flat predicate CHARLOTTE™ Compression Plates. The locking feature of the subject device contains (b)(4) Trade Secret Process

The CHARLOTTE™ CLAW® 3.5 screws are 3.5mm diameter (b)(4) Trade Secret Process same as the DARCO® 3.5 screws. The subject screws are ASTM F138 cold worked stainless steel, same as the CHARLOTTE™ Compression Plate screws, or ASTM F2229 stainless steel, a (b)(4) Trade Secret Process F138 stainless steel. Also, the previously cleared CHARLOTTE™ Compression Plate screws incorporate a cruciform driver/screw interface, whereas the CHARLOTTE™ CLAW® 3.5 utilizes a hex interface.

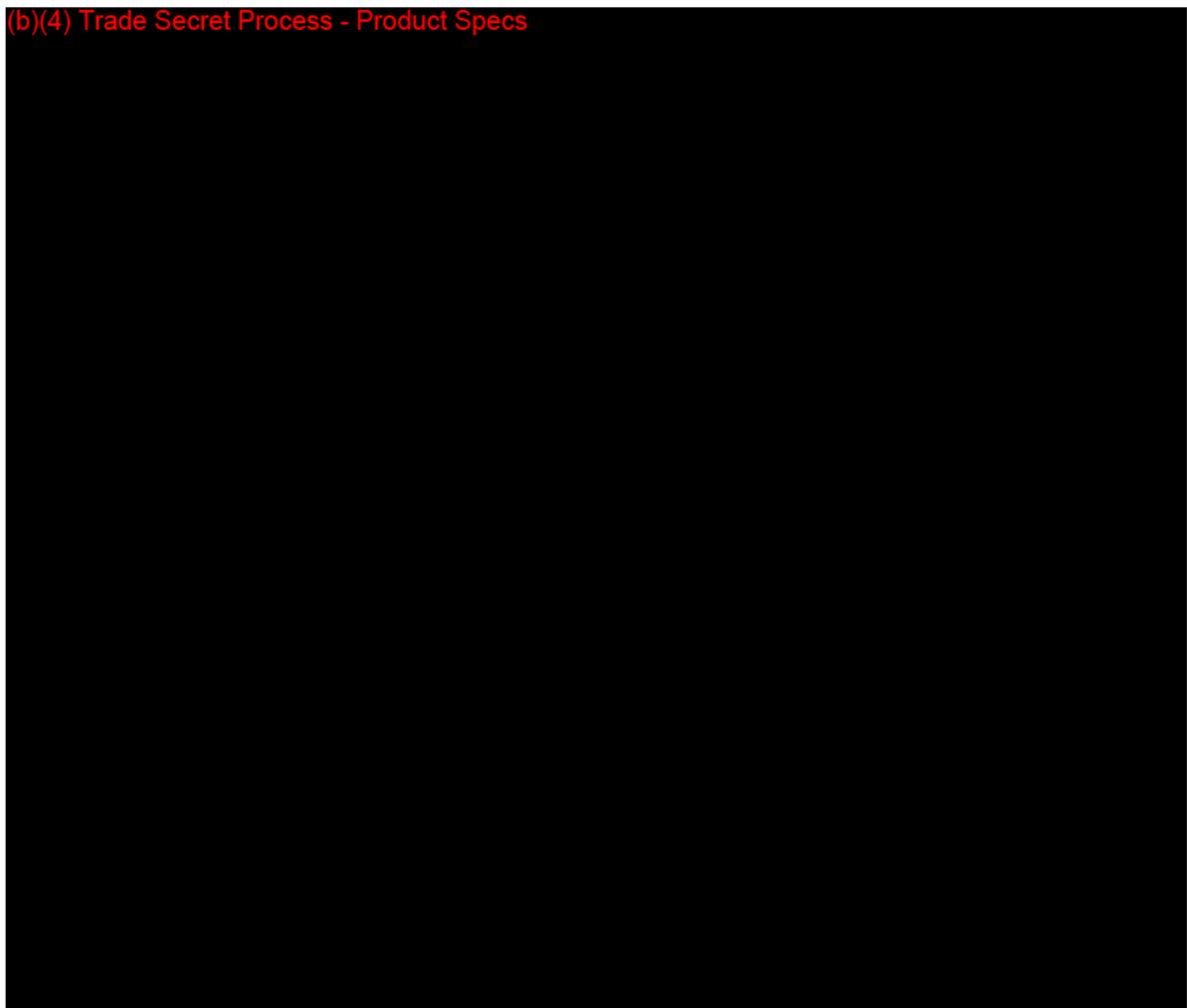
Testing was conducted to verify that the changes to the plate, screw, and plate/screw interface do not affect performance of the device, and therefore do not raise new types of safety and effectiveness concerns.

Does Descriptive or Performance Information Demonstrate Equivalence?

The CHARLOTTE™ CLAW® 3.5 and the predicates have different dimensional specifications, but testing shows that the CHARLOTTE™ CLAW® 3.5 performance is acceptable and equivalent.

(b)(4) Trade Secret Process - Product Specs

(b)(4) Trade Secret Process - Product Specs



Conclusion

Based on the above responses to the questions provided in the 510(k) “Substantial Equivalence” Decision-Making Process (Overview) and data presented within this Premarket Notification, Wright Medical Technology’s CHARLOTTE™ CLAW® 3.5 is substantially equivalent to the CHARLOTTE™ Compression Plate plates and screws and the DARCO® 3.5 screws.

