

**2 510(k) Summary of Safety and Effectiveness**

<b>Date Summary Prepared</b>	November 29, 2011
<b>Manufacturer/Distributor/Sponsor</b>	Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA
<b>510(k) Contact</b>	Courtney Smith Manager, Regulatory Affairs Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA Telephone: 239/643.5553, ext. 1720 Fax: 239/598.5508 Email: <a href="mailto:csmith@arthrex.com">csmith@arthrex.com</a>
<b>Trade Name</b>	<b>Arthrex Fracture System</b>
<b>Common Name</b>	Plate, fixation, bone
<b>Product Code -Classification Name CFR</b>	HWC, HRS, HTN 21 CFR 888.3030: Single/multiple component metallic bone fixation appliances and accessories 21 CFR 888.3040: Smooth or threaded metallic bone fixation fastener.
<b>Predicate Device</b>	<i>K011335</i> : Synthes One-Third Tubular Plates <i>K102998</i> : Acumed Congruent Bone Plate System <i>K043248 / K052776</i> : Arthrex TightRope Syndesmosis and Acromioclavicular (AC) Devices <i>K103705 / K111253</i> : Arthrex Low Profile Screws
<b>Device Description and Intended Use</b>	The <b>Arthrex Fracture System</b> is a family of stainless steel plates, screws, and buttons. The plates may be contoured or straight and may be available in left and right configurations. The plates are to be used with the 2.7mm-4.0mm Low Profile Screws. The screws are solid and fully threaded and may be locking or non-locking. The button is stainless steel and designed to fit securely in the holes of the fracture plates. The button is intended to be used with the previously cleared suture, which is provided separately.  The <b>Arthrex Fracture System</b> is intended to be used for internal bone fixation for bone fractures, fusions, osteotomies and non-unions in the ankle, foot, hand, wrist, clavicle, scapula, olecranon, humerus, radius, ulna, tibia, calcaneous, femur and fibula. The Arthrex Fracture Plates are to be used with the 2.7mm-4.0mm Arthrex Low Profile Screws.  The <b>Clavicle Plate Button</b> is intended for use with the clavicle

K112437 (pg. 2 of 2)

	<p>plates for clavicle indications such as for the treatment of syndesmotomic trauma, such as fixation of acromioclavicular separations due to coracoclavicular ligament disruption, and this button may not be used alone. The button is intended to be used with #5 FiberWire or FiberTape.</p>
<p><b>Substantial Equivalence Summary</b></p>	<p>The Arthrex Fracture System is substantially equivalent to the predicate Synthes One-Third Tubular Plates (K011335), Acumed Congruent Bone Plate System (K102998), Arthrex TightRope Syndesmosis and Acromioclavicular (AC) Devices (K043248 / K052776), and the cleared Arthrex Low Profile Screws (K103705, K111253) in which the basic features and intended uses are the same. Any differences between the <i>Fracture System</i> and the predicates are considered minor and do not raise questions concerning safety and effectiveness.</p> <p>The proposed devices are composed of Stainless Steel which is substantially equivalent to the predicate devices.</p> <p>The submitted mechanical testing data demonstrated that the bending and pull-out strength of the proposed devices are substantially equivalent to the bending and pull-out strength of the predicate devices.</p> <p>Based on the indication for use, technological characteristics, and the comparison to the predicate devices, Arthrex, Inc. has determined that the <i>Fracture System</i> is substantially equivalent to currently marketed predicate devices.</p>



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room W-066-0609  
Silver Spring, MD 20993-0002

Arthrex, Incorporated  
% Ms. Courtney Smith  
Manager, Regulatory Affairs  
1370 Creekside Boulevard  
Naples, Florida 34108

DEC 21 2011

Re: K112437

Trade/Device Name: Arthrex Fracture System  
Regulation Number: 21 CFR 888.3030  
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories  
Regulatory Class: Class II  
Product Code: HTN, HWC, HRS  
Dated: December 12, 2011  
Received: December 14, 2011

Dear Ms. Smith:

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 additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

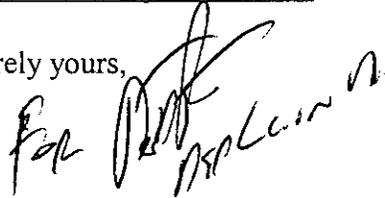
Page 2 – Ms. Courtney Smith

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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

Sincerely yours,



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

Enclosure

**1 Indications for Use Form**

**Indications for Use**

510(k) Number (if known): K112437

Device Name: *Arthrex Fracture System*

**Indications For Use:**

The *Arthrex Fracture System* is intended to be used for internal bone fixation for bone fractures, fusions, osteotomies and non-unions in the ankle, foot, hand, wrist, clavicle, scapula, olecranon, humerus, radius, ulna, tibia, calcaneous, femur and fibula. The Arthrex Fracture Plates are to be used with the 2.7mm-4.0mm Arthrex Low Profile Screws.

The *Clavicle Plate Button* is intended for use with the clavicle plates for clavicle indications such as for the treatment of syndesmotic trauma, such as fixation of acromioclavicular separations due to coracoclavicular ligament disruption, and this button may not be used alone. The button is intended to be used with #5 FiberWire or FiberTape.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

PAGE 1 of 1

for *Michael K...*  
(Division Sign-Off)  
Division of Surgical, Orthopedic,  
and Restorative Devices

510(k) Number K112437



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room W-O66-0609  
Silver Spring, MD 20993-0002

Arthrex, Incorporated  
% Ms. Courtney Smith  
Manager, Regulatory Affairs  
1370 Creekside Boulevard  
Naples, Florida 34108

DEC 21 2011

Re: K112437

Trade/Device Name: Arthrex Fracture System

Regulation Number: 21 CFR 888.3030

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

Regulatory Class: Class II

Product Code: HTN, HWC, HRS

Dated: December 12, 2011

Received: December 14, 2011

Dear Ms. Smith:

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 additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

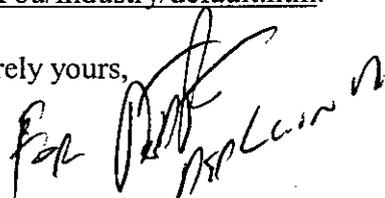
Page 2 – Ms. Courtney Smith

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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

Sincerely yours,



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

Enclosure

**1 Indications for Use Form**

**Indications for Use**

510(k) Number (if known): K112437

Device Name: *Arthrex Fracture System*

**Indications For Use:**

The *Arthrex Fracture System* is intended to be used for internal bone fixation for bone fractures, fusions, osteotomies and non-unions in the ankle, foot, hand, wrist, clavicle, scapula, olecranon, humerus, radius, ulna, tibia, calcaneous, femur and fibula. The Arthrex Fracture Plates are to be used with the 2.7mm-4.0mm Arthrex Low Profile Screws.

The *Clavicle Plate Button* is intended for use with the clavicle plates for clavicle indications such as for the treatment of syndesmotic trauma, such as fixation of acromioclavicular separations due to coracoclavicular ligament disruption, and this button may not be used alone. The button is intended to be used with #5 FiberWire or FiberTape.

Prescription Use  AND/OR Over-The-Counter Use

(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

PAGE 1 of 1

for *Michael [Signature]*  
(Division Sign-Off)  
Division of Surgical, Orthopedic,  
and Restorative Devices

510(k) Number K112437

TRANSMITTED/STORED :	DEC. 30. 2011 9:20AM	ADDRESS	RESULT	PAGE
FILE MODE	OPTION			
26	MEMORY TX	2395985508	OK!	3/3

REASON FOR ERROR  
E-1) HANG UP OR LINE FAIL  
E-3) NO ANSWER  
E-2) BUSY  
E-4) NO FACSIMILE CONNECTION



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room W-066-0609  
Silver Spring, MD 20993-0002

Arthrex, Incorporated  
% Ms. Courtney Smith  
Manager, Regulatory Affairs  
1370 Creekside Boulevard  
Naples, Florida 34108

DEC 20 2011

Re: K112437  
Trade/Device Name: Arthrex Fracture System  
Regulation Number: 21 CFR 888.3030  
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories  
Regulatory Class: Class II  
Product Code: HTN, HWC, HRS  
Dated: December 12, 2011  
Received: December 14, 2011

Dear Ms. Smith:

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 additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set



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

December 14, 2011

ARTHREX, INC.  
1370 CREEKSIDE BLVD.  
NAPLES, FLORIDA 34108-1945  
ATTN: COURTNEY SMITH

510k Number: K112437

Product: ARTHREX FRACTURE SYSTEM

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission **MUST** be sent to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm>. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm>. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

**Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.**

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely,

510(k) Staff

**Grayson, Giovanna \***

---

**From:** Microsoft Exchange  
**To:** 'courtney.smith@arthrex.com'  
**Date:** Wednesday, December 14, 2011 12:01 PM  
**Subject:** Relayed: ack letter

**Delivery to these recipients or distribution lists is complete, but delivery notification was not sent by the destination:**

'courtney.smith@arthrex.com'

Subject: ack letter

---

Sent by Microsoft Exchange Server 2007

**Grayson, Giovanna \***

---

**From:** Grayson, Giovanna \*  
**Sent:** Wednesday, December 14, 2011 12:01 PM  
**To:** 'courtney.smith@arthrex.com'  
**Subject:** ack letter  
**Attachments:** image002.png

**DEPARTMENT OF HEALTH & HUMAN SERVICES****Public Health Service**

U.S. Food and Drug Administration  
 Center for Devices and Radiological Health  
 Document Control Center WO66-G609  
 10903 New Hampshire Avenue  
 Silver Spring, MD 20910-1002

December 14, 2011

SMITH  
 COURTNEY  
 ARTHREX, INC.  
 1370 CREEKSIDE BLVD.  
 NAPLES, FLORIDA 34108-1945  
 ATTN: COURTNEY SMITH  
 510k Number: K112437

Product: ARTHREX FRACTURE SYSTEM

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission **MUST** be sent to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm>. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm>. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

**Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.**

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely,  
510(k) Staff



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

October 31, 2011

ARTHREX, INC.  
1370 CREEKSIDE BLVD.  
NAPLES, FLORIDA 34108-1945  
ATTN: COURTNEY SMITH

510k Number: K112437

Product: ARTHREX FRACTURE SYSTEM

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm>.

The deficiencies identified 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 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/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceProvisionsofFDAModernizationAct/ucm136685.htm>.

If after 30 days the additional information (AI), or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system (21 CFR 807.87(l)). Please note our guidance document entitled, "Guidance for Industry and FDA Staff, FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request. The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089735.htm>. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

113

Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely yours,

Marjorie Shulman  
Consumer Safety Officer  
Premarket Notification Section  
Office of Device Evaluation  
Center for Devices and Radiological Health

**Grayson, Giovanna \***

---

**From:** Microsoft Exchange  
**To:** 'csmith@arthrex.com'  
**Sent:** Monday, October 31, 2011 9:55 AM  
**Subject:** Relayed: ack letter

**Delivery to these recipients or distribution lists is complete, but delivery notification was not sent by the destination:**

'csmith@arthrex.com'

Subject: ack letter

---

Sent by Microsoft Exchange Server 2007

**Grayson, Giovanna \***

**From:** Grayson, Giovanna \*  
**Sent:** Monday, October 31, 2011 9:55 AM  
**To:** 'csmith@arthrex.com'  
**Subject:** ack letter  
**Attachments:** image002.png

**DEPARTMENT OF HEALTH & HUMAN SERVICES****Public Health Service**

U.S. Food and Drug Administration  
 Center for Devices and Radiological Health  
 Document Mail Center, WO66-G609  
 10903 New Hampshire Avenue  
 Silver Spring, MD 20910-1002

October 31, 2011  
 SMITH  
 COURTNEY  
 ARTHREX, INC.  
 1370 CREEKSIDE BLVD.  
 NAPLES, FLORIDA 34108-1945  
 ATTN: COURTNEY SMITH  
 510k Number: K112437

Product: ARTHREX FRACTURE SYSTEM

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm>.

The deficiencies identified 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 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/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceProvisionsofFDAModernizationAct/ucm136685.htm>.

If after 30 days the additional information (AI), or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system (21 CFR 807.87(l)). Please note our guidance document entitled, "Guidance for Industry and FDA Staff, FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request. The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089735.htm>. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely yours,

Marjorie Shulman  
Consumer Safety Officer  
Premarket Notification Section  
Office of Device Evaluation  
Center for Devices and Radiological Health

**Nichols, Karl \***

---

**From:** Microsoft Exchange  
**To:** 'courtney.smith@arthrex.com'  
**Sent:** Wednesday, August 24, 2011 4:09 PM  
**Subject:** Relayed: K112437- Acknowledgement Letter

**Delivery to these recipients or distribution lists is complete, but delivery notification was not sent by the destination:**

'courtney.smith@arthrex.com'

Subject: K112437- Acknowledgement Letter

---

Sent by Microsoft Exchange Server 2007

138



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

August 24, 2011

ARTHREX, INC.  
1370 CREEKSIDE BLVD.  
NAPLES, FLORIDA 34108-1945  
ATTN: COURTNEY SMITH

510k Number: K112437

Received: 8/24/2011

Product: ARTHREX FRACTURE SYSTEM

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

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

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

We remind you that Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) amended the PHS Act by adding new section 402(j) (42 U.S.C. § 282(j)), which expanded the current database known as ClinicalTrials.gov to include mandatory registration and reporting of results for applicable clinical trials of human drugs (including biological products) and devices. Section 402(j) requires that a certification form <http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm> accompany 510(k)/HDE/PMA submissions. The agency has issued a draft guidance titled: "Certifications To Accompany Drug, Biological

Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007"

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134034.htm>. According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

Please note the following documents as they relate to 510(k) review: 1) Guidance for Industry and FDA Staff entitled, "Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements". This guidance can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm>. Please refer to this guidance for information on a formalized interactive review process. 2) Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm>. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.htm>. In addition, the 510(k) Program Video is now available for viewing on line at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm070201.htm>.

**Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.**

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm>. If you have questions on the status of your submission, please contact DSMICA at (301)796-7100 or the toll-free number (800)638-2041, or at their internet address <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm>. If you have procedural questions, please contact the 510(k) Staff at (301)796-5640.

Sincerely,

510(k) Staff

or/olson

K112437

Traditional 510(k): Arthrex Fracture Plates. August 17, 2011



17 AUGUST 2011

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

FDA CDRH DMC  
AUG 24 2011  
K35

**RE: 510(k) Pre-market Notification:  
Arthrex Fracture System**

Dear Madame/Sir:

Pursuant to Section 510(k) of the Federal Food, Drug, and Cosmetic Act (the ACT) and in accordance with subpart E of Part 807 of Title 21 of the Code of Federal Regulations, Arthrex, Inc. submits this **510(k) pre-market notification**, in duplicate (a hardcopy and exact CD copy) to obtain FDA clearance for the *Arthrex Fracture System*, to be distributed domestically.

The device design intent of the *Arthrex Fracture System* is intended to be used for internal bone fixation for bone fractures, fusions, osteotomies, and non-unions.

Pursuant to 21 CFR 807.95 (c) (3) Arthrex, Inc. considers this pre-market submission to be confidential commercial information.

Questions regarding this submission may be directed to Courtney Smith by e-mail at [courtney.smith@arthrex.com](mailto:courtney.smith@arthrex.com) or by telephone at (239) 643-5553 at extension 1720.

Sincerely,



Courtney Smith  
Manager, Regulatory Affairs

Traditional 510(k): Arthrex Fracture Plates, August 17, 2011



**17 AUGUST 2011**

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

**RE: 510(k) Pre-market Notification:  
Arthrex Fracture System**

Dear Madame/Sir:

Pursuant to Section 510(k) of the Federal Food, Drug, and Cosmetic Act (the ACT) and in accordance with subpart E of Part 807 of Title 21 of the Code of Federal Regulations, Arthrex, Inc. submits this **510(k) pre-market notification**, in duplicate (a hardcopy and exact CD copy) to obtain FDA clearance for the *Arthrex Fracture System*, to be distributed domestically.

The device design intent of the *Arthrex Fracture System* is intended to be used for internal bone fixation for bone fractures, fusions, osteotomies, and non-unions.

Pursuant to 21 CFR 807.95 (c) (3) Arthrex, Inc. considers this pre-market submission to be confidential commercial information.

Questions regarding this submission may be directed to Courtney Smith by e-mail at [courtney.smith@arthrex.com](mailto:courtney.smith@arthrex.com) or by telephone at (239) 643-5553 at extension 1720.

Sincerely,

A handwritten signature in blue ink that reads "Courtney Smith".

Courtney Smith  
Manager, Regulatory Affairs

## Arthrex, Inc.

Arthrex, Inc  
1370 Creekside Boulevard  
Naples, FL 34108-1945

Telephone 239/643 5553  
Toll Free: 800/933 7001  
Fax: 239/598 5508

# 510(k) Premarket Notification

## Arthrex Fracture System

### Table of Contents

<b>1</b>	<b>Truth and Accuracy Statement</b>	<b>4</b>
<b>2</b>	<b>Indications for Use Form</b>	<b>5</b>
<b>3</b>	<b>510(k) Summary of Safety and Effectiveness</b>	<b>6</b>
<b>4</b>	<b>Administrative Information Manufacturer / Sponsor / Contact</b>	<b>8</b>
4.1	<i>Manufacture// Sponsor / Contact</i>	8
4.1.1	Manufacturer / Sponsor	8
4.1.2	Contact	8
4.2	<i>Device Identification</i>	8
4.2.1	Proprietary Name	8
4.2.2	Common Name	8
4.2.3	Classification Name and Reference	8
4.2.4	Regulatory Class	9
4.2.5	Device Product Codes	9
4.3	<i>Compliance with Special Controls</i>	9
<b>5</b>	<b>Device Description</b>	<b>10</b>
5.1	<i>Introduction</i>	10
5.2	<i>Device Materials</i>	10
5.3	<i>Device Description</i>	10
5.4	<i>Manufacturing</i>	12
5.5	<i>Accessory Device Information</i>	13
<b>6</b>	<b>Device Labeling</b>	<b>14</b>
6.1	<i>Device Labels</i>	14
6.2	<i>Instructions for Use (IFU) / Directions for Use (DFU)</i>	14

Arthro 510(K): ARTHREX FRACTURE SYSTEM

---

<b>7</b>	<b>Shelf Life</b>	<b>15</b>
<b>8</b>	<b>Packaging and Storage</b>	<b>16</b>
<b>9</b>	<b>Sterility and Pyrogenicity</b>	<b>17</b>
9.1	<i>Fracture System</i>	17
9.2	<i>Fracture System Instruments</i>	17
<b>10</b>	<b>Mechanical Data</b>	<b>18</b>
10.1	(b) Testing	18
10.2	(b)(4) Pull-Out Testing (b)(4)	18
10.3	(b)(b) Testing	19
10.4	(b)(4) Testing	19
<b>11</b>	<b>Substantially Equivalent Predicate Devices</b>	<b>21</b>
<b>12</b>	<b>Similarities and Differences with Marketed Devices</b>	<b>22</b>

**Appendix 1:** Engineering Drawings

**Appendix 2:** Draft Labels, DFU/IFU, Surgical technique

**Appendix 3:** Mechanical Test reports

---

### List of Tables

Table 5-1. Part Numbers and Descriptions for New and Predicate Plates	11
Table 5-2. Part Numbers and Descriptions for New and Cleared Screws	12
Table 5-3. Part Numbers and Descriptions for New and Predicate Buttons	12
Table 5-4. Instrumentation	13
Table 10-1. Bending Strength of Distal Clavicle Plates	18
Table 10-2. Pull-out Testing on 2.7mm Screws	19
Table 10-3. Pull-out Strength of the Distal Clavicle Plate Buttons	19
Table 12-1. Comparison of <i>Fracture System</i> and Predicate Devices	22

 510(k): ARTHREX FRACTURE SYSTEM

## 1 Truth and Accuracy Statement

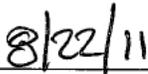
**PREMARKET NOTIFICATION**  
**TRUTHFUL AND ACCURATE STATEMENT**  
*As Required by 21 CFR 807.87(k)*

I certify that, in my capacity as Vice President, Quality Assurance and Regulatory Affairs, at Arthrex, Inc., I believe, to the best of my knowledge, that all data and information submitted in this premarket notification (*Arthrex Fracture System*) is truthful and accurate and that no material fact has been omitted.



\_\_\_\_\_  
*Signature*

Frank Maas, *Vice President, Quality Assurance and Regulatory Affairs*



\_\_\_\_\_  
*Date*

Premarket Notification 510(k) Number: \_\_\_\_\_

## 2 Indications for Use Form

### Indications for Use

510(k) Number (if known): \_\_\_\_\_

Device Name: *Arthrex Fracture System*

#### Indications For Use:

The **Arthrex Fracture System** is intended to be used for internal bone fixation for bone fractures, fusions, osteotomies and non-unions in the ankle, foot, hand, wrist, clavicle, scapula, olecranon, humerus, radius, ulna, tibia, calcaneous, femur and fibula.