List of Exhibits

| | |
|------------|---|
| Exhibit 1 | 510(k): K051908- CHARLOTTE™ Compression Plate 510(k): K061808- DARCO Locking Bone Plate System |
| Exhibit 2 | DARCO Acquisition Letter |
| Exhibit 3 | Truthful and Accurate Statement |
| Exhibit 4 | 510(k) Summary of Safety and Effectiveness Indications Statement |
| Exhibit 5 | Declaration of Conformity with Design Controls |
| Exhibit 6 | CHARLOTTE™ CLAW® 3.5 Drawings |
| Exhibit 7 | CHARLOTTE™ Compression Plate Representative Drawings |
| Exhibit 8 | DARCO 3.5 Screws Representative Drawings |
| Exhibit 9 | [REDACTED] (b) [REDACTED] |
| Exhibit 10 | Sterilization Summary |
| Exhibit 11 | Wright Medical Reconstructive and Fracture Fixation System Package Insert (133763-2) |
| Exhibit 12 | Package Labeling |





DEPARTMENT OF HEALTH & HUMAN SERVICES

AUG 12 2005 Public Health Service

AUG 10 2005

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Wesley L. Reed
Regulatory Affairs Specialist
Wright Medical Technology, Inc.
5677 Airline Road
Arlington, Tennessee 38002

Re: K051908

Trade/Device Name: CHARLOTTE™ Compression Plate
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation
appliances and accessories

Regulatory Class: II

Product Code: HRS

Dated: July 11, 2005

Received: July 14, 2005

Dear Mr. Reed:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

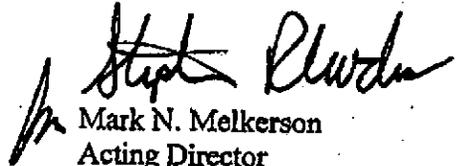
AUG 12 2005

Page 2 - Mr. Wesley L. Reed

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). 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) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (If known): K051908

Device Name: CHARLOTTE™ Compression Plate

Indications For Use:

The Compression 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.

Prescription Use
 (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
 (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE).

1 of 1

Steph Clarke

Special Agent in Charge
Division of General Restorative
and Neurological Devices

510(k) Number: K051908



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 17 2006

DARCO International
% Mr. Mark S. Cooper
Director of Regulatory Affairs
810 Memorial Boulevard
Huntington, West Virginia 25701

Re: K061808

Trade/Device Name: DARCO Locking Bone Plate System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories

Regulatory Class: II
Product Code: HRS
Dated: June 26, 2006
Received: June 28, 2006

Dear Mr. Cooper:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic

Page 2 – Mr. Mark S. Cooper

product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson

Director

Division of General, Restorative
and Neurological Devices

Office of Device Evaluation

Center for Devices and
Radiological Health

Enclosure

**510(k)
Statement of Indications for Use**

510(k) number (if known) K061808

Device Name DARCO Locking Bone Plate System

Indications for Use The DARCO Locking Bone Plate System is intended for use in stabilization and fixation of fresh fractures, revision procedures, joint fusion, and reconstruction of small bones of the hand, feet, wrist, ankles, fingers and toes. The system may be used in both adult and pediatric patients.

Prescription Use XXX Over the Counter Use _____
(Part 21 CFR 801 Subpart D) AND/OR (Part 21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE) Page 1 of 1

Barbara Bruch
(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K061808



Thomas L. McAllister, Esq.
Assistant General Counsel
Direct Dial (901) 867-4819
Facsimile (901) 867-4398
Email tmcallister@wmt.com

January 24, 2008

To Whom It May Concern:

Wright Medical Technology, Inc. purchased certain assets of Darco International, Inc. on April 4, 2007. The assets purchased by Wright Medical Technology, Inc. included the DARCO® Locking Bone Plate System and 510(k) regulatory clearance.

Sincerely,

A handwritten signature in black ink, appearing to read "Tom McAllister". The signature is fluid and cursive, with a long horizontal stroke extending to the left.

Thomas L. McAllister
Assistant General Counsel

TLM/tm

headquarters

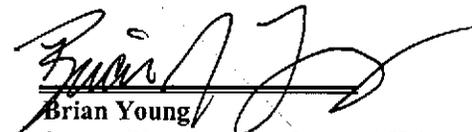
Wright Medical Technology, Inc. 5677 Airline Road · Arlington, TN 38002 · 901.867.9971 phone

www.wmt.com



TRUTHFUL AND ACCURATE STATEMENT

I certify that to the best of my knowledge and belief, and based upon the data and information submitted to me in the course of my responsibilities as Senior Director, Regulatory Affairs, and in reliance thereupon, the data and information submitted in this premarket notification are truthful and accurate, and that no facts material to a review of the substantial equivalence of this device have been knowingly omitted from this submission.



Brian Young
Senior Director, Regulatory Affairs

Jan. 23, 2008
Date



510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

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, this information serves as a Summary of Safety and Effectiveness for the use of the CHARLOTTE™ CLAW 3.5.

| | |
|-------------------------------------|--|
| Submitted By: | Wright Medical Technology, Inc. |
| Date: | January 23, 2005 |
| Contact Person: | Sarah Holtgrewe Regulatory Affairs Specialist |
| Proprietary Name: | CHARLOTTE™ CLAW 3.5 |
| Common Name: | Compression Plate |
| Classification Name and Reference: | 21 CFR 888.3030 Plate, Fixation, Bone – Class II |
| Device Product Code and Panel Code: | Orthopedics/87/HRS |

DEVICE INFORMATION

A. INTENDED USE

The CHARLOTTE™ CLAW® 3.5 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.

B. DEVICE DESCRIPTION

The CHARLOTTE™ CLAW® 3.5 consists of curved 4-hole plates and locking screws of various lengths. All plates and screws are manufactured from stainless steel.

C. SUBSTANTIAL EQUIVALENCE INFORMATION

The design features of the CHARLOTTE™ CLAW® 3.5 system are substantially equivalent to the design features of the predicates identified in this 510(k) submission. The safety and effectiveness of the CHARLOTTE™ CLAW® 3.5 is adequately supported by the substantial equivalence information, materials information, and analysis data provided within this premarket notification.

Indications for Use

510(k) Number (if known):

Device Name: CHARLOTTE™ CLAW 3.5

Indications For Use:

The CHARLOTTE™ CLAW® 3.5 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.

Prescription Use xxx
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

1 of 1



A Wright Medical Group Company

Declaration of Conformity with Design Controls

CHARLOTTE™ CLAW® 3.5

**Verification
Activities**

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

Paul Arrendell
VP of Global Quality System
Wright Medical Technology, Inc.

1/22/08
[Date]

**Manufacturing
Facility**

The manufacturing facility, Wright Medical Technology, Inc., is in conformance with the design control requirements as specified in 21 CFR 820. 30 and the records are available for review.

Paul Arrendell
VP of Global Quality System
Wright Medical Technology, Inc.

1/22/08
[Date]



APPENDIX A

APPENDIX C

APPENDIX D

Prototype Data Collection Sheet

Part Number: 94020256-14 P.O.# 476755 Operation: QA Inspected By: MJS
 Dwg Number: 94020256-14 Part Desc.: Claw Hex Screw, 3.5mm Job Number: 45623 Date: 11-26-07

| | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 |
|------------------|---------|---------------|----------|---------------------|--------|----------|-----------------|---------------|----------------------|-------------|--------|
| Specification | 0.1180 | 0.0987 | .067 Min | T.P. .005 A B | Ø .098 | .075 Max | Ø .120 x 90° | Ø .138 | T.P. Ø.005 A B | Thread Form | Ø .098 |
| Meas. Tech. | OC, OL | Hex gage | Gage, OC | OC | Pin | Pin, OC | OC | Mic | OC | OC, OL | OC, OL |
| Spec. Tol. (+/-) | ± .005 | -.000/+ .0016 | | | ± .003 | | ± .005 x ± 1/2° | + .000/- .006 | 0.005 | | ± .003 |
| max dim | 0.123 | 0.1003 | | | 0.1010 | | .125 x 90° 30' | 0.138 | | | 0.101 |
| min dim | 0.11300 | 0.0987 | | | 0.0950 | | .115 x 95° 30' | 0.132 | | | 0.095 |
| Range | 0.0100 | 0.0016 | | .005 T.P. | 0.0060 | | .010 x 1° | 0.006 | .005 T.P. | | 0.006 |
| 18 | Acc | Acc | .0719 | WI .005 | Acc | .073 | .1208 x 90° | .1367 | WI .005 | Acc | Acc |
| 19 | Acc | Acc | .0726 | WI .005 | Acc | .0725 | .1209 x 90° | .1364 | WI .005 | Acc | Acc |
| 20 | Acc | Acc | .0728 | WI .005 | Acc | .0725 | .1193 x 90° | .1367 | WI .005 | Acc | Acc |
| 21 | Acc | Acc | .0719 | WI .005 | Acc | .073 | .1201 x 90° | .1368 | WI .005 | Acc | Acc |
| 22 | Acc | Acc | .0713 | WI .005 | Acc | .073 | .1177 x 90° | .1367 | WI .005 | Acc | Acc |
| 23 | Acc | Acc | .0708 | WI .005 | Acc | .0725 | .1193 x 90° | .1344 | WI .005 | Acc | Acc |
| 24 | Acc | Acc | .0711 | WI .005 | Acc | .0725 | .1185 x 90° | .1365 | WI .005 | Acc | Acc |
| 25 | Acc | Acc | .0716 | WI .005 | Acc | .0725 | .1153 x 90° | .1363 | WI .005 | Acc | Acc |
| 26 | Acc | Acc | .0716 | WI .005 | Acc | .073 | .1157 x 90° | .1362 | WI .005 | Acc | Acc |
| 27 | Acc | Acc | .072 | WI .005 | Acc | .073 | .1169 x 90° | .1363 | WI .005 | Acc | Acc |
| 28 | Acc | Acc | .0736 | WI .005 | Acc | .075 | .1228 x 90° | .1370 | WI .005 | Acc | Acc |
| 29 | Acc | Acc | .0709 | WI .005 | Acc | .074 | .1211 x 90° | .1372 | WI .005 | Acc | Acc |
| 30 | Acc | Acc | .072 | WI .005 | Acc | .0725 | .122 x 90° | .1369 | WI .005 | Acc | Acc |
| 31 | Acc | Acc | .0695 | WI .005 | Acc | .069 | .1228 x 90° | .1371 | WI .005 | Acc | Acc |
| 32 | Acc | Acc | .0687 | WI .005 | Acc | .0705 | .1207 x 90° | .1371 | WI .005 | Acc | Acc |
| 33 | Acc | Acc | .0714 | WI .005 | Acc | .0715 | .1204 x 90° | .1371 | WI .005 | Acc | Acc |
| 34 | Acc | Acc | .069 | WI .005 | Acc | .068 | .1217 x 90° | .137 | WI .005 | Acc | Acc |



RECONSTRUCTIVE AND FRACTURE FIXATION

133763-2

The following languages are included in this packet:

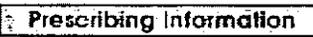
English (en)
Español (es)

Deutch (de)
Italiano (it)

Nederlands (nl)
Português (pt)

Français (fr)
Chinese (sch)

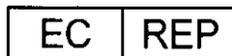
For additional languages, visit our website www.wmt.com

Then click on the  button.

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



Wright Medical Technology, Inc.
P.O. Box 100
Arlington, TN 38002
U.S.A.
901-867-9971



Wright Medical EMEA
Krijgsman 11
1186 DM Amstelveen
The Netherlands

R_x ONLY



August 2007
Printed in U.S.A.

Attention Operating Surgeon
IMPORTANT MEDICAL INFORMATION

WRIGHT MEDICAL
RECONSTRUCTIVE AND FRACTURE FIXATION SYSTEM
(133763-2)

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
 - A. CHARLOTTE™ CLAW® PLATE

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 |

| | |
|---------------------------|--|
| R_x ONLY | 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

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.

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 not provided 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).

This product is for single use only. An implant should never be re-sterilized after contact with body tissues or fluids.

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. **Rinse** in cold water to remove any gross contamination.
2. **Wash** with a detergent with a pH of 7.0 to 10.0.
 - If the contamination contains a heavy organic soil, an enzyme detergent may be used.
3. **Bathe** in an enzymatic solution prepared per manufacturer directions for 5 minutes.
4. **Scrub** components with a soft brush.
5. **Rinse** thoroughly with cold deionized or reverse osmosis water.
6. **Bathe** in a detergent solution prepared per manufacturer directions for 5 minutes.
7. **Scrub** with a soft brush.
8. **Rinse** in deionized water.
9. **Dry** with a clean, disposable, absorbent cloth.
10. **Visually inspect** for cleanliness. All visible surfaces, internal and external, should be visually inspected. If necessary re-clean/disinfect until it is visibly clean.