The button is intended to be used with suture as an adjunct in fracture repair; specifically, to provide fixation during the healing process following syndesmotic trauma.

The **Arthrex Low Profile Screws (2.7mm and larger, solid)** are intended to be used as stand-alone bone screws, or in a plate-screw system for internal bone fixation for bone fractures, fusions, osteotomies and non-unions in the ankle, foot, hand, wrist, clavicle, scapula, olecranon, humerus, radius, ulna, tibia, calcaneous, femur and fibula. When used with a plate, the screws may be used with the Arthrex Fracture System, Distal Extremity Plates, Low Profile and Small Fragment Plates, Humeral Fracture Plates, and Osteotomy Plates.

Prescription Use  AND/OR Over-The-Counter Use \_\_\_\_\_  
(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

PAGE 1 of 1

### 3 510(k) Summary of Safety and Effectiveness

<b>Date Summary Prepared</b>	August 17, 2011
<b>Manufacturer/Distributor/Sponsor</b>	Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA
<b>510(k) Contact</b>	Courtney Smith Manager, Regulatory Affairs Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA Telephone: 239/643.5553, ext. 1720 Fax: 239/598.5508 Email: <a href="mailto:csmith@arthrex.com">csmith@arthrex.com</a>
<b>Trade Name</b>	<i>Arthrex Fracture System</i>
<b>Common Name</b>	Plate, fixation, bone
<b>Product Code -Classification Name CFR</b>	HWC, HRS 21 CFR 888.8030: Single/multiple component metallic bone fixation appliances and accessories 21 CFR 888.3040: Smooth or threaded metallic bone fixation fastener.
<b>Predicate Device</b>	<i>K011335</i> : Synthes One-Third Tubular Plates <i>K102998</i> : Acumed Congruent Bone Plate System <i>K043248 / K052776</i> : Arthrex TightRope Syndesmosis and Acromioclavicular (AC) Devices <i>K103705 / K111253</i> : Arthrex Low Profile Screws
<b>Device Description and Intended Use</b>	The <i>Arthrex Fracture System</i> is a family of stainless steel plates, screws, and buttons. The plates may be contoured or straight and may be available in left and right configurations. The screw family ranges from 2.0 mm to 4.0 mm in diameter and from 8 mm to 80 mm in length. The screws are solid and fully threaded and may be locking or non-locking. The button is stainless steel and designed to fit securely in the holes of the fracture plates. The button is intended to be used with the previously cleared suture, which is provided separately.  The <i>Arthrex Fracture System</i> is intended to be used for internal bone fixation for bone fractures, fusions, osteotomies and non-unions in the ankle, foot, hand, wrist, clavicle, scapula, olecranon, humerus, radius, ulna, tibia, calcaneous, femur and fibula.  The button is intended to be used with suture as an adjunct in

	<p>fracture repair; specifically, to provide fixation during the healing process following syndesmotic trauma.</p> <p>The <b>Arthrex Low Profile Screws (2.7mm and larger, solid)</b> are intended to be used as stand-alone bone screws, or in a plate-screw system for internal bone fixation for bone fractures, fusions, osteotomies and non-unions in the ankle, foot, hand, wrist, clavicle, scapula, olecranon, humerus, radius, ulna, tibia, calcaneous, femur and fibula. When used with a plate, the screws may be used with the Arthrex Fracture System, Distal Extremity Plates, Low Profile and Small Fragment Plates, Humeral Fracture Plates, and Osteotomy Plates.</p>
<p><b>Substantial Equivalence Summary</b></p>	<p>The Arthrex Fracture System is substantially equivalent to the predicate Synthes One-Third Tubular Plates (K011335), Acumed Congruent Bone Plate System (K102998), Arthrex TightRope Syndesmosis and Acromioclavicular (AC) Devices (K043248 / K052776), and the cleared Arthrex Low Profile Screws (K103705, K111253) in which the basic features and intended uses are the same. Any differences between the <b>Fracture System</b> and the predicates are considered minor and do not raise questions concerning safety and effectiveness.</p> <p>The proposed devices are composed of Stainless Steel which is substantially equivalent to the predicate devices.</p> <p>The submitted mechanical testing data demonstrated that the bending and pull-out strength of the proposed devices are substantially equivalent to the bending and pull-out strength of the predicate devices.</p> <p>Based on the indication for use, technological characteristics, and the comparison to the predicate devices, Arthrex, Inc. has determined that the <b>Fracture System</b> is substantially equivalent to currently marketed predicate devices.</p>

## 4 Administrative Information Manufacturer / Sponsor / Contact

### 4.1 Manufacture / Sponsor / Contact

#### 4.1.1 Manufacturer / Sponsor

Arthrex, Inc.  
1370 Creekside Boulevard  
Naples, Florida 34108-1945 USA  
Establishment Registration Number: 1220246

#### 4.1.2 Contact

Courtney Smith  
Manager, Regulatory Affairs  
Arthrex, Inc.  
1370 Creekside Boulevard  
Naples, Florida 34108-1945 USA  
*Telephone:* 239/643.5553, extension 1720  
*Fax:* 239/598.5508  
*Email:* [csmith@arthrex.com](mailto:csmith@arthrex.com)

### 4.2 Device Identification

#### 4.2.1 Proprietary Name

Arthrex Fracture System

#### 4.2.2 Common Name

Plate, fixation, bone

#### 4.2.3 Classification Name and Reference

21 CFR 888.3030: Single/multiple component metallic bone fixation appliances and accessories

21 CFR 888.3040: Smooth or threaded metallic bone fixation fastener

#### **4.2.4 Regulatory Class**

Based on the recommendation of the Orthopedic and Rehabilitation Device Panel, the FDA has classified this device as a Class II medical device.

#### **4.2.5 Device Product Codes**

- HWC
- HRS

#### **4.3 Compliance with Special Controls**

Sections 513 and 514 of the act, as amended under the Safe Medical Devices Act of 1990, do apply to this type of device.

Arthrex, Inc. is not aware of any requirements for post-market surveillance or other special controls for this device.

## 5 Device Description

### 5.1 Introduction

This **traditional 510(k)** premarket notification is submitted to obtain clearance for the Arthrex Fracture System, and to expand the indications for the existing 2.7 and 3.0mm screws. In K103705, 2.7mm and 3.0mm screws were cleared for use in the ankle, foot, hand, and wrist. This indication is being expanded to include the clavicle, scapula, olecranon, humerus, radius, ulna, tibia, calcaneous, femur and fibula.

The fundamental scientific technology and indications for use of the proposed Plates and Screws is substantially equivalent to the predicate Synthes One-Third Tubular Plates (K011335), Acumed Congruent Bone Plate System (K102998), the cleared Arthrex TightRope Syndesmosis and Acromioclavicular (AC) Devices (K043248 / K052776), and Arthrex Low Profile Screws (K103705, K111253).

The *Arthrex Fracture System* is designed by Arthrex, Inc., and requires the submission of a pre-market notification prior to commercialization in the United States.

### 5.2 Device Materials

(b)(4) Stainless Steel (ASTM F-138)

### 5.3 Device Description

#### *Predicate Synthes One-Third Tubular Plates - K011335*

The Synthes One-Third Tubular plates are a family of various sized contoured bone plates with both locking and compression holes. The plates range in length from 81 to 117mm, and are comprised of stainless steel. The plates are to be used with 2.7-3.5mm screws.

#### *Predicate Acumed Congruent Bone Plate System – K102998*

The Acumed Congruent Bone Plate System is a family of various sized contoured bone plates and screws. The clavicle plates range in length from 64 to 121mm, and are comprised of titanium. The clavicle plates are to be used with 2.7-4.0mm screws.

#### *Predicate Low Profile Screws - K103705 / K111253*

The Arthrex Low Profile Screws are a family of stainless steel and titanium screws. The screws may be fully or partially threaded, and solid or cannulated. The screw family ranges from 2.0 mm to 4.0 mm in diameter and from 8 mm to 80 mm in length.

#### *Predicates TightRope Syndesmosis and Acromioclavicular (AC) Devices – K043248 / K052776*

The TightRope Acromioclavicular and Syndesmosis devices are the same device with different indications. The device is designed as two metal buttons (either stainless steel or titanium) and a #5 Suture. The buttons are designed in two sizes, 3.5mm and

6.5mm. The 6.5mm button is circular and has four holes. The 3.5mm button is oblong (3.5 x 10mm) and has two holes. The buttons are pre-threaded with #5 FiberWire suture.

**Proposed Fracture System**

The *Arthrex Fracture System* is a family of stainless steel plates, screws, and buttons. The plates may be contoured or straight and may be available in left and right configurations. The screws, which are used with the Arthrex Plates, include the solid, stainless steel locking and non-locking Low Profile Screws cleared in K103705, with additional lengths. The additional screw lengths do not change the existing size range of the Low Profile Screws. The screw family ranges from 2.0 mm to 4.0 mm in diameter and from 8 mm to 80 mm in length. The button is stainless steel and designed to fit securely in the holes of the fracture plates. The button is intended to be used with the previously cleared suture, which is provided separately. The proposed buttress plate is designed to be used with the existing TightRope Syndesmosis Device (K043248) or TightRope Acromicroclavicular (AC) Device (K052776).

The device numbers and general descriptions of the proposed and cleared predicate devices are listed in Table 5-1, Table 5-2 and Table 5-3. The proposed devices are **bolded and shaded**.

**Table 5-1. Part Numbers and Descriptions for New and Predicate Plates**

Comparison Between Proposed and Predicate Plates						
510(k) Clearance	Product Numbers	Holes	Width (mm)	Length (mm)	Thickness (mm)	Material
	<b>Central Third Clavicle Plates (AR-2650CL – AR-2655CL) (AR-2650CR – AR-2655CR)</b>	7 – 10	9.6	76 – 120	2.3	Stainless Steel
	<b>Distal Clavicle Plates (AR-2656DL – AR-2657DL) AR-2656DR – AR-2657DR)</b>	10 – 13	11.2	70 – 99	2.5	Stainless Steel
	<b>Ankle Fracture Plates (AR-8943C-04 – AR-8943C-12)</b>	4 – 12	9.6	55 - 157	3.1	Stainless Steel
	<b>Buttress Plate AR-8914P</b>	2	5	22	0.5	Stainless Steel
K011335	Synthes One-Third Tubular Plates	2 - 12	9.4	81 - 117	1.0	Stainless Steel
K102998	Acumed Congruent Bone Plates	6 – 16	11	64 - 121	3.5	Titanium

**Table 5-2. Part Numbers and Descriptions for New and Cleared Screws**

Comparison Between Proposed and Predicate Screws					
Clearance	Product Numbers	Product Description	Diameter (mm)	Total Length (mm)	Material
K103705	AR-8727-08 – AR-8727-40	Screw, Solid, FT	2.7	8 – 40	Ti
K102998	CO-27xx	Acumed Congruent Bone Screws	2.7	8-30	Ti
	<b>AR-8827L-08</b>	<b>Screw, Solid, Locking</b>	<b>2.7</b>	<b>8</b>	<b>SS</b>
K103705	AR-8827L-10 – AR-8827L-30	Screw, Solid, Locking	2.7	10 – 30	SS
K103705	AR-8730-10FT – AR-8730-50FT	Screw, Solid, FT	3.0	10 – 50	Ti
K103705	AR-8730-10PT – AR-8730-50PT	Screw, Cannulated, PT	3.0	10 – 50	Ti
K103705	AR-8830-10 – AR-8830-30	Screw, Solid, FT	3.0	10 – 30	SS
K103705	AR-8931-13 – AR-8931-20	Screw, Solid, FT	3.0	13 – 20	Ti
K103705	AR-8933-10 – AR-8933-24	Screw, Solid FT	3.0	10 – 24	Ti
K103705	AR-8933-10PT – AR-8933-50PT	Screw, Cannulated, PT	3.0	10 – 50	Ti
K103705	AR-8933L-10 – AR-8933L-24	Screw, Solid, Locking	3.0	10 – 24	Ti
	<b>AR-8835-08</b>	<b>Screw, Solid, FT</b>	<b>3.5</b>	<b>8</b>	<b>SS</b>
K103705	AR-8835-10 – AR-8835-60	Screw, Solid, FT	3.5	10 – 60	SS
K102998	CO-3xx0	Acumed Congruent Bone Screws	3.5	8-60	Ti
	<b>AR-8835-65 – AR-8835-80</b>	<b>Screw, Solid, FT</b>	<b>3.5</b>	<b>65 – 80</b>	<b>SS</b>
	<b>AR-8835L-08</b>	<b>Screw, Solid, Locking</b>	<b>3.5</b>	<b>8</b>	<b>SS</b>
K103705	AR-8835L-10 – AR-8835L-60	Screw, Solid, Locking	3.5	10 – 60	SS
	<b>AR-8835L-65 – AR-8835L-80</b>	<b>Screw, Solid, Locking</b>	<b>3.5</b>	<b>65 – 80</b>	<b>SS</b>
K111253	AR-8935L-46 – AR-8935L-80	Screw, Solid, Locking	3.5	46 – 80	Ti
K102998	CO-4xx0	Acumed Congruent Bone Screws	4.0	8-80	Ti
K103705	AR-8840-10 – AR-8840-60	Screw, Solid, FT	4.0	16 – 60	SS

**Table 5-3. Part Numbers and Descriptions for New and Predicate Buttons**

Comparison Between Proposed and Predicate Plates						
510(k) Clearance	Product Description	Holes	Length (mm)	Width (mm)	Material	Suture
	Distal Clavicle Plate Button (AR-2658)	2	8.5	5.8	Stainless Steel	FiberTape (K041553) (provided separately)
K052776	TightRope Acromioclavicular (AC) Device	2 4	10 6.5	3.5 6.5	Titanium / Stainless Steel	#5 FiberWire
K043248	TightRope Syndesmosis Device	2 4	10 6.5	3.5 6.5	Titanium / Stainless Steel	#5 FiberWire

Refer to *Appendix 1* for engineering drawings of the devices.

## 5.4 Manufacturing

The Arthro *Fracture System* devices are machined from Stainless Steel.

## 5.5 Accessory Device Information

Class I exempt instruments which are specific to the devices included in this submission are listed in Table 5-1, Table 5-2, and Table 5-3.

Table 5-4. Instrumentation

Part #	Description	Material	Standard
AR-2659	Positioning Handle, Distal Clavicle Plate	Stainless Steel	ASTM F899
AR-2661L	Drill Guide, 2.0 mm Distal Clavicle Plate, L	Stainless Steel	ASTM F899
AR-2661R	Drill Guide, 2.0 mm Distal Clavicle Plate, R	Stainless Steel	ASTM F899

## 6 Device Labeling

### 6.1 Device Labels

Representative draft device labels are provided below:

Figure 6-1. Package label

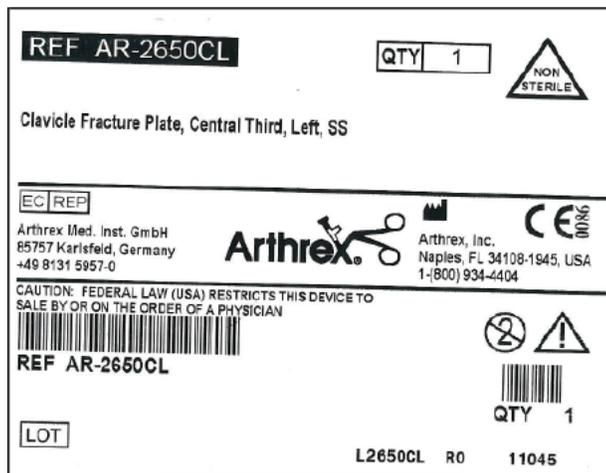


Figure 6-2. Symbol Definition Label

SYMBOL DEFINITIONS			
	See Instructions For Use		Date of Manufacture year
	Use By year & month		Manufacturer
	Do Not Reuse		Storage Temperature Range
REF	Catalog Number	QTY	Quantity
LOT	Lot Number	EC REP European Community Representative	
SN	Serial Number	00001 OF 1 PN02029-1 R 0 FN026	

### 6.2 Instructions for Use (IFU) / Directions for Use (DFU)

A copy of the draft Directions for Use (DFU) for the Arthrex *Fracture System* is provided for reference in *Appendix 2*.

## 7 Shelf Life

The shelf life of non-sterile devices is not limited. The devices in this submission are manufactured from non-degradable stainless steel, which does not raise any questions of device stability.

## 8 Packaging and Storage

The stainless steel *Arthrex Fracture System* will be sold non-sterile, single use.

The packaging material for non-sterile devices is a polyethylene pouch, commonly used in the medical industry.

The non-sterile devices are to be stored in their original unopened packaging.

## 9 Sterility and Pyrogenicity

### 9.1 Fracture System

The devices included in the *Fracture System* are provided non-sterile and are single use devices. The devices should be cleaned and sterilized prior to use. The generally accepted sterilization method is steam sterilization.

Arthrex provides the following sterilization parameters, in accordance with the AAMI Standard ST79 in the Directions for Use (DFU) for the non-sterile instruments.

	Exposure Temperature	Exposure Time	Drying Time
Gravity-Displacement Steam Sterilization Cycle	121°C (250°F)	30 Minutes	15 to 30 Minutes
	132°C (270°F)	15 Minutes	15 to 30 Minutes
	135°C (275°F)	10 Minutes	15 to 30 Minutes
Pre-vacuum Cycle	132°C (270°F)	4 Minutes	20 to 30 Minutes
	135°C (275°F)	3 Minutes	16 Minutes

The Sterility Assurance Level (SAL) is  $10^{-6}$ .

No pyrogenicity claims are made for the Arthrex *Fracture System*.

### 9.2 Fracture System Instruments

The Arthrex *Fracture System* accessory instruments are provided non-sterile and are reusable or single-use.

Arthrex provides the following sterilization parameters, in accordance with the AAMI Standard ST79 in the Directions for Use (DFU) for the non-sterile instruments.

	Exposure Temperature	Exposure Time	Drying Time
Gravity-Displacement Steam Sterilization Cycle	121°C (250°F)	30 Minutes	15 to 30 Minutes
	132°C (270°F)	15 Minutes	15 to 30 Minutes
	135°C (275°F)	10 Minutes	15 to 30 Minutes
Pre-vacuum Cycle	132°C (270°F)	4 Minutes	20 to 30 Minutes
	135°C (275°F)	3 Minutes	16 Minutes

The Sterility Assurance Level (SAL) is  $10^{-6}$ .

No pyrogenicity claims are made for the Arthrex *Fracture System* instruments.