Sterilization

1. If using a 250°F gravity or 270°F pulsing vacuum sterilization cycle, 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 | Set Point |
| Gravity Displacement 250°F (121.1°C) | Exposure Temperature | 250-254°F (121-123°C) |
| | Exposure Time | 30 minutes |
| | Dry Time | 15 minutes |
| Gravity Displacement 270°F (132.2°C) | Exposure Temperature | 270-275°F (132-135°C) |
| | Exposure Time | 10 minutes |
| | Dry Time | 15 minutes |
| Prevacuum 270°F (132.2°C) | Exposure Temperature | 270-275°F (132-135°C) |
| | Exposure Time | 4 minutes |
| | Dry Time | 20 minutes |

Ensure that implants are at room temperature prior to implantation.

These recommendations 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 WMT'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

A. CHARLOTTE™ CLAW® PLATE

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 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.

Trademarks™ and Registered Trademarks®
of Wright Medical Technology, Inc.

SAMPLE LABEL

WRIGHT. **EC REP** Wright Medical EMEA
 Krijgsman 11 1186 DM Amstelveen The Netherlands
 Wright Medical Technology, Inc.
 Arlington, TN., 38002

CLAW® 3.5MM PLATE
CHARLOTTE™ F&A SYSTEM

CONTENTS: 1 EACH
 Foot and Ankle Plate
 Plaque (pied et cheville)
 Fuß- und Knochelplatte
 Placa para pie y tobillo
 Piastră per piede e caviglia
 Voet- en enkelplaat
 足与踝螺钉

R_V ONLY **CE** **0086** **!**

IMPLANT MATERIAL: Stainless Steel

REF: 4013-0020 **LOT 018SAMPLE**

| SIZE | LENGTH | USE WITH |
|------|--------|-------------------|
| 20mm | 4 HOLE | 3.5mm CLAW® SCREW |

CLAW® 3.5MM PLATE
CHARLOTTE™ F&A SYSTEM

NON-STERILE

4274013002015
 S018SAMPLE3X

WRIGHT. **EC REP** Wright Medical EMEA
 Krijgsman 11 1186 DM Amstelveen The Netherlands
 Wright Medical Technology, Inc.
 Arlington, TN., 38002

CLAW® HEX SCREW
CHARLOTTE™ F&A SYSTEM

CONTENTS: 1 EACH
 Foot and Ankle Screw
 Vis (pied et cheville)
 Fuß- und Knochelschraube
 Tornillo para pie y tobillo
 Vite per piede e caviglia
 Voet- en enkelschroef
 足与踝螺钉

R_V ONLY **CE** **0086** **!**

IMPLANT MATERIAL: Stainless Steel

REF: 4013-3514 **LOT 018SAMPLE**

| SIZE | LENGTH | USE WITH |
|-------|--------|-------------|
| 3.5MM | 14MM | CLAW® 3.5MM |

CLAW® HEX SCREW
CHARLOTTE™ F&A SYSTEM

NON-STERILE

4274013351417
 S018SAMPLE71

REF: 4013-0020 **LOT 018SAMPLE**

| SIZE | LENGTH | USE WITH |
|------|--------|-------------|
| 20mm | 4 HOLE | 3.5mm CLAW® |

CLAW® 3.5MM PLATE
CHARLOTTE™ F&A SYSTEM

CE **R_V ONLY** **NON-STERILE**

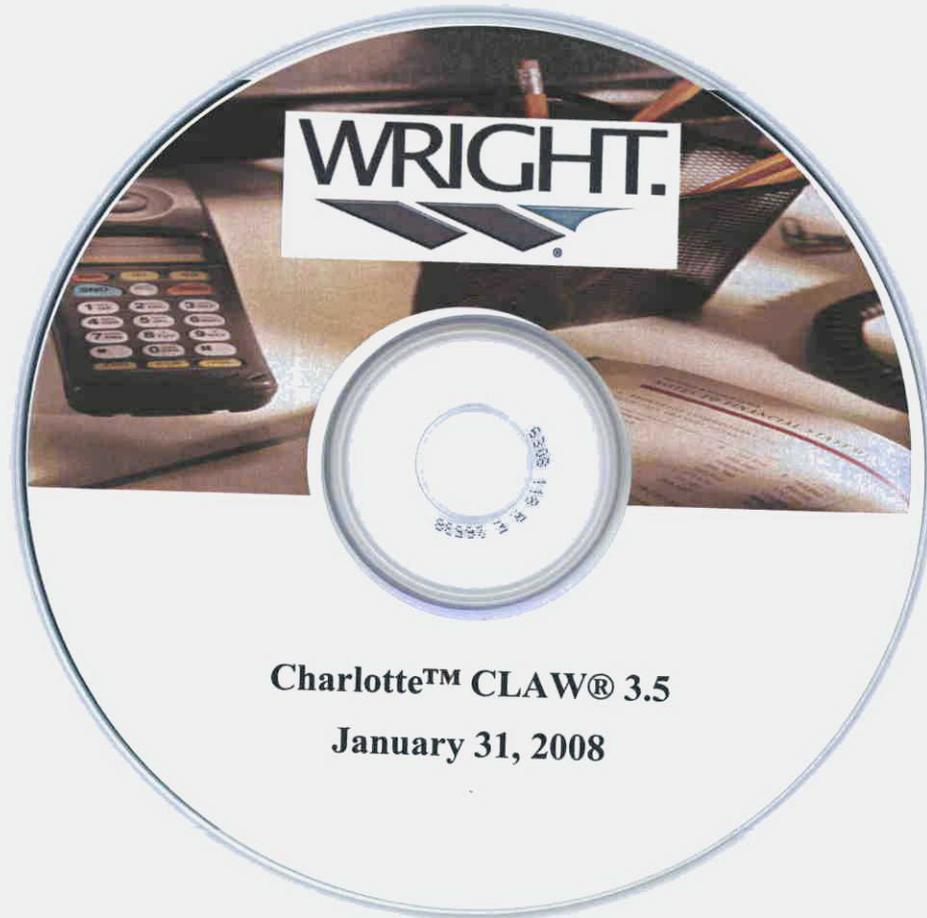
REF: 4013-3514 **LOT 018SAMPLE**

| SIZE | LENGTH | USE WITH |
|-------|--------|-------------|
| 3.5MM | 14MM | CLAW® 3.5MM |

CLAW® HEX SCREW
CHARLOTTE™ F&A SYSTEM

CE **R_V ONLY** **NON-STERILE**





Charlotte™ CLAW® 3.5
January 31, 2008



COVER SHEET MEMORANDUM

From: Reviewer Name TARA SHEPHERD
Subject: 510(k) Number 080285
To: The Record

Please list CTS decision code SE
 Refused to accept (Note: this is considered the first review cycle, See Screening Checklist
[http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/Screening Checklist](http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/ScreeningChecklist))
 Hold (Additional Information or Telephone Hold).
 Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

| Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.): | | YES | NO |
|--|--------------------------------------|-----|----|
| Indications for Use Page | Attach IFU | ✓ | |
| 510(k) Summary /510(k) Statement | Attach Summary | ✓ | |
| Truthful and Accurate Statement. | Must be present for a Final Decision | ✓ | |
| Is the device Class III? | | | |
| If yes, does firm include Class III Summary? | Must be present for a Final Decision | | ✓ |
| Does firm reference standards? (If yes, please attach form from http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4136/ABBREVATEDSTANDARDSDATAFORM.DOC) | | | ✓ |
| Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC) | | | ✓ |
| Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html) | | | ✓ |
| Is this device intended for pediatric use only? | | | ✓ |
| Is this a prescription device? (If both prescription & OTC, check both boxes.) | | ✓ | |
| Is clinical data necessary to support the review of this 510(k)? | | | ✓ |
| Does this device include an Animal Tissue Source? | | | ✓ |
| Is this device subject to Section 522 Postmarket Surveillance? (Postmarket Surveillance Guidance, http://www.fda.gov/cdrh/osb/guidance/316.html) | Contact OSB. | | ✓ |
| Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html) | Contact OC. | | ✓ |

Regulation Number 888.3030 Class* II Product Code HRS
(*If unclassified, see 510(k) Staff)

Additional Product Codes: _____

Review: [Signature] (Branch Chief) OSDB (Branch Code) 2/26/08 (Date)

Final Review: [Signature] (Division Director) 2/27/08 (Date)

PRE-REVIEW FORM: COMPANY/DEVICE HISTORY

Please complete the pre-review form prior to beginning the review of this 510(k). This form is designed to be a tool to identify key items that may be important to consider regarding the regulation of the subject device and if you should even begin the review of the 510(k).

| If you answer YES to questions 1, 2 or 3; do NOT begin the review of this 510(k): | | YES | NO |
|---|---|--|----|
| 1. | Are you aware of the submitter being the subject of an integrity investigation? (Please see H:\INTEGRITY LIST\CDRH REVIEWER SCREENING LIST.DOC) | | ✓ |
| 2. | Is the device exempt from 510(k) by regulation (Please see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4134/510(K)%20EXEMPT%20%20FORM.DOC or subject to enforcement discretion (No regulation - See 510(k) Staff)? | | ✓ |
| 3. | Does this device type require a PMA by regulation? (Please see management.) | | ✓ |
| Questions 4-8 are intended to help you start your review: | | YES | NO |
| 4. | Is this 510(k) a candidate for "Refuse to Accept"? (If so, please use the Traditional/Abbreviated or Special 510(k) Refuse to Accept Screening Checklist, http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4d69/Screening%20Checklist.doc) | | ✓ |
| 5. | a. Did the firm request expedited review? (See management.) b. Was expedited review granted? (See <i>Guidance for Industry and FDA Staff: Expedited Review of Devices for Premarket Submissions</i> , http://www.fda.gov/cdrh/mdufma/guidance/108.html) | | ✓ |
| 6. | To the best of your knowledge, was there a pre-IDE, 513(g) or other pre-submission for this type of device? | Please list document number and/or date, here: | ✓ |
| 7. | To the best of your knowledge, has a 510(k) previously been submitted for this specific device (i.e., previously found NSE or withdrawn)? | Please list document number, here: | ✓ |
| 8. | Does this device have indications or technology that are cross-cutting and impact the review policy of another branch(es)? (Please contact other branch(es) and see <i>Guidance for Industry and FDA Staff on Bundling Multiple Devices or Multiple Indications in a Single Submission</i> http://www.fda.gov/cdrh/mdufma/guidance/1215.html) | | ✓ |

SPECIAL 510(k): Device Modification
ODE Review Memorandum (Decision Making Document is Attached)

To: THE FILE

RE: DOCUMENT NUMBER K080295

Date: February 25, 2008

From: Tara Shepherd, Biomedical Engineer (HFZ-410)

Division: DGRND/OJDB

TNS 2/25/08

Device Name: Charlotte Claw 3.5

ELF 2/25/08

Classification: 888.3030 Single/multiple component metallic bone fixation appliances and accessories.
HRS

Company: Wright Medical Technology, Inc.

5677 Airline Rd.
Arlington, TN 38002

Contact: Sarah Holtgrewe

Phone: 901-867-4476; Fax: 901-867-4190; Email:sholtgrewe@wmt.com

Recommendation: I recommend the device be determined **Substantially Equivalent (SE)** to the previously cleared (or their preamendment) device.

This 510(k) submission contains information/data on modifications made to the SUBMITTER'S own Class II, Class III or Class I devices requiring 510(k). The following items are present and acceptable (delete/add items as necessary):

1. The name and 510(k) number of the SUBMITTER'S previously cleared device. (For a preamendments device, a statement to this effect has been provided.)
 - Charlotte Comproression Plate (K051908)
 - DARCO Locking Bone Plate System (K061808)

(b)(4) Trade Secret Process - Product Specs

2. Submitter's statement that the **INDICATION/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED** along with the proposed labeling which includes instructions for use, package labeling, and, if available, advertisements or promotional materials (labeling changes are permitted as long as they do not affect the intended use).

The CHARLOTTE CLAW 3.5 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 metatarsocunriform joint to reposition and stabilize metatarsus primus varus.