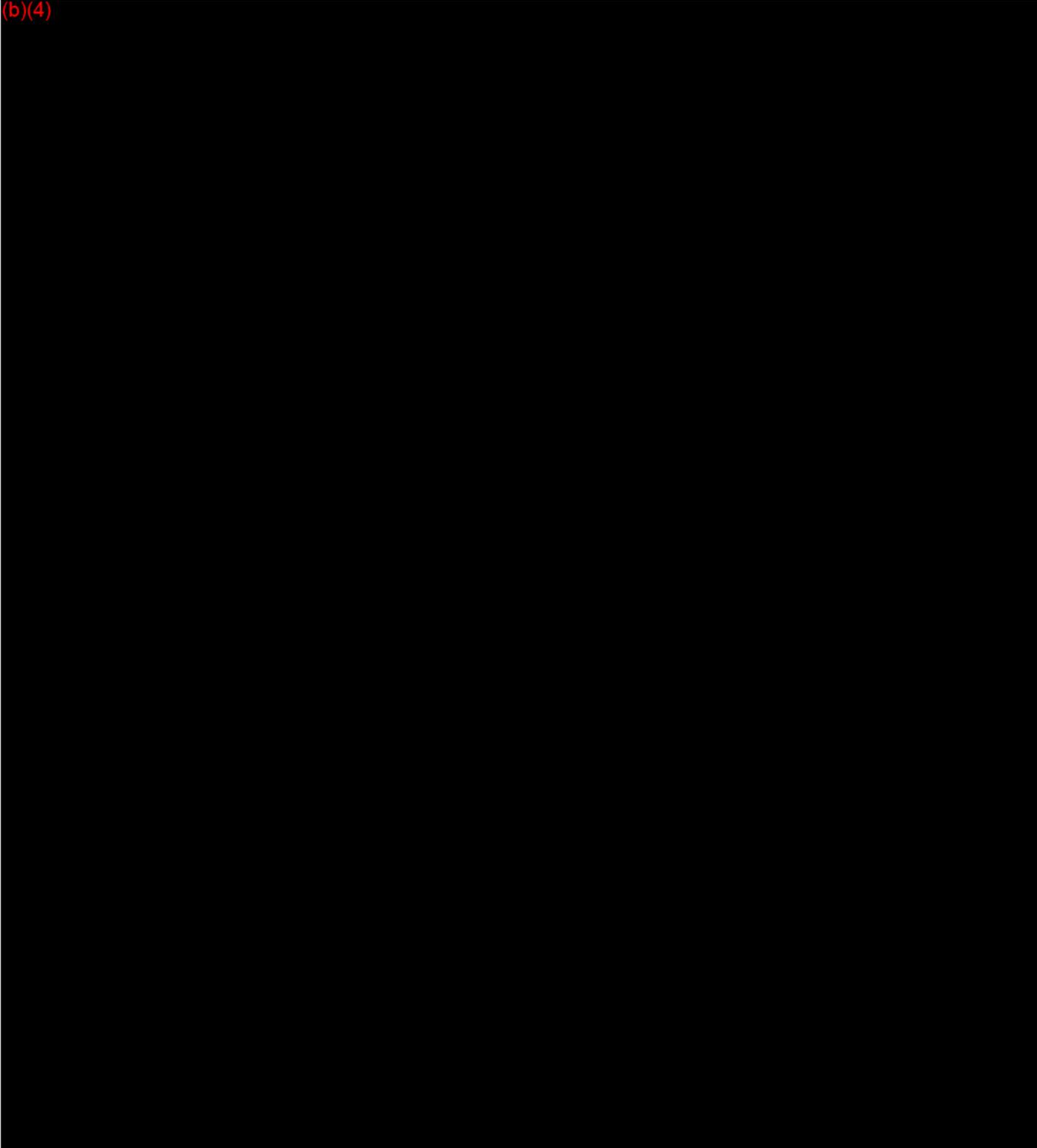
ArthroX 510(K): ARTHREX FRACTURE SYSTEM

---

## 10 Mechanical Data

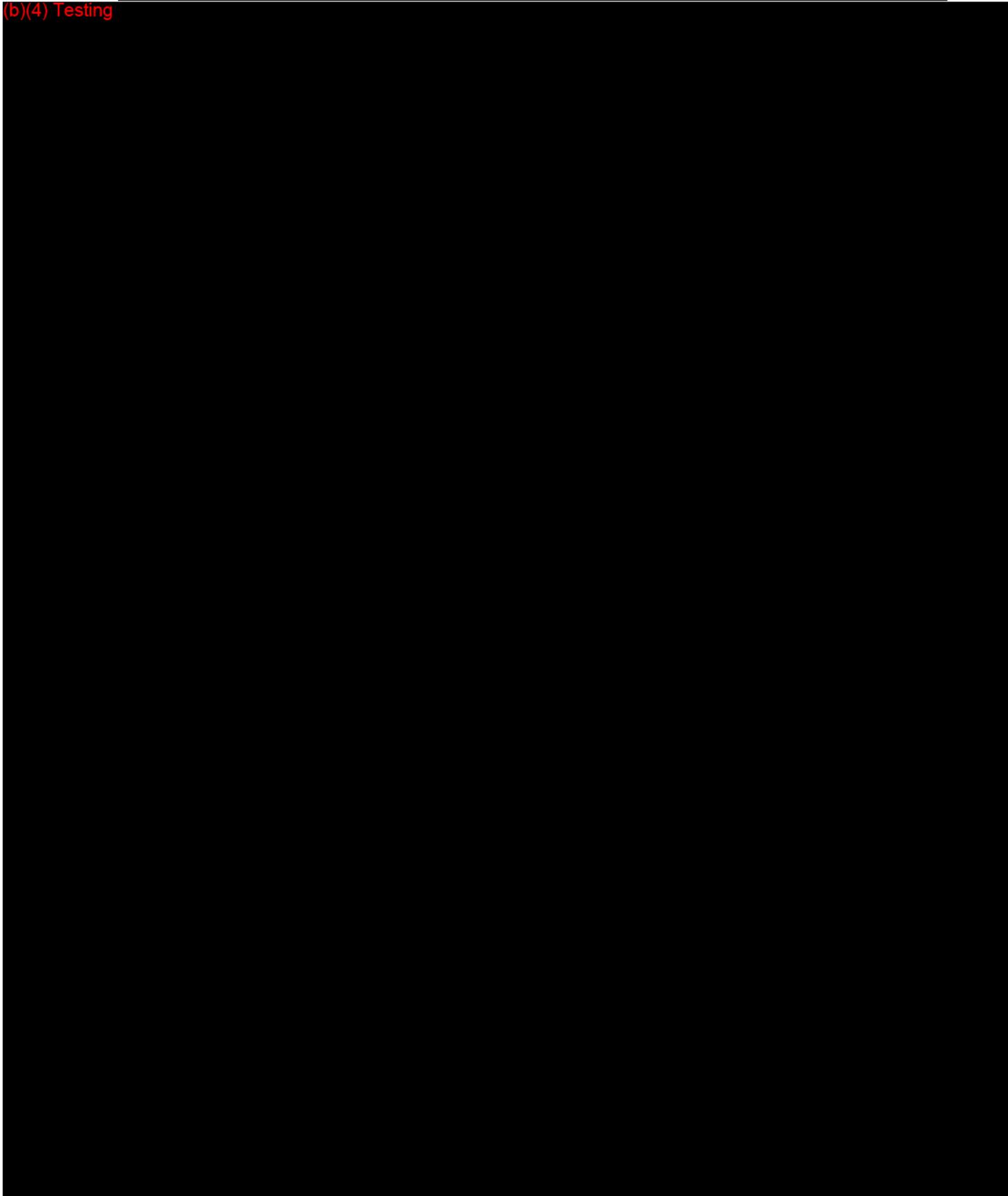
### (b)(4) Testing

(b)(4)

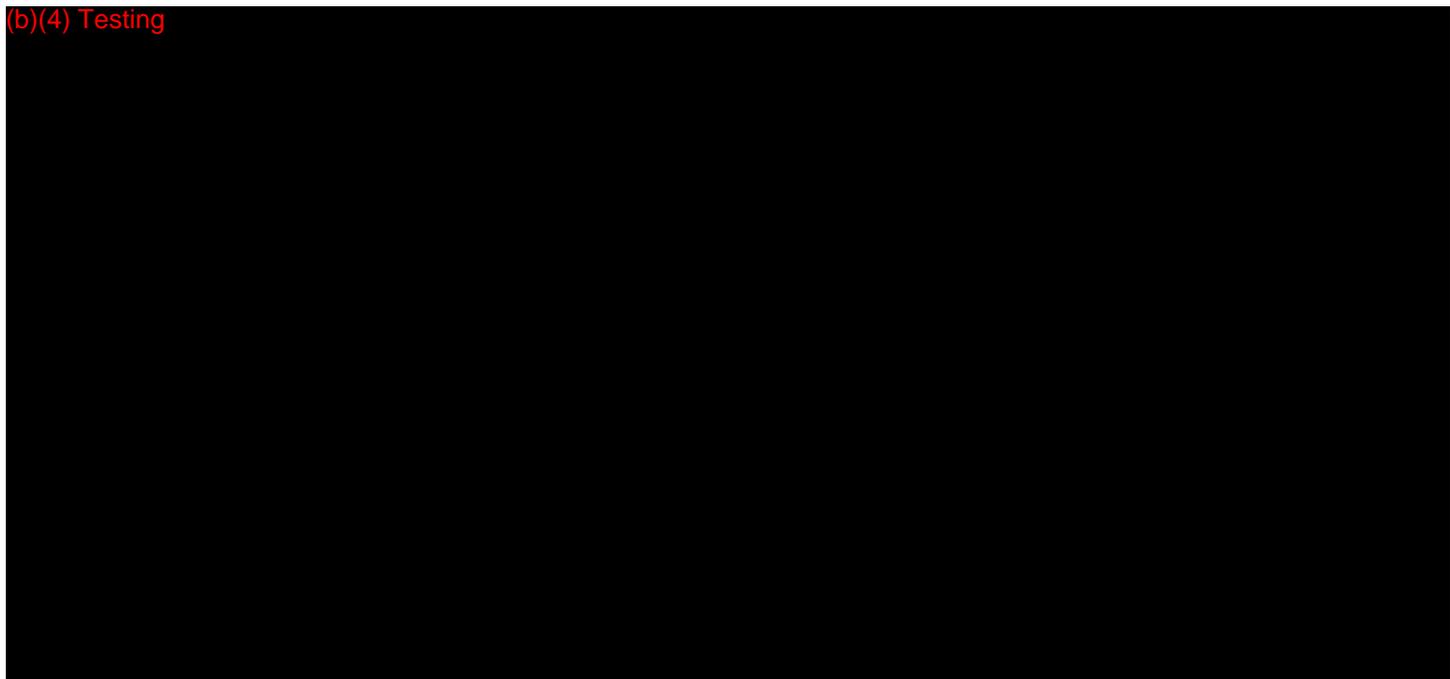


Arthro 510(K): ARTHREX FRACTURE SYSTEM

(b)(4) Testing



(b)(4) Testing



7

## 11 Substantially Equivalent Predicate Devices

The *Arthrex Plates and Screws* are substantially equivalent to the following predicate device where basic features, materials, and intended uses are the same or very similar.

***K011335: Synthes One-Third Tubular Plates***

***K102998: Acumed Congruent Bone Plate System***

***K043248 / K052776: Arthrex TightRope Syndesmosis and Acromioclavicular (AC) Devices***

***K103705 / K111253: Arthrex Low Profile Screws***

Any differences between the *Arthrex Fracture System* and the above predicate devices are considered minor and do not raise any new questions concerning safety and effectiveness.

## 12 Similarities and Differences with Marketed Devices

By definition, substantial equivalence means that a device has the same intended use and technological characteristics as a predicate device. It might also have the same intended use and different technological characteristics, and demonstrate that it is as safe and effective as a predicate device without raising new questions regarding safety and effectiveness.

The fundamental scientific technology and intended use of the *Arthrex Fracture System* is not changed from the predicate devices.

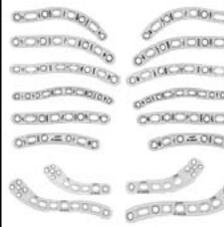
The *Arthrex Fracture System* is substantially equivalent to the predicate Synthes One-Third Tubular Plates (K011335), Acumed Congruent Bone Plate System (K102998) and the cleared Arthrex TightRope Syndesmosis and Acromioclavicular (AC) Devices (K043248 / K052776), Arthrex Low Profile Screws (K103705 / K111253) where fundamental scientific technology, design features, materials, and intended uses are the same or very similar.

Based on the information submitted including mechanical testing, Arthrex, Inc. has determined that the *Arthrex Fracture System* is substantially equivalent to the predicate devices.

The *Arthrex Fracture System* does not raise new questions regarding safety and effectiveness.

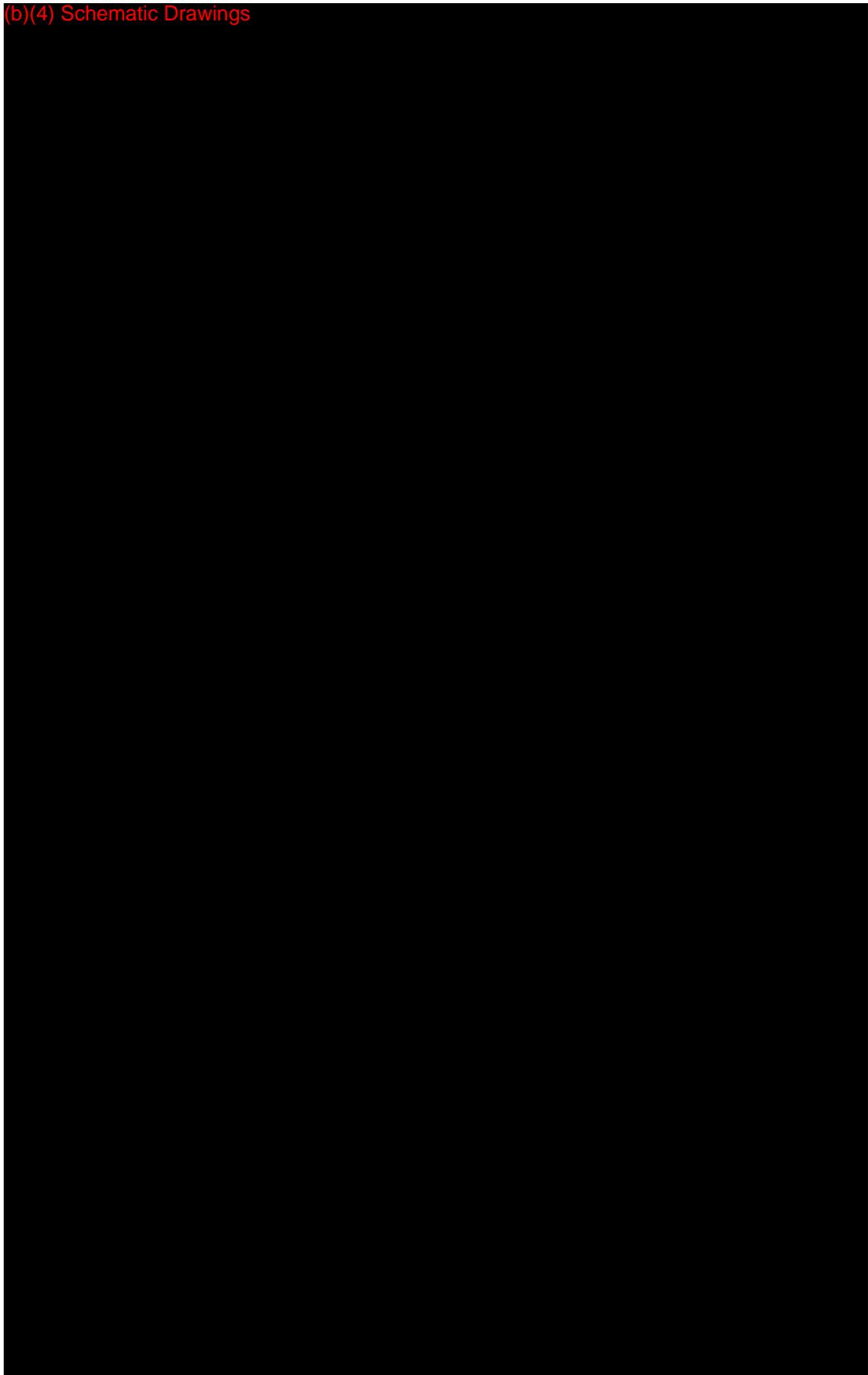
Refer to Table 12-1 for a comparison of the similarities and differences between the *Fracture System* and the predicate devices.

**Table 12-1. Comparison of *Fracture System* and Predicate Devices**

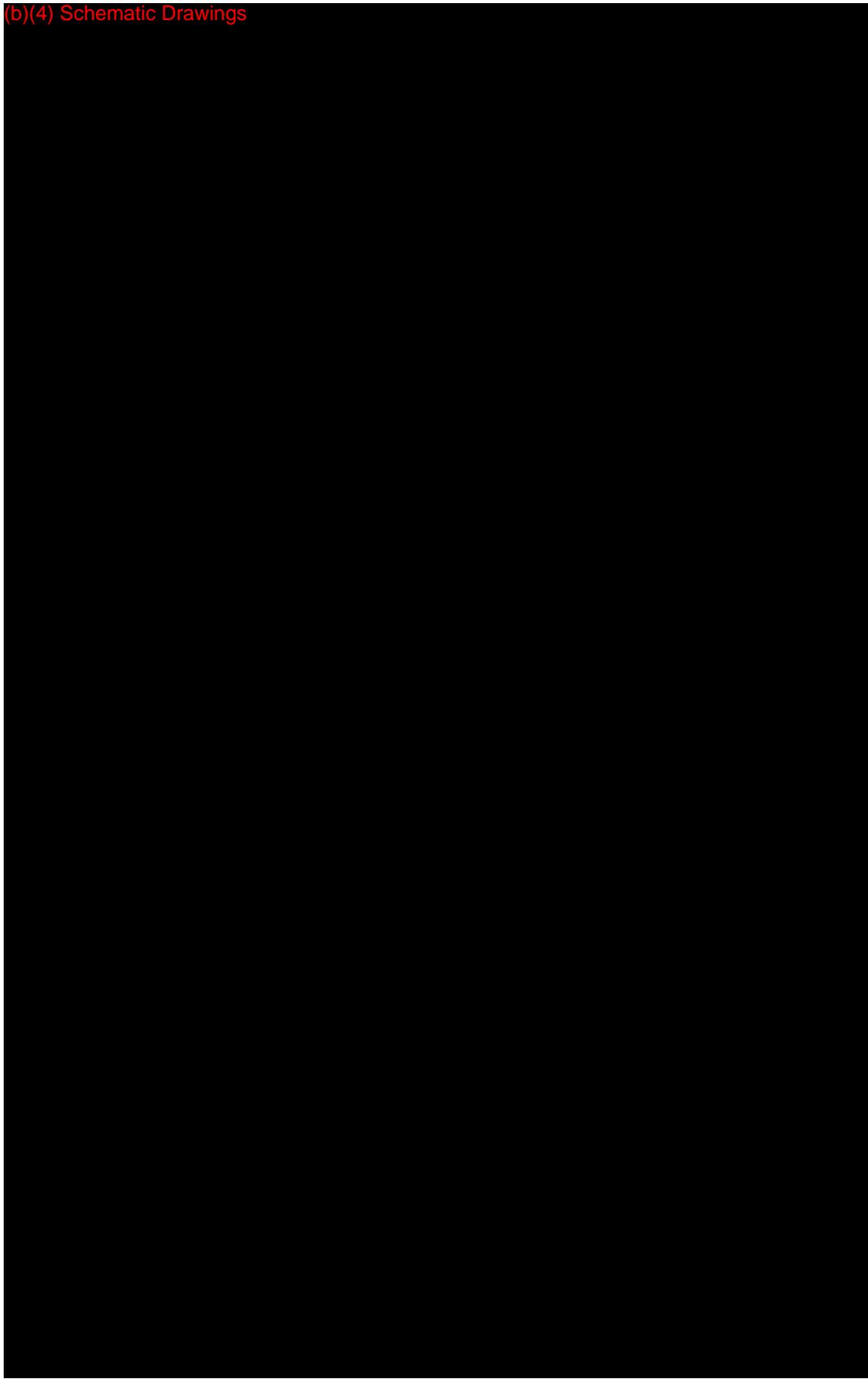
Device Similarities & Differences	Arthrex Fracture System - This submission -	Synthes One-Third Tubular Plate (K011335)	Acumed Congruent Bone Plate System (K102998)	Arthrex TightRope Syndesmosis and Acromioclavicular (AC) Devices (K043248 / K052776)	Arthrex Low Profile Screws (K103705 / K111253)
Product Code	HRS, HWC	HRS	HRS	HRS	HRS, HWC
21 CFR	888.3030, 888.3040	888.3030	888.3030	888.3030	888.3030, 888.3040
Plates				Not Applicable	Not Applicable

<i>Device Similarities &amp; Differences</i>	Arthrex Fracture System - This submission -	Synthes One-Third Tubular Plate (K011335)	Acumed Congruent Bone Plate System (K102998)	Arthrex TightRope Syndesmosis and Acromioclavicular (AC) Devices (K043248 / K052776)	Arthrex Low Profile Screws (K103705 / K111253)
<b>Screws</b>	 2.7 – 4.0mm	 2.7 – 3.5mm	 2.7 – 4.0mm	Not Applicable	 2.0 – 4.0mm
<b>Button</b>		Not Applicable	Not Applicable		Not Applicable
<b>Intended Use</b>	Intended to be used for internal bone fixation for bone fractures, fusions, osteotomies and non-unions.	Intended for fixation of fractures, osteotomies and nonunions	Provides fixation for fractures, fusions, or osteotomies.	Intended as an adjunct in fracture repair and as an adjunct in fixation systems	Intended to be used for internal bone fixation for bone fractures, fusions, or osteotomies.
<b>Material</b>	Stainless Steel	Stainless Steel	Titanium	Stainless Steel / Titanium	Stainless Steel / Titanium
<b>Packaging</b>	Polyethylene pouch	Not available	Not available	Plastic pouch	Polyethylene pouch
<b>Sterile</b>	Non-Sterile / Steam	Non-Sterile / Steam	Non-Sterile / Steam	Non-Sterile / Steam	Non-Sterile / Steam
<b>Shelf life</b>	Non-sterile device: no shelf life	Non-sterile device: no shelf life	Non-sterile device: no shelf life	Non-sterile device: no shelf life	Non-sterile device: no shelf life
<b>Single Use</b>	Yes	Yes	Yes	Yes	Yes

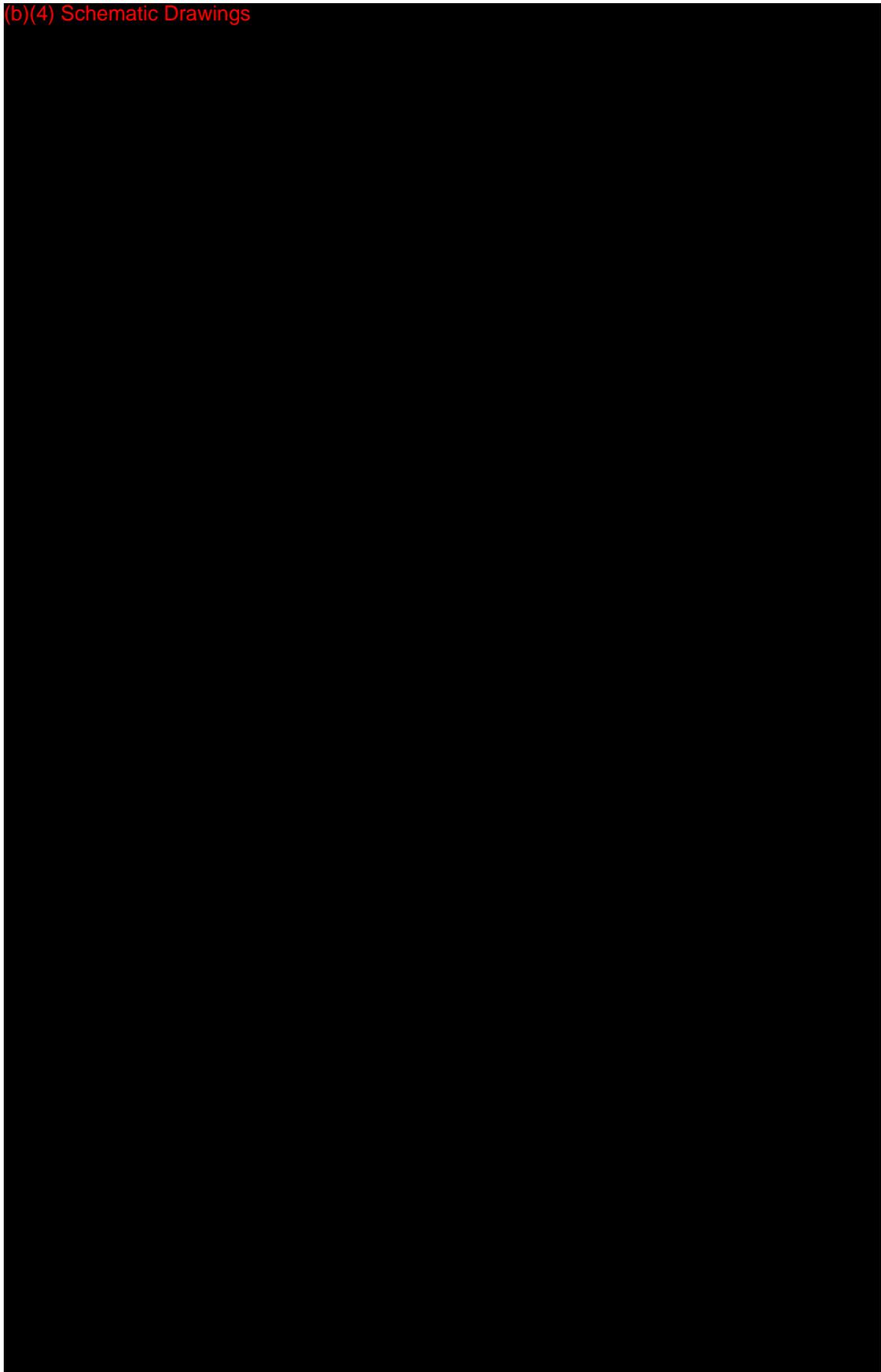
(b)(4) Schematic Drawings



(b)(4) Schematic Drawings



(b)(4) Schematic Drawings























































# Fracture Plate and Screw System

## DFU-0125

### Draft 0

#### A. DEVICE DESCRIPTION

Plates are available in different shapes, sizes and orientations (e.g. left and right types). The plates have specific sized holes for screws to provide fixation.

The screws are headed and self-tapping. They are available as fully or partially threaded, and solid or cannulated. The screw family ranges from 2.0 mm to 6.7 mm in diameter and from 8 mm to 120 mm in length (in 1, 2 or 5 mm increments).

The Distal Clavicle Plate Button is designed to fit securely in the holes of the fracture plates. The Buttress Plate contains two titanium buttons, FiberWire® suture, Guide Pin, two Low Profile Screws, Buttress Plate, Cannulated Drill Bit, Guidewire with Trocar tip, Hexalobe Driver and Pin Tip Drill Bit.

#### B. INDICATIONS

**The Arthrex Fracture Plates** are intended to be used for internal bone fixation for bone fractures, fusions, osteotomies and non-unions in the ankle, foot, hand, wrist, clavicle, scapula, olecranon, humerus, radius, ulna, tibia, calcaneous, femur and fibula.

The button is intended to be used with suture as an adjunct in fracture repair; specifically, to provide fixation during the healing process following syndesmotic trauma.

**The Arthrex Low Profile Screws (2.0-2.4mm solid)** are intended to be used as stand-alone bone screws, or in a plate-screw system for internal bone fixation for bone fractures, fusions, osteotomies and non-unions in the ankle, foot, hand, and wrist. When used with a plate, the screw may be used with the Arthrex Low Profile and Small Fragment Plates.

**The Arthrex Low Profile Screws (2.0-3.0mm cannulated)** are intended to be used as stand-alone bone screws for internal bone fixation for bone fractures, fusions, osteotomies and non-unions in the ankle, foot, hand, and wrist.

**The Arthrex Low Profile Screws (2.7mm and larger, solid)** are intended to be used as stand-alone bone screws, or in a plate-screw system for internal bone fixation for bone fractures, fusions, osteotomies and non-unions in the ankle, foot, hand, wrist, clavicle, scapula, olecranon, humerus, radius, ulna, tibia, calcaneous, femur and fibula. When used with a plate, the screws may be used with the Arthrex Low Profile and Small Fragment Plates, Humeral Fracture Plates, and Osteotomy Plates.

**The Arthrex Low Profile Screws (3.5mm and larger, cannulated)** are intended to be used as stand-alone bone screws for internal bone fixation for bone fractures, fusions, osteotomies and non-unions in the ankle, foot, hand, wrist, clavicle, scapula, olecranon, humerus, radius, ulna, tibia, calcaneous, femur and fibula.

### **C. CONTRAINDICATIONS**

1. Insufficient quantity or quality of bone.
2. Blood supply limitations and previous infections, which may retard healing.
3. Foreign-body sensitivity. Where material sensitivity is suspected, appropriate tests should be made and sensitivity ruled out prior to implantation.
4. Any active infection or blood supply limitations.
5. Conditions that tend to limit the patient's ability or willingness to restrict activities or follow directions during the healing period.
6. The use of this device may not be suitable for patients with insufficient or immature bone. The physician should carefully assess bone quality before performing orthopedic surgery on patients who are skeletally immature. The use of this medical device and the placement of hardware or implants must not bridge, disturb or disrupt the growth plate.
7. Do not use for surgeries other than those indicated.

### **D. ADVERSE EFFECTS**

1. Infections, both deep and superficial.
2. Foreign body reactions.

### **E. WARNINGS**

1. An internal fixation device must never be reused.
2. All metallic implant devices used for this surgical procedure should have the same metallurgical composition.

3. Postoperatively and until healing is complete, fixation provided by this device should be considered as temporary and may not withstand weight bearing or other unsupported stress. The fixation provided by this device should be protected. The postoperative regimen prescribed by the physician should be strictly followed to avoid adverse stresses applied to the device.
4. Pre-operative and operating procedures, including knowledge of surgical techniques and proper selection and placement of the device, are important considerations in the successful utilization of this device. The appropriate Arthrex delivery system is required for proper implantation of the device.
5. Any decision to remove the device should take into consideration the potential risk to the patient of a second surgical procedure. Device removal should be followed by adequate postoperative management.
6. Detailed instructions on the use and limitations of this device should be given to the patient.
7. This is a single use device. Reuse of this device could result in failure of the device to perform as intended and could cause harm to the patient and/or user.
8. The device has not been evaluated for safety and compatibility in the magnetic resonance (MR) environment. The device has not been tested for heating or migration in the MR environment. If the implant is manufactured from a metallic material, surgeons can expect that MR artifacts will be present during routine MR Imaging.
9. Removal of supplemental fixation after healing. If the supplemental fixation is not removed following the completion of its intended use, any of the following complications may occur: (1) Corrosion, with localized tissue reaction or pain; (2) Migration of implant position resulting in injury; (3) Risk of additional injury from postoperative trauma; (4) Bending, loosening, and/or breakage, which could make removal impractical or difficult; (5) Pain, discomfort, or abnormal sensations due to the presence of the device; (6) Possible increased risk of infection; and (7) Bone loss due to stress shielding. The surgeon should carefully weigh the risks versus benefits when deciding whether to remove the implant. Implant removal should be followed by adequate postoperative management to avoid re-fracture.

## F. PRECAUTIONS

1. Surgeons are advised to review the product-specific surgical technique prior to performing any surgery. Arthrex provides detailed surgical techniques in print, video, and electronic formats. The Arthrex website also provides detailed surgical technique information and demonstrations. Or, contact your Arthrex representative for an onsite demonstration.
2. Use the appropriately sized drill bit for the screw.
3. Damage to the driver or screw may result from failure to seat the driver fully into the screw or to align the driver properly with the screw.
4. It is not recommended to bend the insertion post (of QuickFix™ screws) to remove it from the Arthrex QuickFix™ screw head.
5. Do not bend the plate near the locking hole. Bending the plate near the locking hole can distort the holes threading, which prohibits insertion of the screw
6. Repeated bending of the plate at the same location, or by creating excessive acute angles may potentially lead to premature plate fatigue, failure and or breakage in situ.
7. Screws should be inserted by hand and not with powered equipment.

## G. PACKAGING AND LABELING

1. Arthrex devices should be accepted only if the factory packaging and labeling arrive intact.
2. Contact Customer Service if the package has been opened or altered.

## H. STERILIZATION

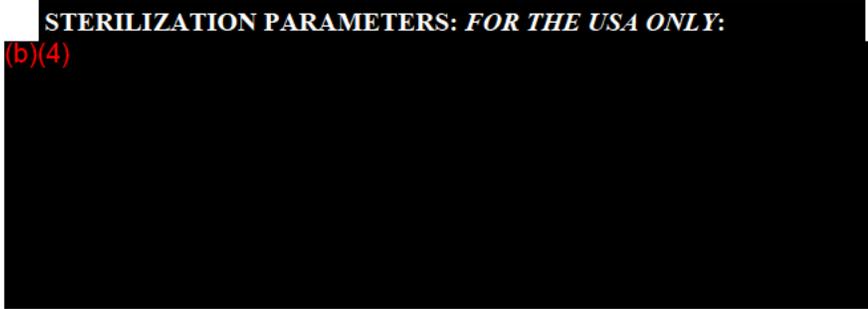
This device is provided sterile or non-sterile. Refer to the package label for the sterilization method.

This device can be resterilized. It must be adequately cleaned, then sterilized using one of the following sterilization parameters.

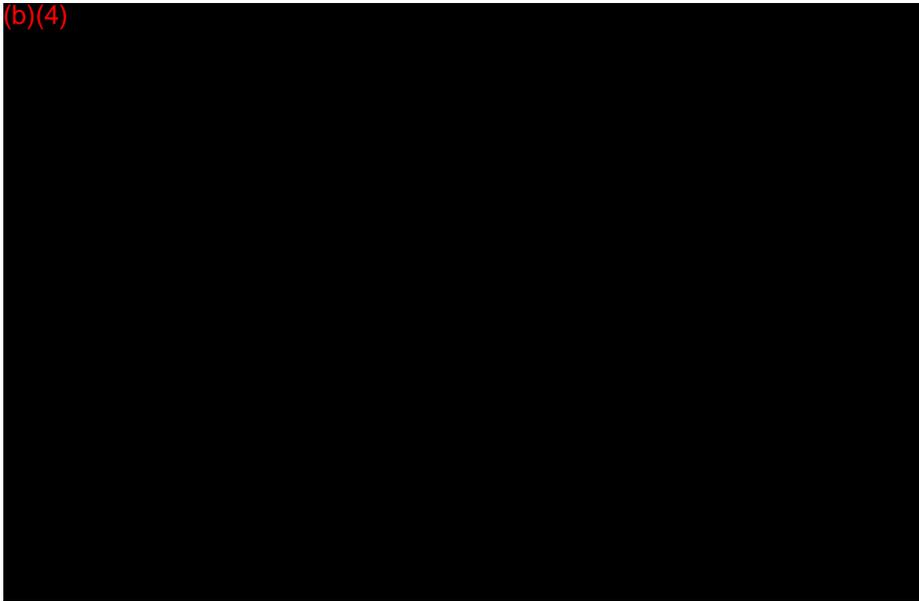
Follow your country-specific guidelines, standards, and requirements.

### **STERILIZATION PARAMETERS: *FOR THE USA ONLY:***

(b)(4)



(b)(4)



Certain Arthrex devices that may be used during this procedure are provided non-sterile and must be adequately cleaned and sterilized prior to use or re-use. Please refer to DFU-0023 and ANSI/AAMI ST79, "Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities" for specific information.

Sterilizers vary in design and performance characteristics. Cycle parameters and the load configuration should always be verified against the sterilizer manufacturer's instructions.

Cooling – The device must be adequately cooled, after being removed from the sterilizer.

## **I. MATERIAL SPECIFICATIONS**

Refer to the package label for the materials. This device is made of titanium or stainless steel.

## **J. STORAGE CONDITIONS**

Sterile devices must be stored in the original unopened packaging, away from moisture and should not be used after the expiration date.

Non-sterile metal devices should be stored in a clean, dry environment. The shelf life of non-sterile devices is not limited; the devices are manufactured from non-degradable material, which does not raise any question of device stability when stored under recommended conditions.

## **K. INFORMATION**

Surgeons are advised to review the product specific surgical technique prior to performing any surgery. Arthrex provides detailed surgical techniques in print, video, and electronic formats.

The Arthrex website also provides detailed surgical technique information and demonstrations.  
Or, contact your Arthrex representative for an onsite demonstration.













































































**COVER SHEET MEMORANDUM**

**From:** Reviewer Name Elizabeth Frank  
**Subject:** 510(k) Number K112437/81  
**To:** The Record

Please list CTS decision code SE

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

Not Substantially Equivalent (NSE) Codes

- NO NSE for lack of predicate
- NI NSE for new intended use
- NQ NSE for new technology that raises new questions of safety and effectiveness
- NP NSE for lack of performance data
- NM NSE requires PMA
- NS NSE no response
- NH NSE for another reason

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	<i>Attach IFU</i>	✓	
510(k) Summary /510(k) Statement	<i>Attach Summary</i>	✓	
Truthful and Accurate Statement.	<i>Must be present for a Final Decision</i>	✓	
Is the device Class III?			✓
If yes, does firm include Class III Summary?	<i>Must be present for a Final Decision</i>		✓
Does firm reference standards? (If yes, please attach form from <a href="http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf">http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf</a> )		✓	
Is this a combination product? (Please specify category _____, see <a href="http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC">http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC</a> )			✓
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, <a href="http://www.fda.gov/cdrh/ode/guidance/1216.html">http://www.fda.gov/cdrh/ode/guidance/1216.html</a> )			✓
Is this device intended for pediatric use only?		✓	
Is this a prescription device? (If both prescription & OTC, check both boxes.)		✓	
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			✓
Is clinical data necessary to support the review of this 510(k)?			✓
For United States-based clinical studies <b>only</b> : Did the application include a completed FORM FDA 3674, <i>Certification with Requirements of ClinicalTrials.gov Data Bank?</i> (If study was conducted in the United States, and FORM FDA 3674 was not included or incomplete, then applicant must be contacted to obtain completed form.)			✓
Does this device include an Animal Tissue Source?			✓
All Pediatric Patients age<=21			✓

Neonate/Newborn (Birth to 28 days)		✓
Infant (29 days -< 2 years old)		✓
Child (2 years -< 12 years old)		✓
Adolescent (12 years -< 18 years old)		✓
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)		✓
Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)		✓
Nanotechnology		✓
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, <a href="http://www.fda.gov/cdrh/comp/guidance/169.html">http://www.fda.gov/cdrh/comp/guidance/169.html</a> )	Contact OC.	✓

Regulation Number 888.3030 Class\* II Product Code HTN

Additional Product Codes: HRS, HWC (\*If unclassified, see 510(k) Staff)

Review: *Michael...* 05BB 12/22/11  
(Branch Chief) (Branch Code) (Date)

Final Review: *[Signature]* 12/23/11  
(Division Director) (Date)

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

**K112437/S1**

**Date:** December 21, 2011

**To:** The Record

**From:** Elizabeth Frank, MS, Biomedical Engineer

**Office:** ODE

**Division:** DSORD/OJDB

**510(k) Holder:** Arthrex, Inc.

**Device Name:** Arthrex Fracture System

**Contact:** Courtney Smith  
Manager, Regulatory Affairs  
1370 Creekside Boulevard  
Naples, FL 34108-1945

**Phone:** 239-643-5553 ext. 1720

**Fax:** 239-598-5508

**Email:** [csmith@arthrex.com](mailto:csmith@arthrex.com)

**I. Purpose and Submission Summary**

The 510(k) holder would like to introduce the Arthrex Fracture System into interstate commerce. The system is a family of stainless steel plates, screws and buttons. The **Arthrex Fracture System** is intended to be used for internal bone fixation for bone fractures, fusions, and osteotomies and non-unions in the ankle, foot, hand, wrist, clavicle, scapula, olecranon, humerus, radius, ulna, tibia, calcaneous, femur and fibula. The Arthrex Fracture Plates are to be used with the 2.7mm – 4.0mm Arthrex Low Profile Screws. The plates may be contoured or straight and may be available in left and right configurations. The sponsor removed the Buttress Plate from this submission; it is not considered a component in this submission.

The screw family ranges from 2.7mm to 4.0mm in diameter and from 8mm to 80mm in length. The screws are solid and fully threaded and may be locking or non-locking.

The **Clavicle Plate Button** is intended for use with the clavicle plates for clavicle indications such as the treatment of syndesmotic trauma, such as coracoclavicular ligament disruption, and this button may not be used alone. The button is stainless steel and designed to fit securely in the holes of the fracture plates. The button is intended to be used with FiberWire or FiberTape suture, which is clearly specified in the labeling.

In Supplement 1 the sponsor provides a surgical technique guide outlining coracoclavicular ligament disruption repair. The sponsor has provided fatigue testing of the construct in comparison to the TightRope device, screw pull out testing, plate bending testing and button pull-out testing. The subject device results are comparable to the performance of the predicate plates, screws or TightRope for coracoclavicular ligament disruption. Therefore, the subject device is similar in design, material, intended use and performance and I recommend the system be found **Substantially Equivalent** to the Arthrex TightRope, and existing plates and screws.

**II. Administrative Requirements**

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

K112437.S1

Page 1 of 21

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

	Yes	No	N/A
Class III Summary			X
Standards Data Report for 510(k)s (Form 3654)	X		
Clinical Trials Form (Form 3674)			X

**Reviewer Comments:** The 510(k) Summary includes contact information, device information, classification, predicate devices, device description, indications for use, a substantial equivalence summary and a testing summary (Amendment 1).

In Supplement 1, the sponsor provided the Standards Data Report Form for the following Standards:

- AAMI/ANSI ST79: 2006 and A1:2008, A2:2009 Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care
- ISO 14971:2007, Medical Devices – Application of risk management to medical devices

In Supplement 1 the sponsor indicated they do not need to submit a Clinical Trials Form if there is not clinical data in the submission, the sponsor is correct, this is adequate.

**III. Device Description**

	Yes	No	N/A
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)?	X		
Does the device design use software?		X	
Is the device sterile?		X	
Is the device reusable (not reprocessed single use)? Are "cleaning" instructions included for the end user?		X	

The *Arthrex Fracture System* is a family of stainless steel plates, screws, and buttons. The plates may be contoured or straight and may be available in left and right configurations. The screws, which are used with the Arthrex Plates, include the solid, stainless steel locking and non-locking Low Profile Screws (K103705) with additional lengths. The additional screw lengths do not change the existing size range of the Low Profile Screws. The screw family ranges from 2.0 – 4.0mm in diameter and from 8 to 80mm in length.

Plates

Table 1: Proposed Plates – The sponsor removed the Buttress Plate in Supplement 1.