Reviewer's Response: Adequate. Indications same as predicate (K051908).

3. A description of the device **MODIFICATION(S)**, including clearly labeled diagrams, engineering drawings, photographs, user's and/or service manuals in sufficient detail to demonstrate that the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed**.

This change was for

- Increase number of screw holes
- Curved plate rather than flat plate

- Increase plate thickness
 - Additional plate size available (b)(4) Trade Secret
 - Screw material type change
4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics, and

| | Charlotte Claw 3.5 (proposed) | Charlotte Compression Plate (K051908) |
|------------------------|--|--|
| Materials | Stainless Steel, Cold Worked (ASTM F138) | Stainless Steel, Cold Worked (ASTM F139) |
| Number of holes | 4 | 2 |
| Size Range (interaxis) | (b)(4) Trade Secret | (b)(4) Trade Secret |
| Plate Thickness | (b)(4) 1 | (b)(4) |
| Plate Curvature | (4) Curved | Flat |
| Compression Feature | Diamond shaped slot compression | Diamond shaped slot compression |
| Locking detail | (b)(4) Trade Secret | (b)(4) Trade Secret |
| Sterility | Gamma sterilized, Non-sterile | Gamma sterilized |

| | Charlotte Claw 3.5 (proposed) | DARCO 3.5 (K061808) | Charlotte Compression plate (K051908) |
|--------------------------|--|---|---|
| Materials | Stainless Steel, Cold Worked (ASTM F138) Stainless Steel, BIODUR (ASTM F2229) | Titanium Alloy (ISO 5832-3) | Stainless Steel, Cold Worked (ASTM F138) |
| Screw Diameter | 3.5mm | 3.5mm | 2.7mm |
| Screw Lengths | (b)(4) Trade Secret Process - Product Specs | | |
| Thread details | 3.5 mm threaded dia. 4.5mm threaded locking head | 3.5 mm threaded dia. 4.5mm threaded locking head | 2.7 mm threaded dia. 4.1mm threaded locking head |
| Locking Drive Connection | 2.5mm hex head drive | 2.5mm hex head drive | Cruciform drive connection |
| Sterility | End user, Gamma sterilized | End user | Gamma sterilized |