Comparison Between Proposed and Predicate Plates						
510(k) Clearance	Product Numbers	Holes	Width (mm)	Length (mm)	Thickness (mm)	Material
	Central Third Clavicle Plates (AR-2650CL – AR-2655CL) (AR-2650CR – AR-2655CR)	7 – 10	9.6	76 – 120	2.3	Stainless Steel
	Distal Clavicle Plates (AR-2656DL – AR-2657DL) AR-2656DR – AR-2657DR)	10 – 13	11.2	70 – 99	2.5	Stainless Steel
	Ankle Fracture Plates (AR-8943C-04 – AR-8943C-12)	4 – 12	9.6	55-157	3.1	Stainless Steel
K011335	Synthes One-Third Tubular Plates	2 - 12	9.4	81 - 117	1.0	Stainless Steel
K102998	Acumed Congruent Bone Plates	6 – 16	11	64 - 121	3.5	Titanium

*Reviewer Comments:*

(b)(4)

(b)(4)

Screws

The Low Profile Screws are the trade name for the stainless steel and titanium screws, which are used for all of the sponsor's plates. The existing screws range in diameter from 2.0-6.7mm in diameter and 8-80mm in length. Table 2 outlines the screws to be used with the Arthrex Fracture Plates. The screws range in diameter from 2.7-4.0mm; the 2.7mm screws are 8-30mm in length, the 3.0mm screws are 10-50mm in length, the 3.5mm screws are 8-80mm in length, and the 4.0mm screws are 8-80mm in length. The screw drawings included in the submission are for the line extensions added in the submission.

Table 2: Low Profile Screws to be used with the Arthrex Fracture Plates

Low Profile Screws to be used with the Arthrex Fracture Plates					
Clearance	Product Numbers	Product Description	Diameter	Length	Material
This submission	AR-8827L-08*	Screw, Solid, Locking	2.7	8	SS
K103705	AR-8827L-10 – AR-8827L-30	Screw, Solid, Locking	2.7	10 – 30	SS
K103705	AR-8830-10 – AR-8830-30	Screw, Solid, FT	3.0	10 – 30	SS
This submission	AR-8835-08	Screw, Solid, FT	3.5	8	SS
K103705	AR-8835-10 – AR-8835-60	Screw, Solid, FT	3.5	10 – 60	SS
This submission	AR-8835-65 – AR-8835-80	Screw, Solid, FT	3.5	65 – 80	SS
This submission	AR-8835L-08	Screw, Solid, Locking	3.5	8	SS
K103705	AR-8835L-10 – AR-8835L-60	Screw, Solid, Locking	3.5	10 – 60	SS
This submission	AR-8835L-65 – AR-8835L-80	Screw, Solid, Locking	3.5	65 – 80	SS
K103705	AR-8840-10 – AR-8840-60	Screw, Solid, FT	4.0	16 – 60	SS

**Reviewer Comments:** The sponsor provided a table clearly outlining the screws intended to be used with the Fracture Plate System. The sponsor identifies the 2.7x8mm screw as a new small screw and indicates the Acumed 2.7x8mm screw (K102998) is a legally marketed screw of the same size. Pull out of the screw is addressed in the performance testing section. All of the proposed screws are stainless steel to correspond to the stainless steel plates.

Distal Clavicle Plate Button

The button is stainless steel and designed to fit securely in the holes of the fracture plates. The button is intended to be used with FiberTape or #5 FiberWire, which is provided separately.

Table 3: Buttons

Comparison Between Proposed and Predicate Plates						
510(k) Clearance	Product Description	Holes	Length (mm)	Width (mm)	Material	Suture
	Distal Clavicle Plate Button (AR-2658)	2	8.5	5.8	Stainless Steel	FiberTape (K041553) (provided separately)
K052776	TightRope Acromioclavicular (AC) Device	2	10	3.5	Titanium / Stainless Steel	#5 FiberWire
		4	6.5	6.5		
K043248	TightRope Syndesmosis Device	2	10	3.5	Titanium / Stainless Steel	#5 FiberWire
		4	6.5	6.5		

**Reviewer Comment:** In Supplement 1 the sponsor clarifies the button must be used with the clavicle plate. The sponsor also specifies the button must be used with FiberTape or #5 FiberWire. This is included in the Indications for Use statement.

*Instrumentation*

The following stainless steel instruments are specific to the components listed in the tables above.

- Positioning handle, distal clavicle plate
- Drill guide, 2.0mm distal clavicle plate, L and R

**Reviewer Comments:** The instrumentation is generic instrumentation.

**IV. Indications for Use**

The **Arthrex Fracture System** is intended to be used for internal bone fixation for bone fractures, fusions, and osteotomies and non-unions in the ankle, foot, hand, wrist, clavicle, scapula, olecranon, humerus, radius, ulna, tibia, calcaneus, femur and fibula. The Arthrex Fracture Plates are to be used with the 2.7mm – 4.0mm Arthrex Low Profile Screws.

The **Clavicle Plate Button** is intended for use with the clavicle plates for clavicle indications such as the treatment of syndesmotic trauma, such as coracoclavicular ligament disruption, and this button may not be used alone. The button is intended to be used with #5 FiberWire or FiberTape.

**Reviewer Comment:** Please see the complete indications for use of the predicate devices in the predicate device comparison Table 4. The proposed bone plate and screw indications for use are adequate.

In Supplement 1 the sponsor modified their indications to limit their indications to the clavicle, such as the indications of the TightRope AC device or the Synthes Clavicle Hook Plate (K061753) intended for fixation of lateral clavicle fractures and dislocations of the acromioclavicular joint. In addition, the TightRope AC device is indicated as an adjunct in external and intramedullary fixation systems involving plates and rods, so there is a predicate AC device used as an adjunct to fixation systems utilizing a plate.

The indications for use included in Supplement 1 included repair of the acromioclavicular ligament, which is a different surgical procedure. (b)(4)

(b)(4)

(b)(4)

adequate.

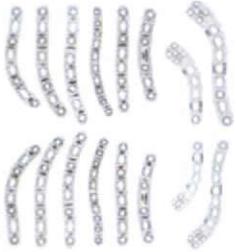
The indications for use are

**V. Predicate Device Comparison**

The sponsor provided a predicate device comparison in Table 4.

Table 4: Predicate Device Comparison

Manufacturer	Arthrex	Synthes	Acumed	Arthrex	Arthrex
Device Name	Fracture System	One-Third Tubular Plate	Congruent Bone Plate System	Low Profile Screws	TightRope Syndesmotic and Acromioclavicular (AC) Devices
510(k) Number	Subject	K011335	K102998	K103705/K111253	K043248/K052776
Product Code	HTN, HRS, HWC	HRS	HRS	HRS, HWC	HTN
Classification	888.3030, 888.3040	888.3030	888.3030	888.3040	888.3030
Intended Use	Intended to be used for internal bone fixation for bone fractures, fusions, and osteotomies and non-unions. The <b>Arthrex Fracture System</b> is intended to be used for internal bone fixation for bone fractures, fusions, and osteotomies and non-unions in the ankle, foot, hand, wrist, clavicle, scapula, olecranon, humerus, radius, ulna, tibia, calcaneous, femur and fibula. The <b>Arthrex Fracture Plates</b> are to be used with the 2.7mm – 4.0mm <b>Arthrex Low Profile Screws</b> .	Intended for fixation of fractures, osteotomies, and nonunions.  Intended for fixation of fractures, osteotomies, and non-unions of the clavicle, scapula, olecranon, humerus, radius, ulna, pelvis, distal tibia and fibula, particularly in osteopenic bone.	Provides fixation for fractures, fusions, or osteotomies.  Fixation for fractures, fusions, or osteotomies for the clavicle, humerus, radius, ulna, metacarpal, metatarsal, malleolus, tibia, and fibula.	Intended to be used for internal bone fixation for bone fractures, fusions or osteotomies.	Intended as an adjunct in fracture repair and as an adjunct in fixation systems.  The <b>Arthrex TightRope Syndesmosis Device</b> is intended as an adjunct in fracture repair involving metaphyseal and periarticular small bone fragments where screws are not indicated, and as an adjunct in external and intramedullary fixation systems involving plates and rods, with fracture braces and casting.  Specifically, the <b>Arthrex TightRope Syndesmosis Device</b> is intended to provide fixation during the healing process following a syndesmotic trauma, such as fixation of syndesmosis
Indications for Use					

	<p>for use with the clavicle plates for clavicle indications such as the treatment of syndesmotic trauma, such as coraciacular ligament disruption, and this button may not be used alone. The button is intended to be used with #5 FiberWire or FiberTape.</p>		<p>Various sized contoured bone plates with both locking and compression holes.</p>	<p>Various sized contoured bone plates and screws.</p>	<p>(syndesmosis disruptions) in connection with Weber B and C ankle fractures.</p> <p>Specifically, the Arthrex TightRope AC Device is intended to provide fixation during the healing process following a syndesmotic trauma, such as fixation of acromioclavicular separations due to coracoclavicular ligament disruptions.</p>
<p><b>Description</b></p>	<p>Various sized contoured plates, screws and buttons.</p>	<p>Various sized contoured bone plates with both locking and compression holes.</p>	<p>Various sized contoured bone plates and screws.</p>	<p>Fully or partially threaded screws, and solid or cannulated.</p>	<p>Two metal buttons (stainless steel or titanium) and a #5 suture.</p>
<p><b>Plates</b></p>				<p>Not applicable</p>	<p>Not applicable</p>
<p><b>Plate Material</b></p>	<p>Stainless Steel</p>	<p>Stainless Steel</p>	<p>Titanium</p>	<p>Not applicable</p>	<p>Not applicable</p>
<p><b>Plate Range</b></p>	<p>22 – 121mm</p>	<p>81 – 117mm</p>	<p>Clavicle Plates: 64-121mm</p>	<p>Not applicable</p>	<p>Not applicable</p>

Screws					Not applicable
Screw Material	Stainless Steel	Stainless Steel	Titanium	Stainless Steel Titanium	Not applicable
Screw Diameters	2.7 – 4.0mm	2.7 – 3.5mm	Clavicle Screws: 2.7-4.0mm	2.0 – 4.0mm	Not applicable
Screw Lengths	8, 65 – 80mm		8 – 80mm	8 – 60mm	Not applicable
Button Description	Designed to fit securely in the holes of the fracture plates. Length: 8.5mm, Width: 5.8mm 2 holes	Not applicable	Not applicable	Not applicable	3.5mm button is oblong (3.5x10) with 2 holes. 6.5mm button is circular with 4 holes. Pre-threaded with #5 FiberWire suture.
Buttons		Not applicable	Not applicable	Not applicable	
Button Material	Stainless Steel	Not applicable	Not applicable	Not applicable	Stainless Steel Titanium

Reviewer Comments: Please see the Indications for Use comparison in the Indications for Use section. The specifications of the proposed plates and screws

are comparable. The smallest screw the sponsor adds is a 2.7x8mm screw with is comparable to the Acumed Screw (K102998). The sponsor provides screw pull out testing (b)(4). The dimensions of the button are comparable to the dimensions of the TightRope and are not of concern as the button snaps into the plate and the sponsor clearly specifies the button is to be used with the plate.

The Acu-Sinch Repair System (K112111) is another system of clavicle plates and sutures that was recently cleared.

## VI. Labeling

### Package Insert

In Supplement 1 the sponsor separated the package insert into two package inserts: 1) Arthrex Fracture Plates and 2) Arthrex Low Profile Screws. The Fracture Plate package insert includes the distal clavicle plate button. It includes the indications, contraindications, adverse effects, warnings including not evaluated in the MR environment, precautions, and sterilization. The sterilization parameters meet ST79 and differentiate between sterilization parameters for inside and outside of the US. The components are composed of stainless steel.

The screw package insert includes a device description with the screws ranging from 2.0–6.7mm in diameter and 8-120mm in length. The indications are broken down by size and solid or cannulated. The package insert also includes contraindications, adverse effects, warnings, precautions and sterilization parameters that meet ST79. The components are composed of stainless steel and titanium.

**Reviewer Comments:** *The indications for use are consistent with the Indications for Use page based on the revised versions submitted in Amendment 1. In Supplement 1 the sponsor verified the plates are composed of stainless steel and removed titanium from the package insert for the Fracture Plates. The package insert is very similar to the package insert for the Arthrex Low Profile Screws (K111253) and includes comparable indications, contraindications, warnings, precautions, adverse effects, sterilization information, etc.*

### Surgical Technique

The sponsor provided a surgical technique guide in Amendment 1 dated December 21, 2011.

#### *Arthrex Clavicle Plate and Screw System Technique Guide*

The sponsor includes specific indications for the Arthrex Fracture System and the Clavicle Plate Button. The indications state the button must be used with a plate. The surgical approach outlines lining up the plate and inserting locking screws.

The instructions include "Distal Clavicle Plate Button Fixation." The surgeon should determine which plate slot will be used for the Distal Clavicle Plate Button and the slot should be left vacant of any screws. The AC guide is then placed underneath the lateral side of the coracoid, seating it as close to the base of the coracoid as possible. Use the drill guide to drill through all four cortices exiting under the coracoid. Pass a Nitinol wire through the cannulation and retrieve the wire from under the coracoid. Attach a Dog Bone Button to a strand of FiberTape or FiberWire making sure that the concavity of the button will seat against the base of the coracoid and shuttle the suture limbs retrograde through the coracoid and clavicle. Place the suture limbs so the Dog Bone Button seats at the base of the coracoid. Insert suture limbs through the Distal Clavicle Plate Button and reduce the button to the plate, so the button should seat flush with the plate. Tie a knot and cut the excess suture limbs. Confirm final reduction and placement. Removal instructions are included as well. Figure 1 illustrates the final implanted device with the sutures tied off.



Figure 1: Distal Plate Button Implanted

**Reviewer Comments:** The sponsor has provided text and photographs outlining how the distal plate button is implanted for coracoclavicular ligament disruption. The steps are clearly outlined with photographs. The minimum required information is included in the draft surgical technique guide.

Package Labels

The package labels include the device name, manufacturer information, lot number, non-sterile, single use only and see Instructions for Use. A separate package label defines the symbols.

**Reviewer's Comments:** The package labels include the relevant information.

**VII. Sterilization**

The devices included in the Fracture System are provided non-sterile and are single use only. The devices should be cleaned and sterilized prior to use. The sponsor provides the following sterilization

(b)(4)

**Reviewer's Comment:** The sponsor has clearly outlined the sterilization parameters. The sterilization information is adequate.

**VIII. Biocompatibility**

The Arthrex Fracture System components in this submission are composed of stainless steel.

**Reviewer Comment:** Stainless steel is commonly used in orthopedic implants. The identified predicate devices are composed of the same materials.

**IX. Software – Not Applicable**

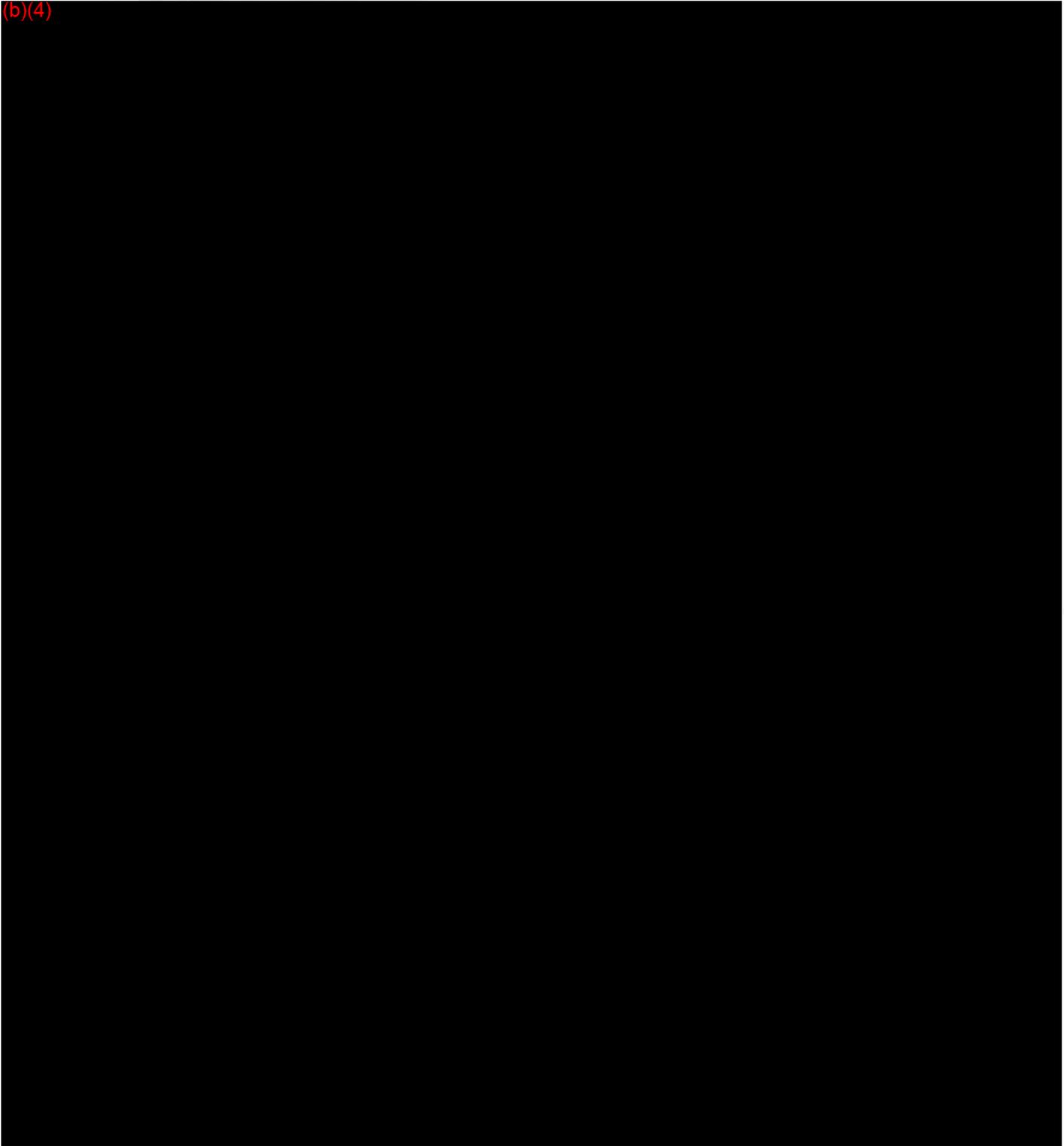
There is no software component with the subject device.

**X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety – Not Applicable**

The sponsor has addressed MR compatibility with a warning in the package insert.

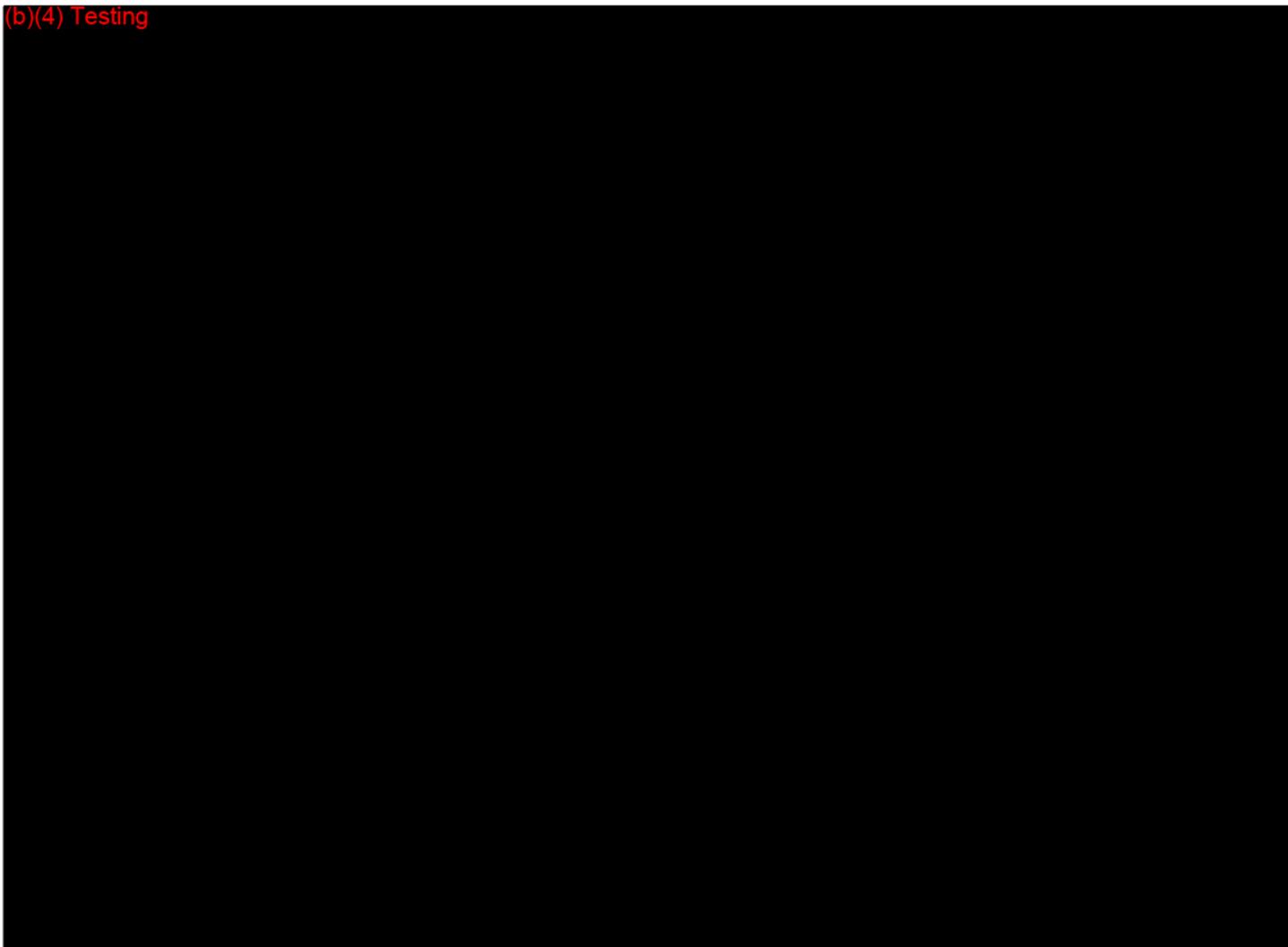
**XI. Performance Testing – Bench**

(b)(4)





(b)(4) Testing



**XII. Performance Testing – Animal – Not Applicable**

Animal Testing is not necessary to demonstrate the substantial equivalence of the Arthrex Fracture System.