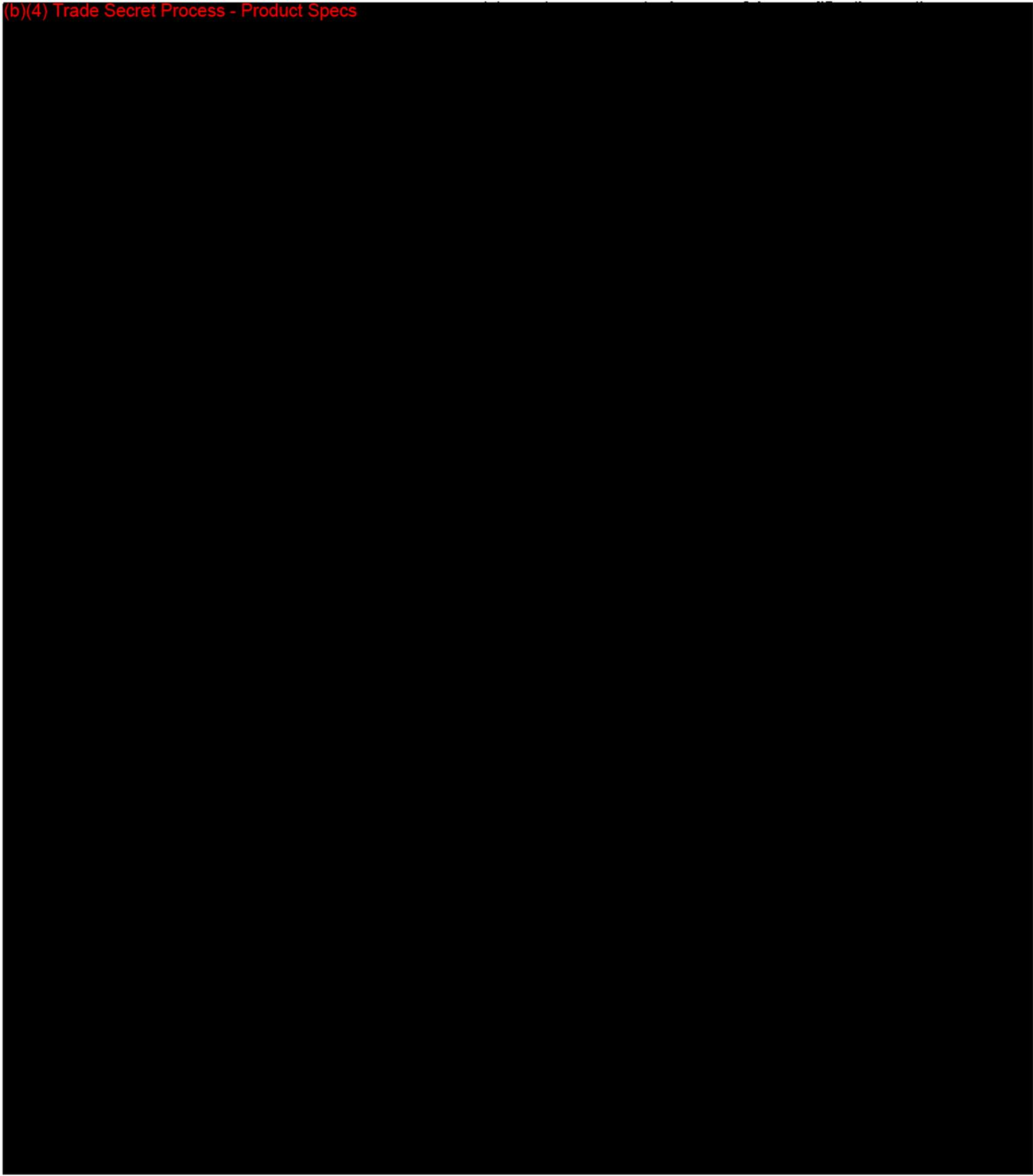
Sterilization Process

Method: Gamma radiation

(b)(4) Trade Secret Process - Product Specs

5. A Design Control Activities Summary which includes:

(b)(4) Trade Secret Process - Product Specs

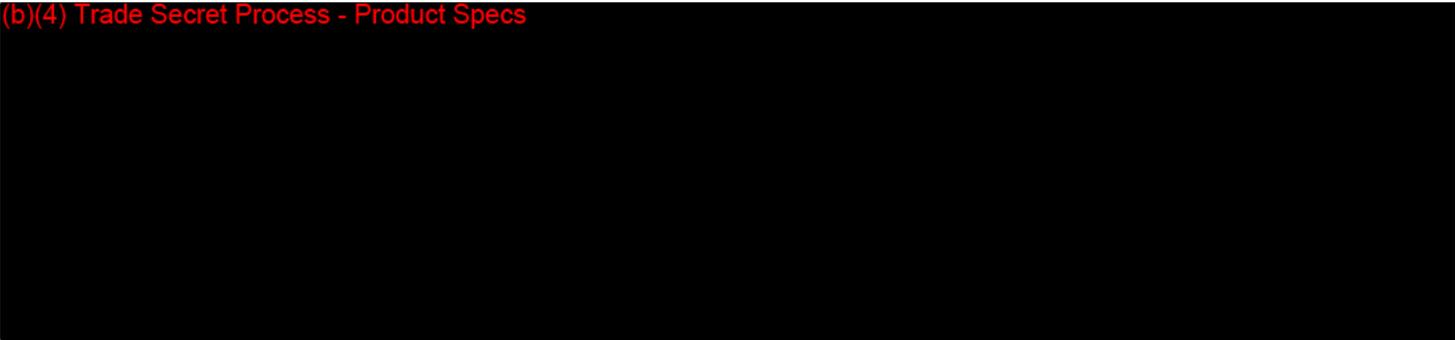


- c) A declaration of conformity with design controls. The declaration of conformity should include:
 - i) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met, and
 - ii) A statement signed by the individual responsible, that the manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.

Reviewer's Comments: Exhibit 5

6. A Truthful and Accurate Statement, a 510(k) Summary or Statement and the Indications for Use Enclosure (and Class III Summary for Class III devices).

(b)(4) Trade Secret Process - Product Specs



J. N. Jones
Comments (Reviewer's Signature)

2/25/08
(Date)

Jonata 76 2/25/08

revised:8/1/03

(b)(4) Trade Secret Process - Product Specs



Reviewer's Response: Adequate.

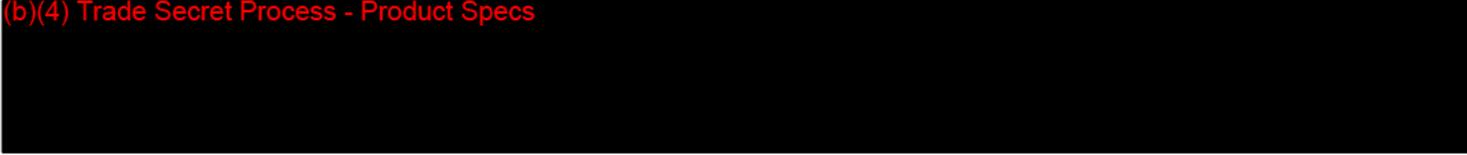
"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

| | Yes | No | |
|--|-----|----|--|
| 1. Same Indication Statement? | X | | If YES = Go To 3 |
| 2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness? | | | If YES = Stop NSE |
| 3. Same Technological Characteristics? | X | | If YES = Go To 5 |
| 4. Could The New Characteristics Affect Safety Or Effectiveness? | | | If YES = Go To 6 |
| 5. Descriptive Characteristics Precise Enough? | | X | If NO = Go To 8 If YES = Stop SE |
| 6. New Types Of Safety Or Effectiveness Questions? | | | If YES = Stop NSE |
| 7. Accepted Scientific Methods Exist? | | | If NO = Stop NSE |
| 8. Performance Data Available? | X | | If NO = Request Data |
| 9. Data Demonstrate Equivalence? | X | | Final Decision: SE |

5. Explain how descriptive characteristics are not precise enough:
Performance testing necessary
8. Explain how the performance data demonstrates that the device is or is not substantially equivalent:
Performance testing illustrated device will perform as well as predicate device.

| | |
|-------------------------|---|
| Date: 02/12/2008 | Topic: .Screw Lengths, Package Label |
| Type: Email | User: Tara Shepherd |

(b)(4) Trade Secret Process - Product Specs



| | |
|-----------------------------|--------------------------------------|
| Date: 02/12/2008 | Topic: Additional Information |
| Type: Telephone Call | User: Tara Shepherd |

(b)(4) Trade Secret Process - Product Specs



Shepherd, Tara N

From: sholtgrewe@wmt.com
Sent: Tuesday, February 12, 2008 6:30 PM
To: Shepherd, Tara N
Subject: Re: K080295 - Charlotte Claw 3.5
Attachments: CLAW 3.5 pages 3 & 5 revised.pdf

Ms. Sheperd,

Thank you for reviewing my 510(k) submission. (b)(4) Trade Secret Process - Product Specs

1. The screw lengths listed in the drawings are correct. (b)(4) Trade Secret Process - Product Specs

(b)(4) Trade Secret Process - Product Specs

Best Regards,

Sarah

2/13/2008

Sarah Holtgrewe
Regulatory Affairs Specialist
Wright Medical Technology, Inc.
Phone: 901.867.4476
Fax: 901.867.4190
Email: sholtgrewe@wmt.com

"Shepherd, Tara N" <Tara.Shepherd@fda.hhs.gov>

To sholtgrewe@wmt.com

cc

02/12/2008 09:57 AM

Subject K080295 - Charlotte Claw 3.5

Ms. Holtgrewe,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission, we require the following additional information:

1. In your comparison table of the Charlotte Claw 3.5 screws and the predicate screws you have indicated that

(b)(4) Trade Secret Process - Product Specs

(b)(4) Trade Secret Process - Product Specs

Thanks,
Tara

Tara N. Shepherd, M.S.
Biomedical Engineer
Orthopedic Joint Devices Branch
U.S. Food and Drug Administration
240-276-3683 (phone)
240-276-3761 (fax)
tara.shepherd@fda.hhs.gov