**XIII. Performance Testing – Clinical – Not Applicable**

Clinical data is not necessary to demonstrate the substantial equivalence of the Arthrex Fracture System.

**XIV. Substantial Equivalence Discussion**

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

Note: See

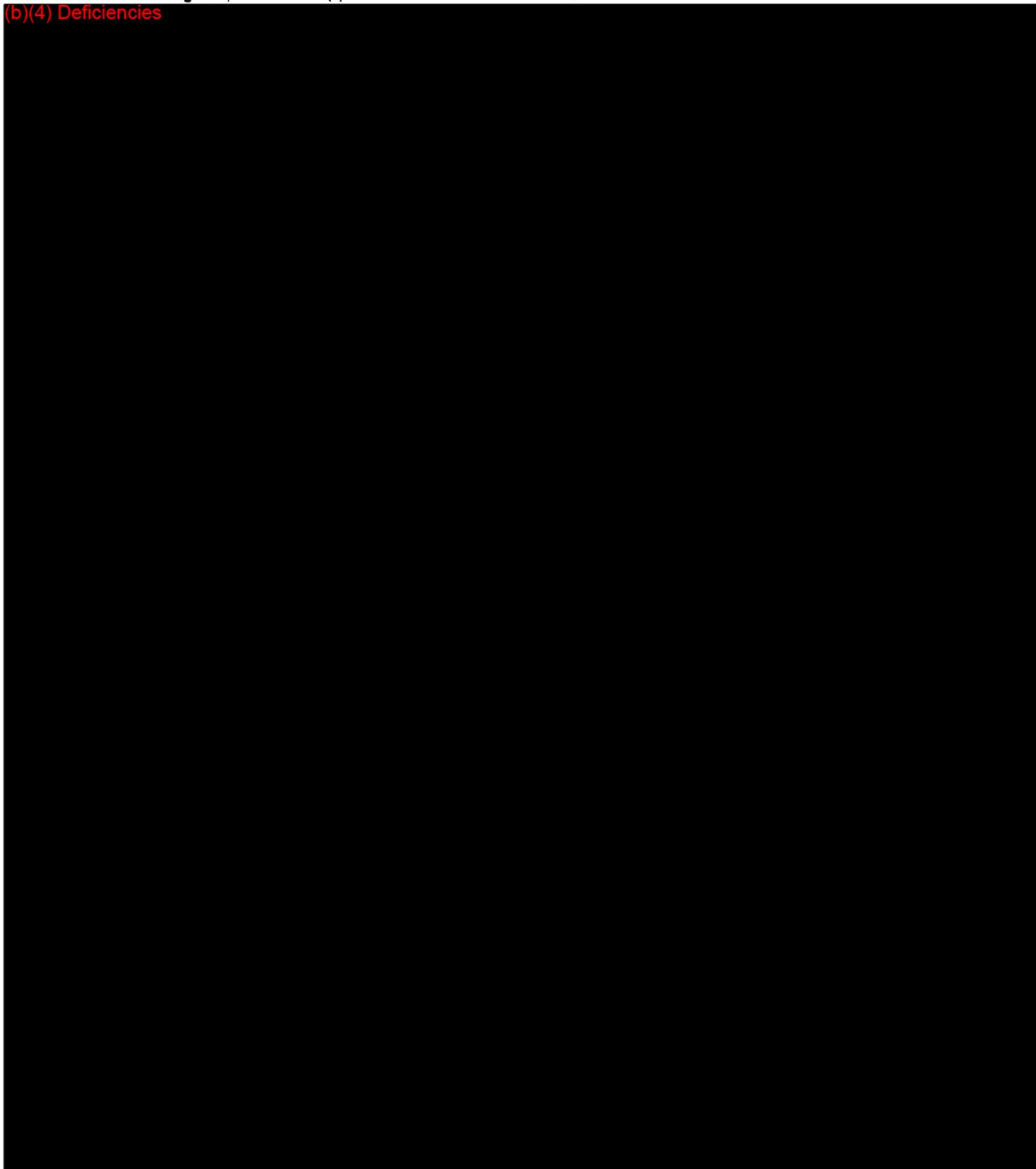
[http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPreMarketNotification510kProgram/0\\_4148/FLOWCART%20DECISION%20TREE%20.DOC](http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPreMarketNotification510kProgram/0_4148/FLOWCART%20DECISION%20TREE%20.DOC) for Flowchart to assist in decision-making process. Please complete the above table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

1. **Explain how the new indication differs from the predicate device's indication:**  
*The sponsor is combining the indications of a fracture fixation system and AC repair.*
2. **Explain why there is or is not a new effect or safety or effectiveness issue:**  
*There are legally marketed predicate devices intended for both fracture fixation and AC repair.*
3. **Describe the new technological characteristics:**  
*The proposed device is a button that snaps into a plate where the predicate TightRope for AC repair is not designed to fit into a plate.*
4. **Explain how new characteristics could or could not affect safety or effectiveness:**  
*The button and plate combination will affect AC joint repair.*
5. Explain how descriptive characteristics are not precise enough:
6. **Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:**  
*Clavicle fracture healing and AC joint repair are not new questions; this is only a new method repairing them together.*
7. Explain why existing scientific methods can not be used:
8. Explain what performance data is needed.
9. **Explain how the performance data demonstrates that the device is or is not substantially equivalent:**  
*The sponsor provided bending strength testing of the plates, pull-out force of the screws and button and construct fatigue testing to demonstrate substantial equivalence to the predicate TightRope system.*

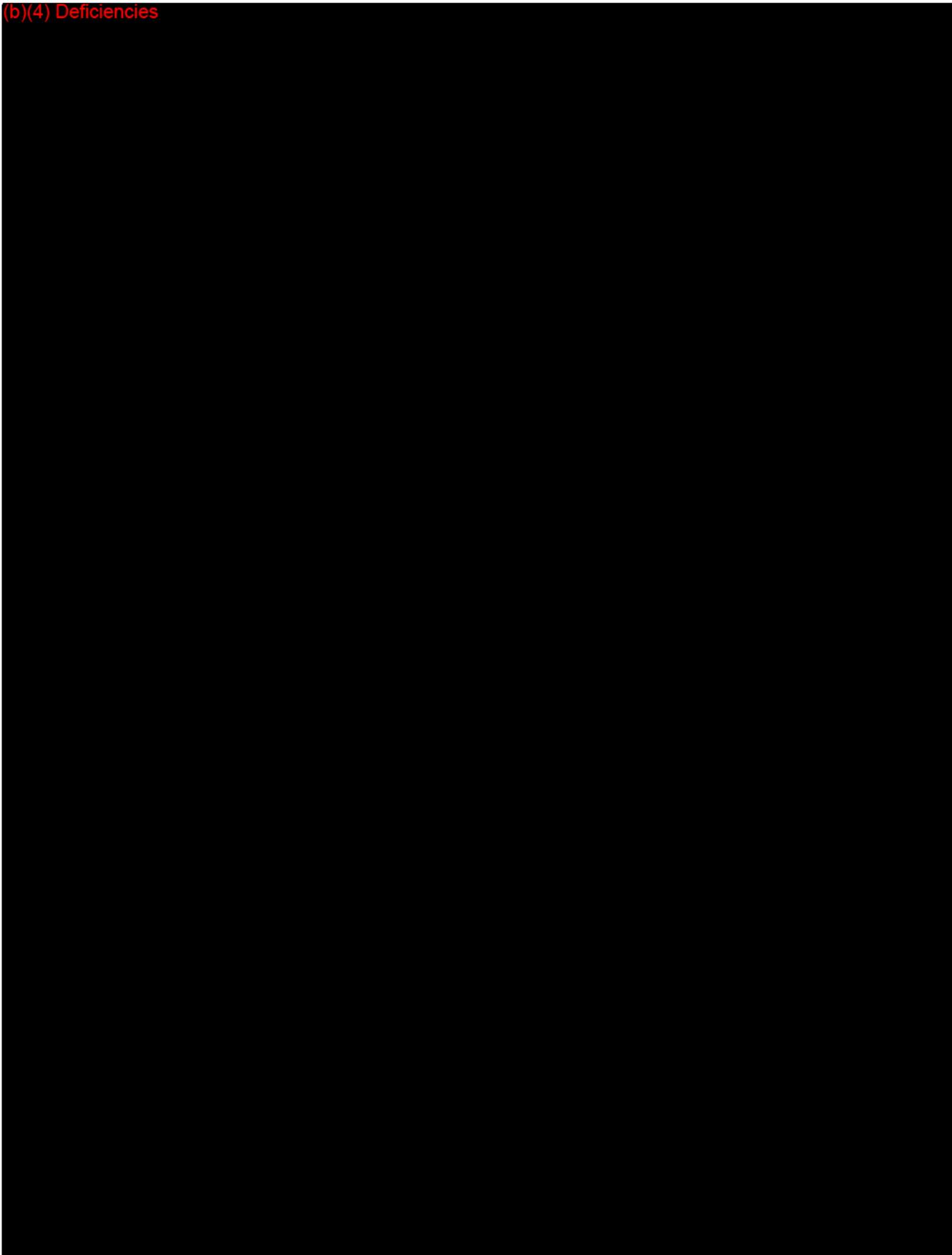
**XV. Deficiencies and Contact History**

The file was placed on hold with the following deficiencies on October 28, 2011. The sponsor provided the following response in Supplement 1 on December 14, 2011.

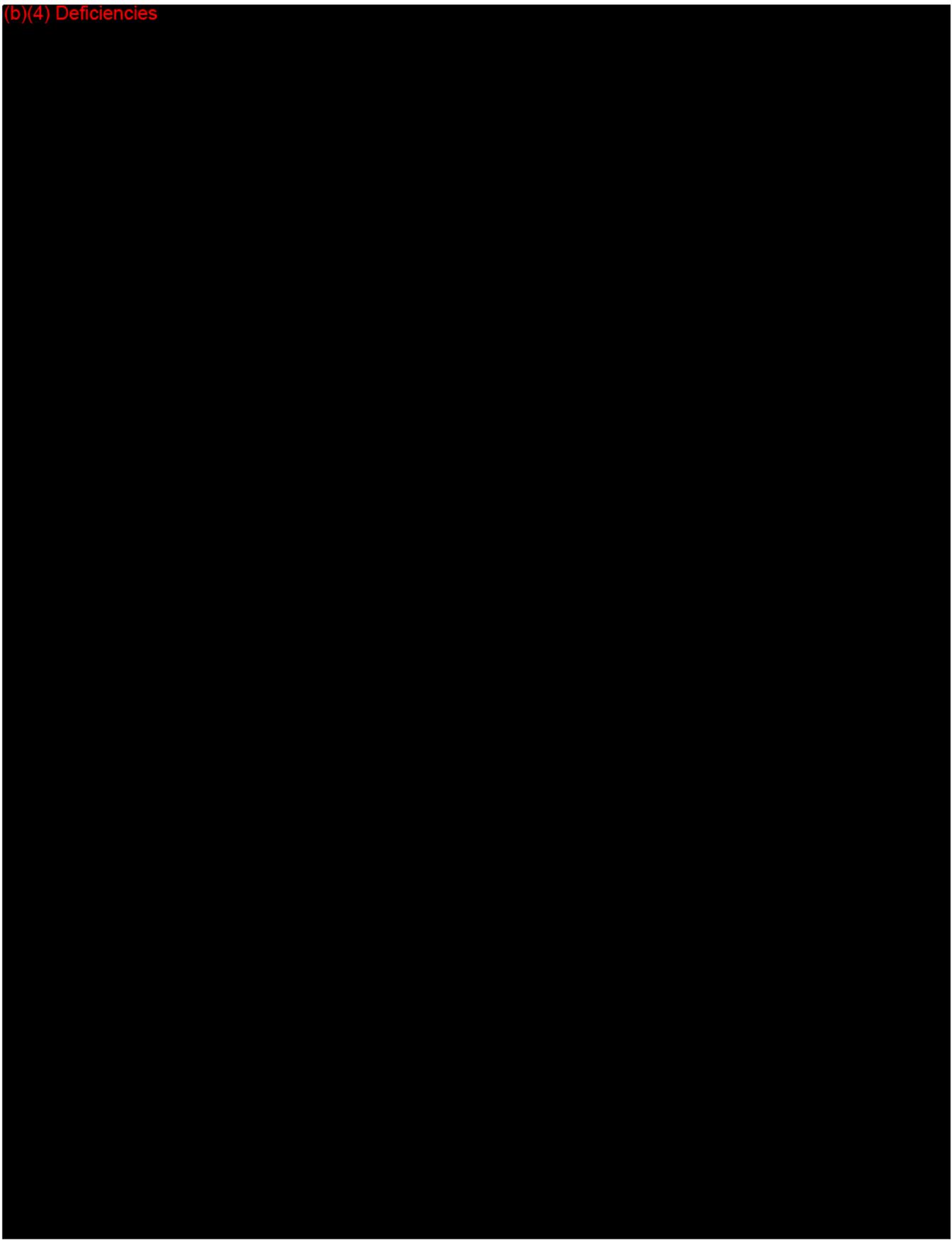
(b)(4) Deficiencies



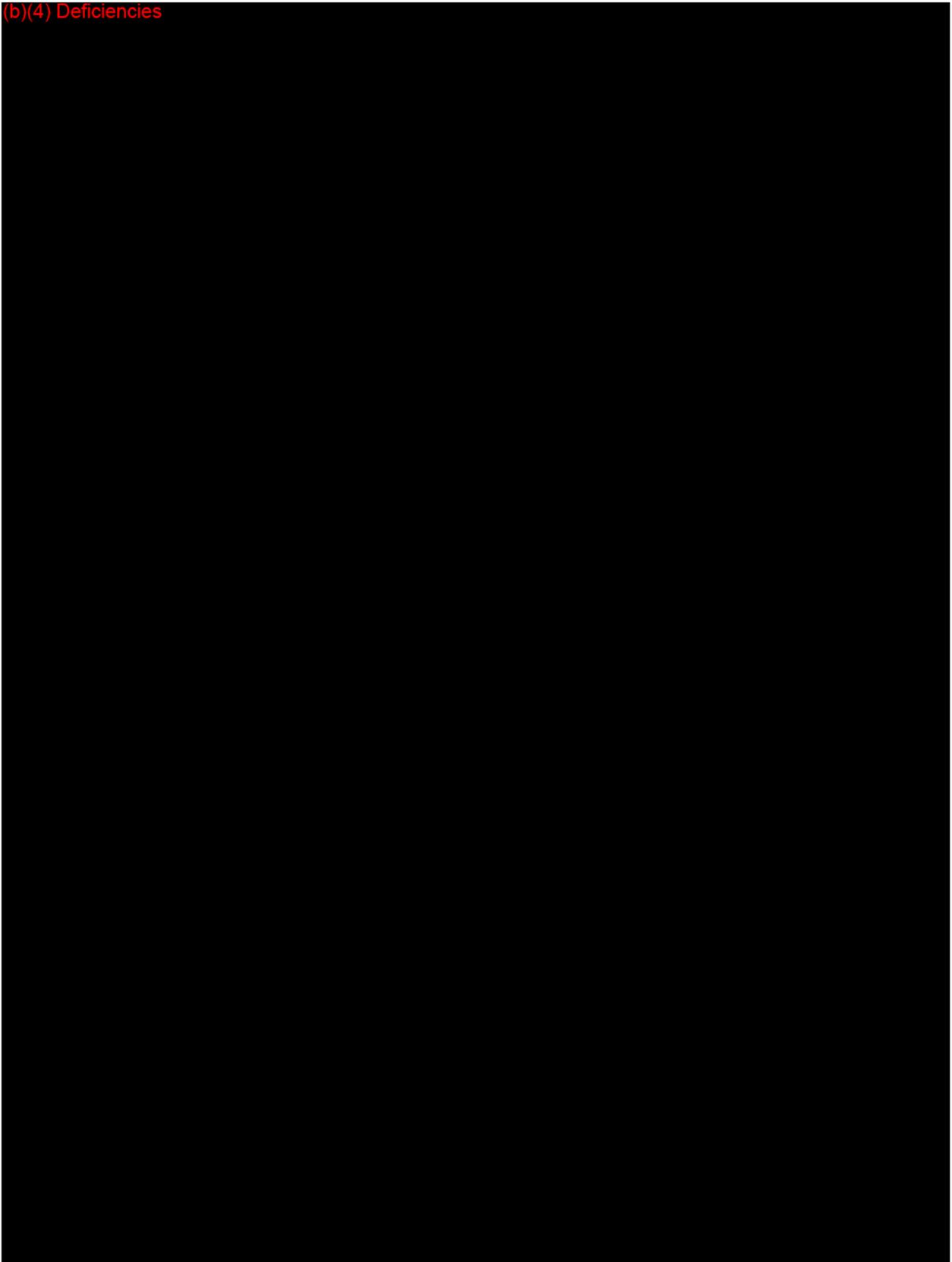
(b)(4) Deficiencies



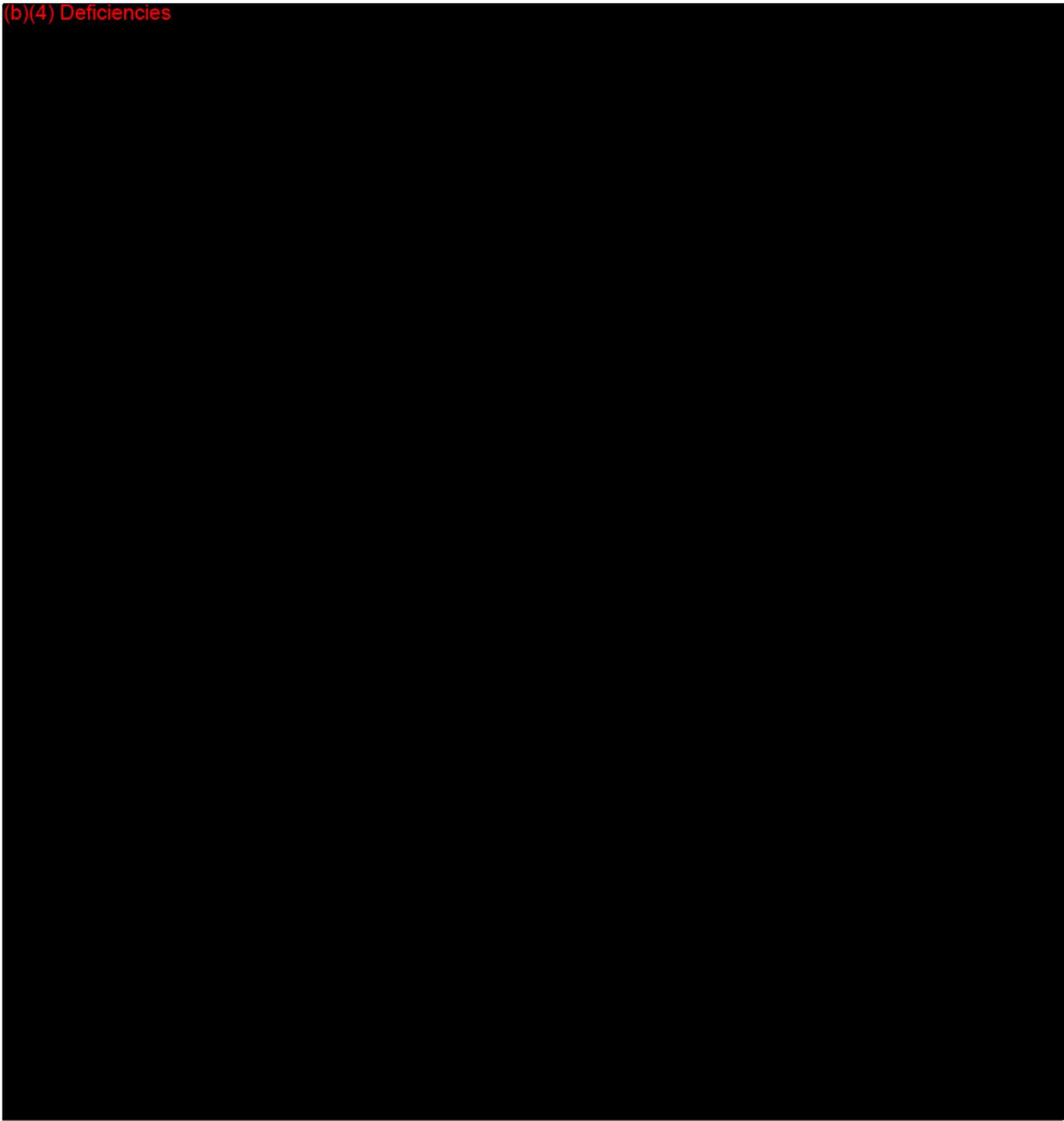
(b)(4) Deficiencies



(b)(4) Deficiencies



(b)(4) Deficiencies



**Reviewer Comments:** *The sponsor's response is adequate, there is no clinical data in this submission and they will not be asked to submit a Clinical Trials Form.*

**XVI. Recommendation**

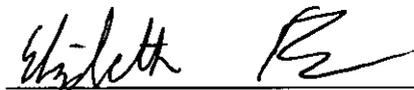
The subject device is similar in design, material, intended use and performance to the Arthrex TightRope, and existing plates and screws. I recommend the system be found **Substantially Equivalent**.