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2/13/2008

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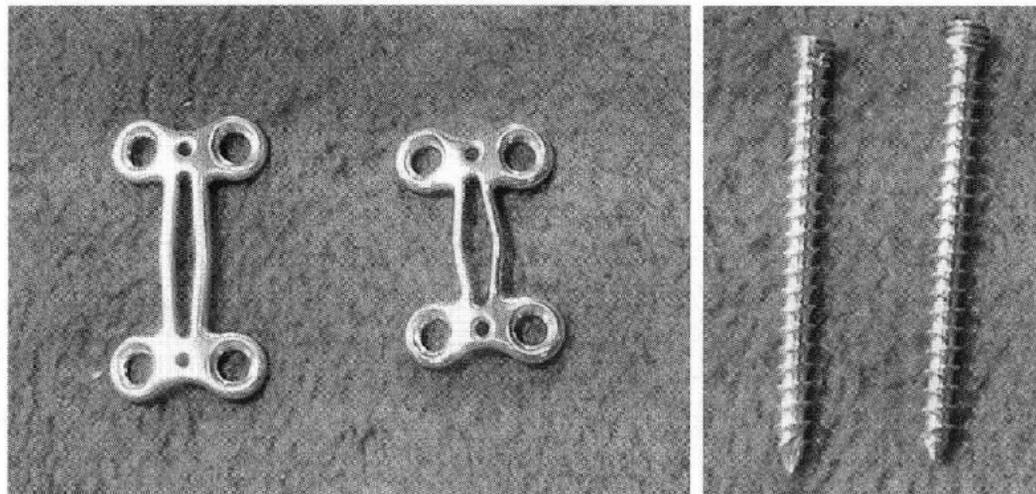


Figure 1 Wright Medical Technology's CHARLOTTE™ CLAW® 3.5
(from left to right):

(b)(4) Trade Secret Process - Product Specs

The design features of the CHARLOTTE™ CLAW® 3.5 are summarized below:

Plate

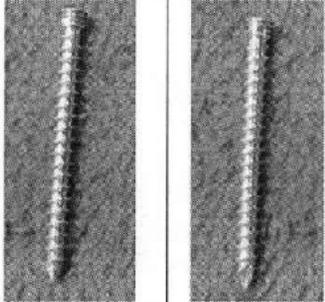
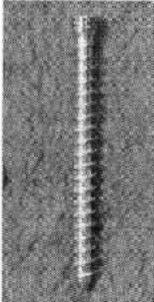
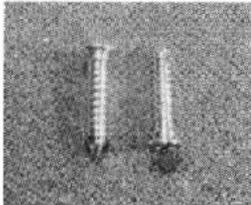
- Manufactured from ASTM F138 Type 316L stainless steel, cold worked
- 4 screw holes
- 2 K-wire holes for 1.6mm k-wire (Wright Medical k-wires are not used as implants)
- 3 sizes available: (b)(4) Trade Secret Process - Product
- Diamond shape slot compression feature
- Curved plate to generally fit bones in midfoot and hindfoot
- Locking detail to prevent screw back-out
- Packaged sterile or non-sterile

Screws

- Manufactured from ASTM F138 Type 316L stainless steel, cold worked or ASTM F2229 stainless steel
- 3.5mm threaded diameter
- 14 lengths available: (b)(4) Trade Secret
- 4.5mm threaded tapered locking head to engage plate
- Self tapping feature
- 2.5 mm hex head drive
- Packaged sterile or non-sterile

Table 1 compares the design features of the CHARLOTTE™ CLAW® 3.5 plate to the design features of the predicate CHARLOTTE™ Compression Plate. Table 2 compares the design features of the CHARLOTTE™ CLAW® 3.5 screws to the

Table 2 Comparison of the CHARLOTTE™ CLAW® 3.5 screws and the predicate screws.

| | CHARLOTTE™ CLAW® 3.5 | | DARCO® 3.5 | CHARLOTTE™ Compression Plate |
|--------------------------|---|-------------------------------------|--|---|
| Device | Subject Device | | Predicate (K061808) | Predicate (K051908) |
| Picture |  | |  |  |
| Materials | ASTM F138 Stainless Steel, Cold Worked (standard) | ASTM F2229 Stainless Steel (BIODUR) | ISO 5832-3 Titanium Alloy | ASTM F138 Stainless Steel, Cold Worked |
| Screw Diameter | 3.5mm | | 3.5mm | 2.7mm |
| Screw Lengths | (b)(4) Trade Secret Process - Product Specs | | | |
| Thread Details | 3.5mm threaded diameter 4.5mm threaded locking head | | 3.5mm threaded diameter 4.5mm threaded locking head | 2.7mm threaded diameter 4.1mm locking head |
| Locking Drive Connection | 2.5mm hex head drive | | 2.5mm hex head drive | Cruciform drive connection |
| Sterility | Performed by end user or Gamma sterilized | | Performed by end user | Gamma sterilized |

D. MATERIALS

The CHARLOTTE™ CLAW® 3.5 system and the CHARLOTTE™ Compression Plate system are both manufactured from stainless steel.

- **CHARLOTTE™ CLAW® 3.5 Plate (subject)**
 ASTM F138 Standard Specification for Wrought 18 Chromium-14 Nickel-2.5 Molybdenum Stainless Steel Bar and Wire for Surgical Implants
- **CHARLOTTE™ Compression Plate (predicate)**
 ASTM F139 Standard Specification for Wrought 18 Chromium-14 Nickel-2.5 Molybdenum Stainless Steel Sheet and Strip for Surgical Implants
- **CHARLOTTE™ CLAW® 3.5 Screws (subject)**
 - ASTM F138 Standard Specification for Wrought 18 Chromium-14 Nickel-2.5 Molybdenum Stainless Steel Bar and Wire for Surgical Implants
 - ASTM F2229 Standard Specification for Wrought, Nitrogen Strengthened 23Manganese-21Chromium-1Molybdenum Low Nickel Stainless Steel Alloy Bar and Wire for Surgical Implants