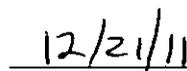
**Regulation Number:** 21 CFR 888.3030

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

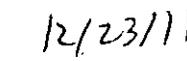
**Regulatory Class:** Class II

**Product Code:** HTN, HWC, HRS

  
\_\_\_\_\_  
Reviewer

  
\_\_\_\_\_  
Date

  
\_\_\_\_\_  
Branch Chief

  
\_\_\_\_\_  
Date

**K112437**  
**CTS Interactive Review Summary**

<b>Date:</b> 12/21/2011	<b>Topic:</b> Indications
<b>Type:</b> Telephone Call	<b>User:</b> Beth Frank
<b>Summary:</b>  Sponsor removed acromioclavicular ligament disruptions from the indications for use statement. Sponsor provided corresponding Indications for Use, 510(k) Summary, Package Insert and Surgical Technique Guide for review.	

<b>Date:</b> 12/21/2011	<b>Topic:</b> Bench Testing - Suture
<b>Type:</b> Telephone Call	<b>User:</b> Beth Frank
<b>Summary:</b>  (b)(4)	

**Frank, Elizabeth L**

---

**From:** Courtney Smith [Courtney.Smith@Arthrex.com]  
**Sent:** Wednesday, December 21, 2011 1:52 PM  
**To:** Frank, Elizabeth L  
**Subject:** revised Indications  
**Attachments:** DFU 01xxx - plates 12\_21\_11.pdf; Indications for Use Summary -12\_21\_11.pdf; Surgical  
Technique 12\_21\_11.pdf

Dear Elizabeth,

As discussed, the indications for the Clavicle Plate Button have been revised as indicated below, which is identical to that of the cleared AC TightRope (K052776)

The *Clavicle Plate Button* is intended for use with the clavicle plates for clavicle indications such as for the treatment of syndesmotic trauma, such as fixation of acromioclavicular separations due to coracoclavicular ligament disruption, and this button may not be used alone. The button is intended to be used with #5 FiberWire or FiberTape.

Attached are the revised 510(k) summary, Indications for Use page, DFU, and Surgical Technique.

Please don't hesitate to contact me if you have any further questions.

Best Regards,

*Courtney*

**Courtney Smith**  
Manager, Regulatory Affairs

This e-mail and any files transmitted with it are the property of Arthrex, Inc. and/or its affiliates, are confidential, and are intended solely for the use of the individual or entity to whom this e-mail is addressed. If you are not one of the named recipient(s) or otherwise have reason to believe that you have received this message in error, please notify the sender at 239-643-5553 and delete this message immediately from your computer. Any other use, retention, dissemination forwarding, printing or copying of this e-mail is strictly prohibited. Please note that any views or opinions presented in this email are solely those of the author and do not necessarily represent those of the company. Finally, while Arthrex uses virus protection, the recipient should check this email and any attachments for the presence of viruses. The company accepts no liability for any damage caused by any virus transmitted by this email.

# Arthrex Clavicle Plate and Screw System



## Technique Guide

## Indications

The **Arthrex Fracture System** is intended to be used for internal bone fixation for bone fractures, fusions, osteotomies and non-unions in the ankle, foot, hand, wrist, clavicle, scapula, olecranon, humerus, radius, ulna, tibia, calcaneous, femur and fibula. The Arthrex Fracture Plates are to be used with the 2.7mm-4.0mm Arthrex Low Profile Screws.

The **Clavicle Plate Button** is intended for use with the clavicle plates for clavicle indications such as for the treatment of syndesmotic trauma, such as fixation of acromioclavicular separations due to coracoclavicular ligament disruption, and this button may not be used alone. The button is intended to be used with #5 FiberWire or FiberTape.

## Patient Positioning

The patient is placed on the OR table. The beach chair position is recommended. The affected extremity is prepped and draped free in the normal sterile fashion. A roll or pad placed between the shoulder blades allows retraction to aid in reduction. An arm holder can also be very helpful to maintain the position of the injured extremity.

## Surgical Approach

Make a 3-5 cm horizontal incision over the superior clavicle. Subcutaneous dissection allows for identification of supraclavicular nerve branches.

## Fracture Reduction

Reduce the fracture and use fluoroscopy to confirm reduction. Using reduction forceps can be very helpful in maintaining reduction.

## Plate Selection

Select the appropriate plate to match the patient anatomy. The plates are pre-contoured to reduce the need to bend. If contouring the plate is necessary, use the appropriate plate benders.

## Plate Placement

Place the plate onto the reduced clavicle and temporarily attach it to the bone using K-wires, BB-Taks or plate holding forceps.



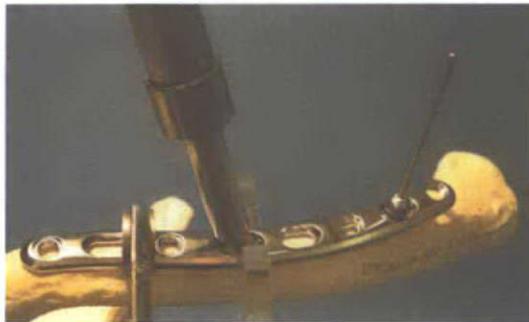
## Screw Insertion

### Nonlocking Screw Insertion

Place the 3.5/ 2.5 mm Drill Guide into the appropriate plate slot and prepare a hole using the 2.5 mm Drill Bit. If drilling bicortically, place a retractor under the clavicle to protect the neurovascular structures.



Measure for screw length using the Screw Depth Gauge.

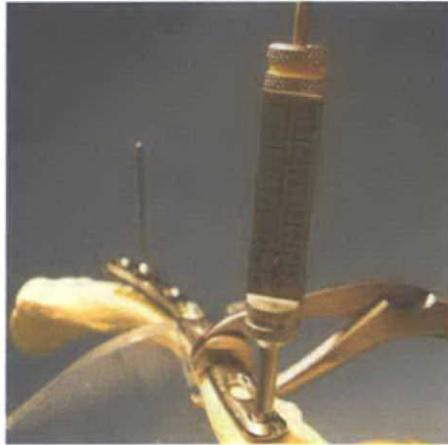


Select appropriate 3.5 mm or 4.0 mm screw and insert using the hexalobe screwdriver.



## Locking Screw Insertion

Place the 3.5 mm Threaded Drill Guide into the appropriate locking hole and prepare a hole using the 2.5 mm Calibrated Drill Bit. Read the corresponding screw length from the line on the drill bit.



Alternately the Screw Depth Gauge may be used to determine screw length.

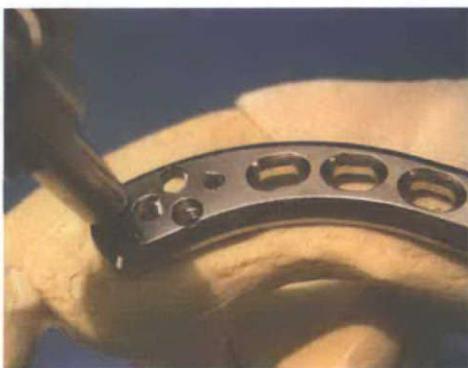


Select appropriate 3.5 mm locking screw and insert using the hexalobe screwdriver.



## Locking Screw Insertion for 2.7mm Screws

Place a K-wire in the distal end of the plate. Slide the appropriate Drill Guide over the K-wire and thread it into the locking hole. Use the 2.0 mm Calibrated Drill and drill to the desired depth. Use the Depth Gauge to determine the screw length. Select the appropriate 2.7 mm screw and insert using the hexalobe screwdriver.



### Alternate Method:

Thread the 2.7 mm Threaded Drill Guide into a 2.7 mm locking hole until fully seated. Use the 2.0 mm Calibrated Drill and drill to the desired depth. Read the corresponding screw length from the line on the drill bit. Select the appropriate 2.7 mm screw and insert using the hexalobe screwdriver.



## Distal Clavicle Plate Button Fixation

Insert screws as previously described. Determine which plate slot will be used for the Distal Clavicle Plate Button. This slot should be left vacant of any screws.

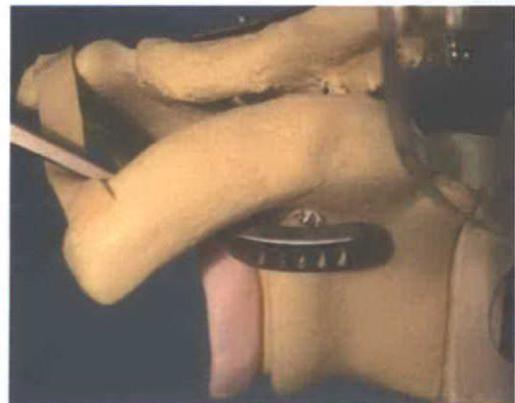
Use an elevator or a radio-frequency device to define the lateral and medial aspect of the coracoid process. Place the appropriate AC Guide underneath the lateral side of the coracoid, seating it as close to the base of the coracoid as possible.



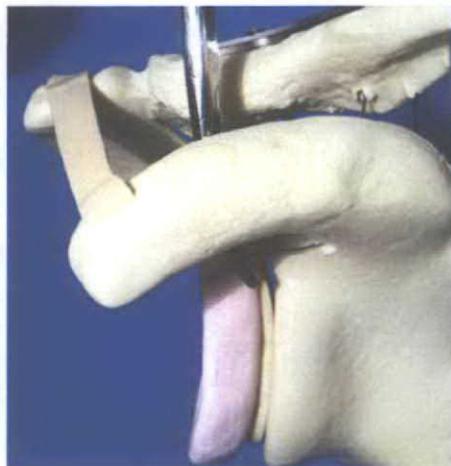
### Alternate Method

Place blunt retractors medially and laterally under the coracoid process to protect the neurovascular structures. A hemostat or other blunt instrument can be placed on the lateral side underneath the coracoid process to feel the transition to the neck of the glenoid and the anterior scapula. The 3 mm Cannulated Reamer should exit underneath the coracoid at the identified transition zone.

Place the 3 mm Drill Guide in the identified plate slot and using the 3 mm Cannulated Reamer, drill through all four cortices, exiting underneath the coracoid. Fluoroscopy may be used to verify tunnel placement.



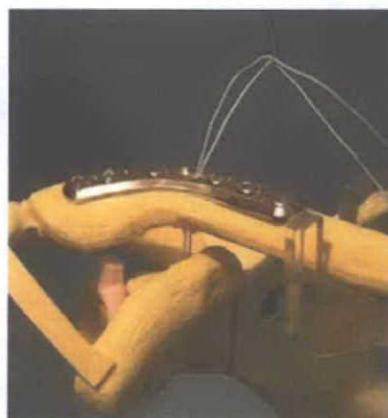
Remove the guide arm or retractors from under the coracoid. Remove the trocar from the cannulated reamer. Pass a Nitinol wire through the cannulation and using a hemostat or other grasping instrument, retrieve the wire from under the coracoid.



Attach a Dog Bone Button to a strand of FiberTape or FiberWire, making sure that the concavity of the button will seat against the base of the coracoid.



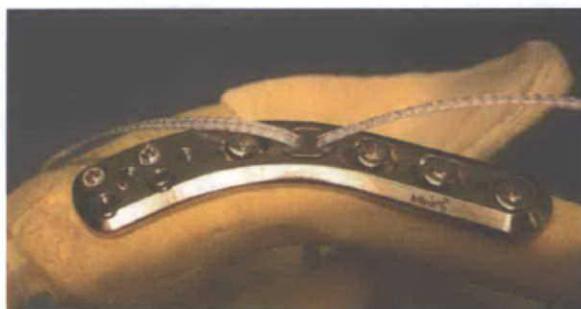
Shuttle the suture limbs retrograde through the coracoid and clavicle.



Pull suture limbs so the Dog Bone Button seats at the base of the coracoid. Confirm placement under the coracoid using fluoroscopy.



Insert both suture limbs through the Distal Clavicle Plate Button and reduce the button to the plate. The button should seat flush with the plate.



Tie a knot over the button with the suture limbs. Cut the excess limbs, making sure to leave a sufficient tail.



## Confirm Reduction and Fixation

Confirm the final reduction and plate and screw fixation both visually and with fluoroscopy.

## **Plate and Screw Removal**

If the plate and screws need to be removed, make an incision over the clavicle. Use the appropriate screw driver to remove each screw.

To remove the Distal Clavicle Plate Button, cut the sutures and remove the button from the plate slot. Reach under the coracoid laterally with a hemostat or other grasping instrument to remove the Dog Bone Button.

## 1 Indications for Use Form

### Indications for Use

510(k) Number (if known): \_\_\_\_\_

Device Name: *Arthrex Fracture System*

#### Indications For Use:

The *Arthrex Fracture System* is intended to be used for internal bone fixation for bone fractures, fusions, osteotomies and non-unions in the ankle, foot, hand, wrist, clavicle, scapula, olecranon, humerus, radius, ulna, tibia, calcaneous, femur and fibula. The Arthrex Fracture Plates are to be used with the 2.7mm-4.0mm Arthrex Low Profile Screws.

The *Clavicle Plate Button* is intended for use with the clavicle plates for clavicle indications such as for the treatment of syndesmotic trauma, such as fixation of acromioclavicular separations due to coracoclavicular ligament disruption, and this button may not be used alone. The button is intended to be used with #5 FiberWire or FiberTape.

Prescription Use  AND/OR Over-The-Counter Use \_\_\_\_\_  
(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

---

Concurrence of CDRH, Office of Device Evaluation (ODE)

PAGE 1 of 1

## 2 510(k) Summary of Safety and Effectiveness

<b>Date Summary Prepared</b>	November 29, 2011
<b>Manufacturer/Distributor/Sponsor</b>	Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA
<b>510(k) Contact</b>	Courtney Smith Manager, Regulatory Affairs Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA Telephone: 239/643.5553, ext. 1720 Fax: 239/598.5508 Email: <a href="mailto:csmith@arthrex.com">csmith@arthrex.com</a>
<b>Trade Name</b>	<b>Arthrex Fracture System</b>
<b>Common Name</b>	Plate, fixation, bone
<b>Product Code -Classification Name CFR</b>	HWC, HRS, HTN 21 CFR 888.3030: Single/multiple component metallic bone fixation appliances and accessories 21 CFR 888.3040: Smooth or threaded metallic bone fixation fastener.
<b>Predicate Device</b>	<i>K011335</i> : Synthes One-Third Tubular Plates <i>K102998</i> : Acumed Congruent Bone Plate System <i>K043248 / K052776</i> : Arthrex TightRope Syndesmosis and Acromioclavicular (AC) Devices <i>K103705 / K111253</i> : Arthrex Low Profile Screws
<b>Device Description and Intended Use</b>	<p>The <b>Arthrex Fracture System</b> is a family of stainless steel plates, screws, and buttons. The plates may be contoured or straight and may be available in left and right configurations. The plates are to be used with the 2.7mm-4.0mm Low Profile Screws. The screws are solid and fully threaded and may be locking or non-locking. The button is stainless steel and designed to fit securely in the holes of the fracture plates. The button is intended to be used with the previously cleared suture, which is provided separately.</p> <p>The <b>Arthrex Fracture System</b> is intended to be used for internal bone fixation for bone fractures, fusions, osteotomies and non-unions in the ankle, foot, hand, wrist, clavicle, scapula, olecranon, humerus, radius, ulna, tibia, calcaneous, femur and fibula. The Arthrex Fracture Plates are to be used with the 2.7mm-4.0mm Arthrex Low Profile Screws.</p> <p>The <b>Clavicle Plate Button</b> is intended for use with the clavicle</p>

	<p>plates for clavicle indications such as for the treatment of syndesmotic trauma, such as fixation of acromioclavicular separations due to coracoclavicular ligament disruption, and this button may not be used alone. The button is intended to be used with #5 FiberWire or FiberTape.</p>
<p><b>Substantial Equivalence Summary</b></p>	<p>The Arthrex Fracture System is substantially equivalent to the predicate Synthes One-Third Tubular Plates (K011335), Acumed Congruent Bone Plate System (K102998), Arthrex TightRope Syndesmosis and Acromioclavicular (AC) Devices (K043248 / K052776), and the cleared Arthrex Low Profile Screws (K103705, K111253) in which the basic features and intended uses are the same. Any differences between the <b>Fracture System</b> and the predicates are considered minor and do not raise questions concerning safety and effectiveness.</p> <p>The proposed devices are composed of Stainless Steel which is substantially equivalent to the predicate devices.</p> <p>The submitted mechanical testing data demonstrated that the bending and pull-out strength of the proposed devices are substantially equivalent to the bending and pull-out strength of the predicate devices.</p> <p>Based on the indication for use, technological characteristics, and the comparison to the predicate devices, Arthrex, Inc. has determined that the <b>Fracture System</b> is substantially equivalent to currently marketed predicate devices.</p>

## Arthrex Fracture Plates

DFU-0xxx

Draft 0

### A. DEVICE DESCRIPTION

Plates are available in different shapes, sizes and orientations (e.g. left and right types). The plates have specific sized holes for screws to provide fixation.

The Distal Clavicle Plate Button is designed to fit securely in the holes of the fracture plates. i

### B. INDICATIONS

The **Arthrex Fracture Plates** are intended to be used for internal bone fixation for bone fractures, fusions, osteotomies and non-unions in the ankle, foot, hand, wrist, clavicle, scapula, olecranon, humerus, radius, ulna, tibia, calcaneus, femur and fibula. The Arthrex Fracture Plates are to be used with the 2.7mm-4.0mm Arthrex Low Profile Screws.

The **Clavicle Plate Button** is intended for use with the clavicle plates for clavicle indications such as for the treatment of syndesmotic trauma, such as fixation of acromioclavicular separations due to coracoclavicular ligament disruption, and this button may not be used alone. The button is intended to be used with #5 FiberWire or FiberTape.

### C. CONTRAINDICATIONS

1. Insufficient quantity or quality of bone.
2. Blood supply limitations and previous infections, which may retard healing.
3. Foreign-body sensitivity. Where material sensitivity is suspected, appropriate tests should be made and sensitivity ruled out prior to implantation.
4. Any active infection or blood supply limitations.
5. Conditions that tend to limit the patient's ability or willingness to restrict activities or follow directions during the healing period.

6. The use of this device may not be suitable for patients with insufficient or immature bone. The physician should carefully assess bone quality before performing orthopedic surgery on patients who are skeletally immature. The use of this medical device and the placement of hardware or implants must not bridge, disturb or disrupt the growth plate.
7. Do not use for surgeries other than those indicated.

#### **D. ADVERSE EFFECTS**

1. Infections, both deep and superficial.
2. Foreign body reactions.

#### **E. WARNINGS**

1. An internal fixation device must never be reused.
2. All metallic implant devices used for this surgical procedure should have the same metallurgical composition.
3. Postoperatively and until healing is complete, fixation provided by this device should be considered as temporary and may not withstand weight bearing or other unsupported stress. The fixation provided by this device should be protected. The postoperative regimen prescribed by the physician should be strictly followed to avoid adverse stresses applied to the device.
4. Pre-operative and operating procedures, including knowledge of surgical techniques and proper selection and placement of the device, are important considerations in the successful utilization of this device. The appropriate Arthrex delivery system is required for proper implantation of the device.
5. Any decision to remove the device should take into consideration the potential risk to the patient of a second surgical procedure. Device removal should be followed by adequate postoperative management.
6. Detailed instructions on the use and limitations of this device should be given to the patient.
7. This is a single use device. Reuse of this device could result in failure of the device to perform as intended and could cause harm to the patient and/or user.
8. The device has not been evaluated for safety and compatibility in the magnetic resonance (MR) environment. The device has not been tested for heating or migration

in the MR environment. If the implant is manufactured from a metallic material, surgeons can expect that MR artifacts will be present during routine MR Imaging.

9. Removal of supplemental fixation after healing. If the supplemental fixation is not removed following the completion of its intended use, any of the following complications may occur: (1) Corrosion, with localized tissue reaction or pain; (2) Migration of implant position resulting in injury; (3) Risk of additional injury from postoperative trauma; (4) Bending, loosening, and/or breakage, which could make removal impractical or difficult; (5) Pain, discomfort, or abnormal sensations due to the presence of the device; (6) Possible increased risk of infection; and (7) Bone loss due to stress shielding. The surgeon should carefully weigh the risks versus benefits when deciding whether to remove the implant. Implant removal should be followed by adequate postoperative management to avoid re-fracture.

## **F. PRECAUTIONS**

1. Surgeons are advised to review the product-specific surgical technique prior to performing any surgery. Arthrex provides detailed surgical techniques in print, video, and electronic formats. The Arthrex website also provides detailed surgical technique information and demonstrations. Or, contact your Arthrex representative for an onsite demonstration.
2. Do not bend the plate near the locking hole. Bending the plate near the locking hole can distort the holes threading, which prohibits insertion of the screw
3. Repeated bending of the plate at the same location, or by creating excessive acute angles may potentially lead to premature plate fatigue, failure and or breakage in situ.
4. Screws should be inserted by hand and not with powered equipment.

## **G. PACKAGING AND LABELING**

1. Arthrex devices should be accepted only if the factory packaging and labeling arrive intact.
2. Contact Customer Service if the package has been opened or altered.

## **H. STERILIZATION**

This device is provided sterile or non-sterile. Refer to the package label for the sterilization method.

This device can be resterilized. It must be adequately cleaned, then sterilized using one of the following sterilization parameters.

Follow your country-specific guidelines, standards, and requirements.

<b>STERILIZATION PARAMETERS: FOR THE USA ONLY:</b>			
	<b>Exposure Temperature</b>	<b>Exposure Time</b>	<b>Drying Time</b>
<b>Gravity-Displacement Steam Sterilization Cycle</b>	121°C (250°F)	30 Minutes	15 to 30 Minutes
	132°C (270°F)	15 Minutes	15 to 30 Minutes
	135°C (275°F)	10 Minutes	30 Minutes
<b>Pre-vacuum Cycle</b>	132°C (270°F)	4 Minutes	20 to 30 Minutes
	135°C (275°F)	3 Minutes	16 Minutes

<b>STERILIZATION PARAMETERS: FOR OUTSIDE THE USA ONLY:</b>			
	<b>Exposure Temperature</b>	<b>Exposure Time</b>	<b>Drying Time</b>
<b>Gravity-Displacement Steam Sterilization Cycle</b>	132°C – 135°C (270°F – 275°F)	18 Minutes	15 to 30 Minutes
	121°C (250°F)	30 Minutes	15 to 30 Minutes
<b>Pre-vacuum Cycle</b>	132°C - 135°C (270°F - 275°F)	4 Minutes	20 to 30 Minutes

Certain Arthrex devices that may be used during this procedure are provided non-sterile and must be adequately cleaned and sterilized prior to use or re-use. Please refer to DFU-0023 and ANSI/AAMI ST79, "Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities" for specific information.

Sterilizers vary in design and performance characteristics. Cycle parameters and the load configuration should always be verified against the sterilizer manufacturer's instructions.

Cooling – The device must be adequately cooled, after being removed from the sterilizer.

**I. MATERIAL SPECIFICATIONS**

Refer to the package label for the materials. This device is made of stainless steel.

**J. STORAGE CONDITIONS**

Sterile devices must be stored in the original unopened packaging, away from moisture and should not be used after the expiration date.

Non-sterile metal devices should be stored in a clean, dry environment. The shelf life of non-sterile devices is not limited; the devices are manufactured from non-degradable material,

which does not raise any question of device stability when stored under recommended conditions.

**K. INFORMATION**

Surgeons are advised to review the product specific surgical technique prior to performing any surgery. Arthrex provides detailed surgical techniques in print, video, and electronic formats. The Arthrex website also provides detailed surgical technique information and demonstrations. Or, contact your Arthrex representative for an onsite demonstration.



**COVER SHEET MEMORANDUM**

From: Reviewer Name Elizabeth Frank  
Subject: 510(k) Number K112437  
To: The Record

Please list CTS decision code TH

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

Not Substantially Equivalent (NSE) Codes

- NO NSE for lack of predicate
- NI NSE for new intended use
- NQ NSE for new technology that raises new questions of safety and effectiveness
- NP NSE for lack of performance data
- NM NSE requires PMA
- NS NSE no response
- NH NSE for another reason

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 <a href="http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf">http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf</a> )			
Is this a combination product? (Please specify category _____, see <a href="http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC">http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC</a> )			
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, <a href="http://www.fda.gov/cdrh/ode/guidance/1216.html">http://www.fda.gov/cdrh/ode/guidance/1216.html</a> )			
Is this device intended for pediatric use only?			
Is this a prescription device? (If both prescription & OTC, check both boxes.)			
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank? :			
Is clinical data necessary to support the review of this 510(k)?			
For United States-based clinical studies <b>only</b> : Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank? (If study was conducted in the United States, and FORM FDA 3674 was not included or incomplete, then applicant must be contacted to obtain completed form.)			
Does this device include an Animal Tissue Source?			
All Pediatric Patients age <=21			

118

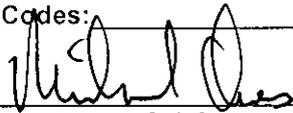
Neonate/Newborn (Birth to 28 days)  
Infant (29 days - < 2 years old)  
Child (2 years - < 12 years old)  
Adolescent (12 years - < 18 years old)  
Transitional Adolescent A (18 - < 21 years old) Special considerations are being given to this group, different from adults age  $\geq 21$  (different device design or testing, different protocol procedures, etc.)  
Transitional Adolescent B (18 -  $\leq 21$ ; No special considerations compared to adults  $\Rightarrow 21$  years old)  
Nanotechnology  
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, <http://www.fda.gov/cdrh/comp/guidance/169.html>) Contact OC.

**Regulation Number** **Class\*** **Product Code**

(\*if unclassified, see 510(k) Staff)

Additional Product Codes: \_\_\_\_\_

Review: \_\_\_\_\_

  
(Branch Chief)

OSTD B  
(Branch Code)

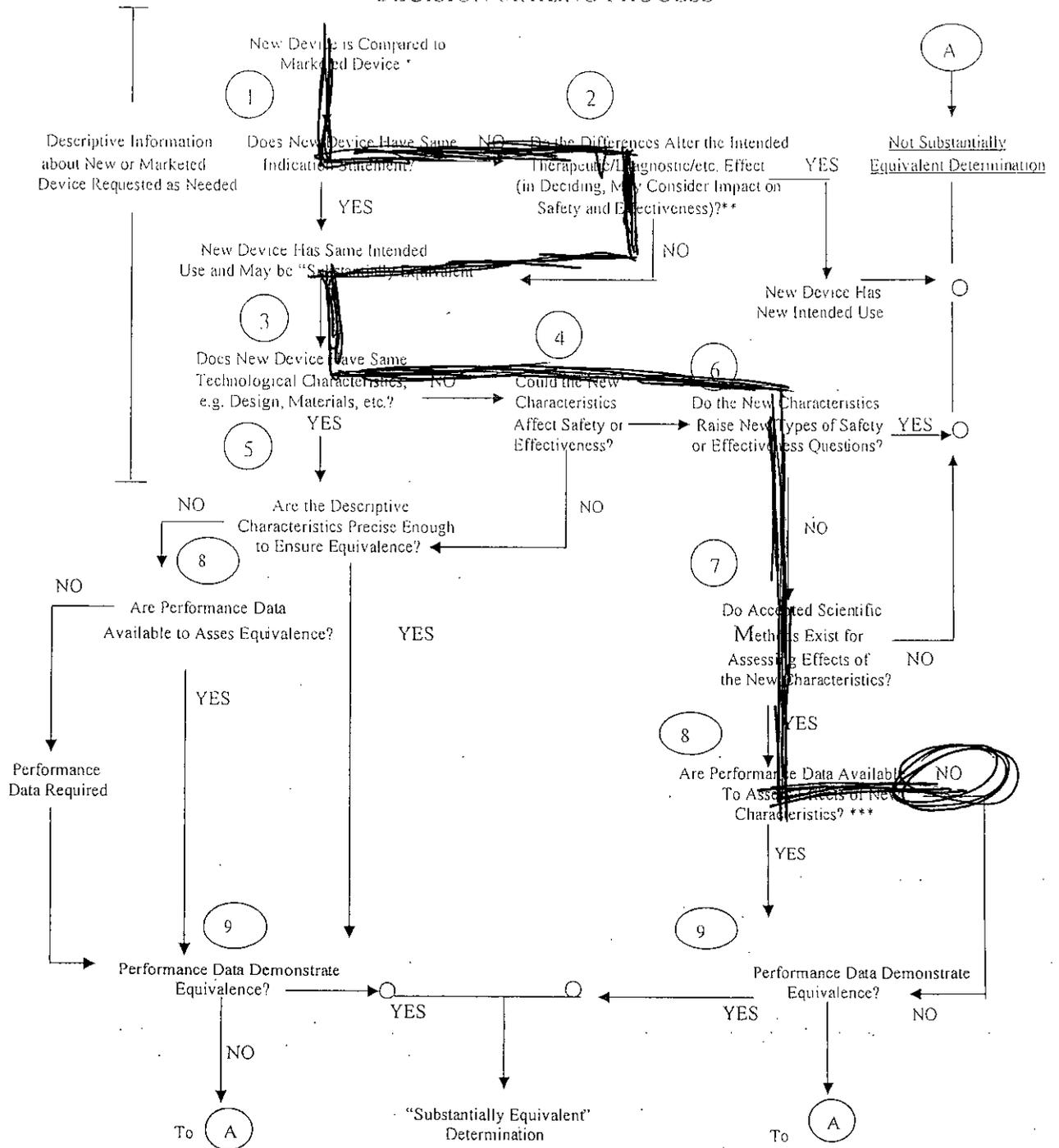
10/28/11  
(Date)

Final Review: \_\_\_\_\_

(Division Director)

(Date)

### 510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



\* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

\*\* This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

\*\*\* Data may be in the 510(k), other 510(k)s, the Center's classification files, or the literature.

**Frank, Elizabeth L**

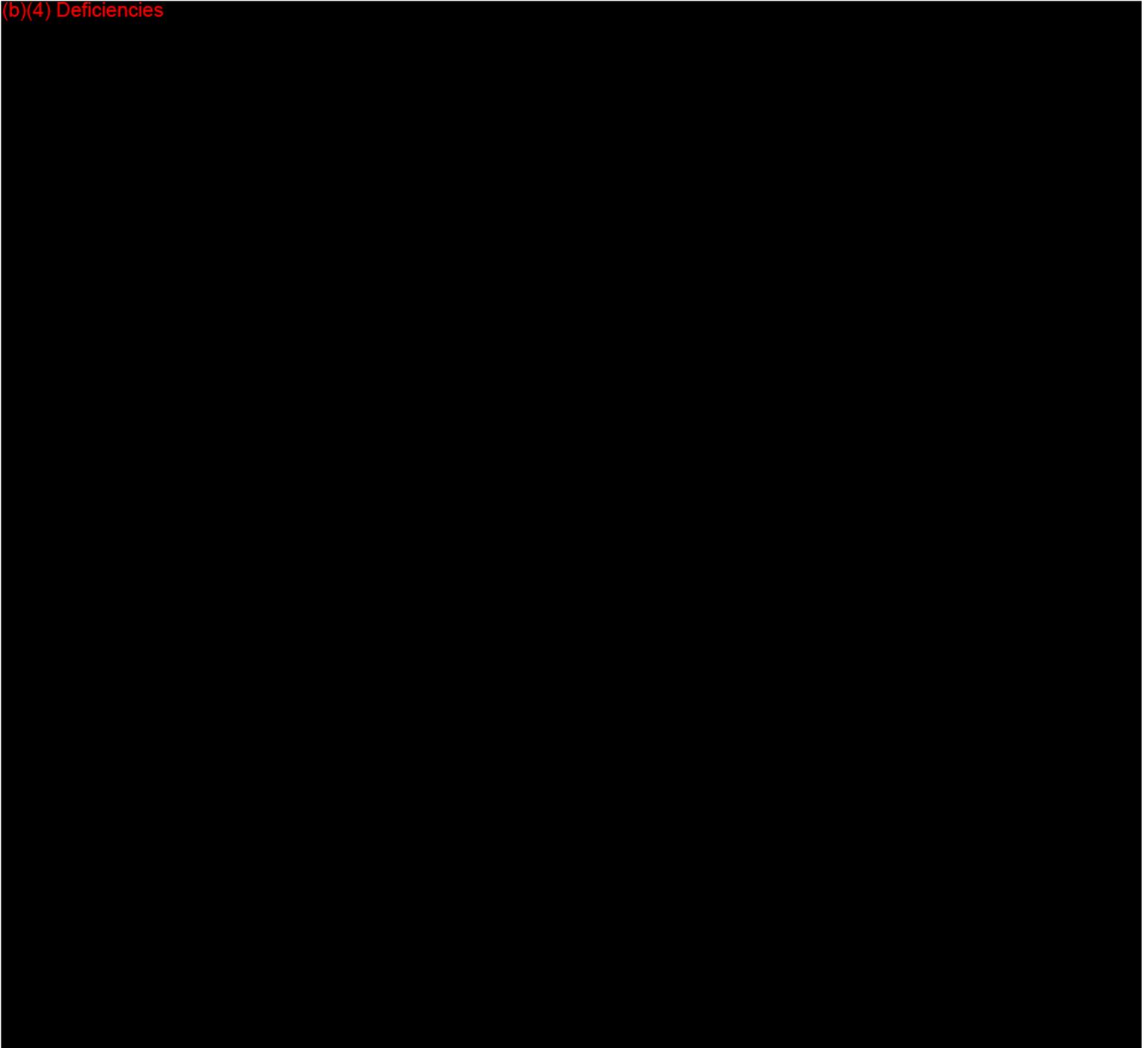
---

**Subject:** Arthrex Fracture System (K112437) - Telephone Hold

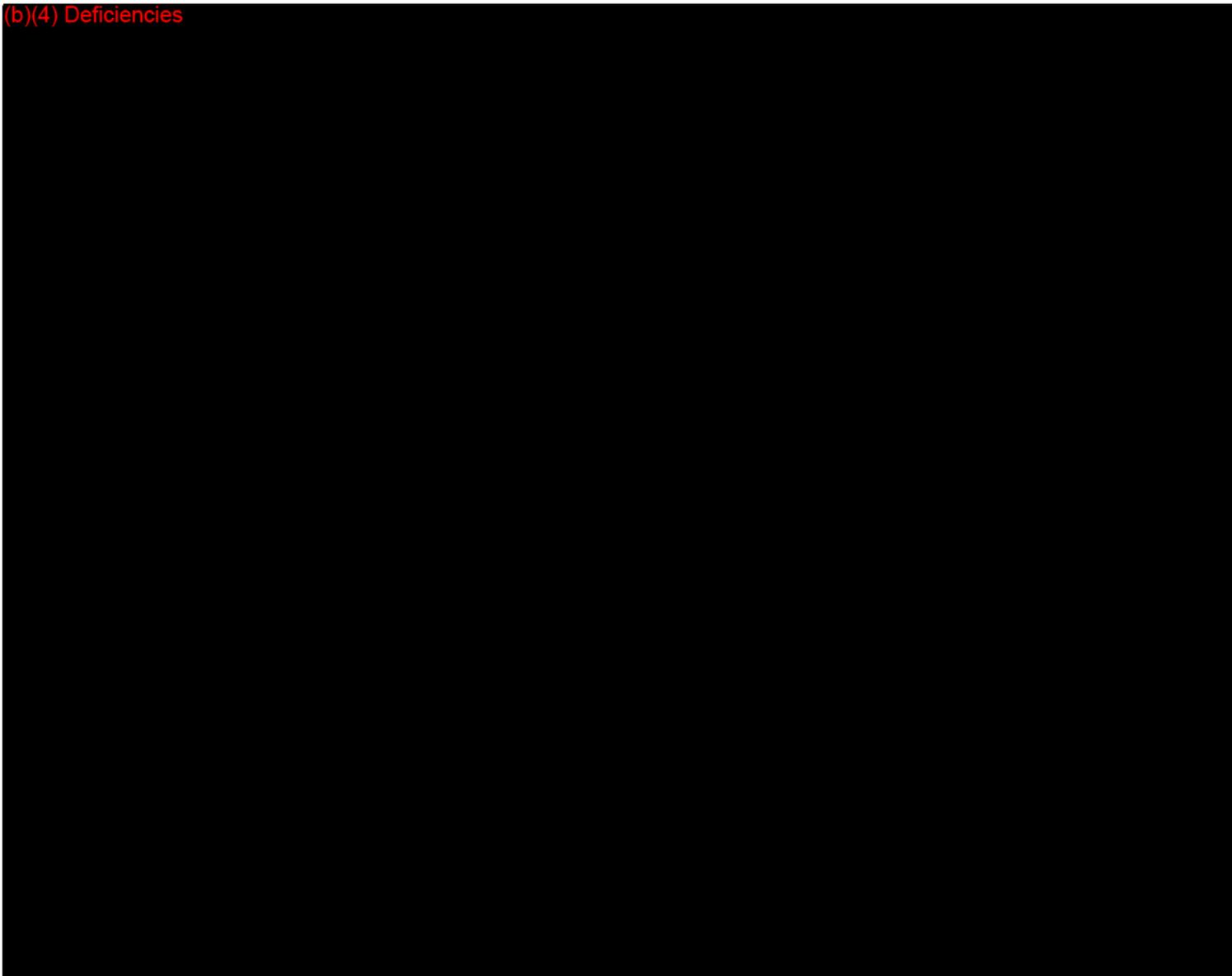
Dear Ms. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the Arthrex Fracture System (K112437). We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information provided. To complete the review of your submission, we require the following additional information:

(b)(4) Deficiencies



121



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 (Act) for determining substantial equivalence of your device.

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(l), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Act. You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations (21 CFR 812).

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k)(21 CFR 807.87(l)); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete. For guidance on 510(k) actions, please see our guidance document entitled, "FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment" at <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM089>

738.pdf

If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the additional information request.

The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act.

The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to:

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

If you have any questions concerning the contents of the letter, please contact me at 301-796-6439.

Best regards,

Beth

Elizabeth L. Frank, M.S.  
Biomedical Engineer  
Orthopedic Joint Devices Branch  
Division of Surgical, Orthopedic, and Restorative Devices  
Phone: 301-796-6439  
Fax: 301-847-8119

[elizabeth.frank@fda.hhs.gov](mailto:elizabeth.frank@fda.hhs.gov)

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please notify the sender immediately by e-mail or phone.

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

**K112437**

**Date:** October 27, 2011

**To:** The Record

**From:** Elizabeth Frank, MS, Biomedical Engineer

*ELF 10/27/11*

**Office:** ODE

**Division:** DSORD/OJDB

**510(k) Holder:** Arthrex, Inc.

**Device Name:** Arthrex Fracture System

**Contact:** Courtney Smith  
Manager, Regulatory Affairs  
1370 Creekside Boulevard  
Naples, FL 34108-1945

**Phone:** 239-643-5553 ext. 1720

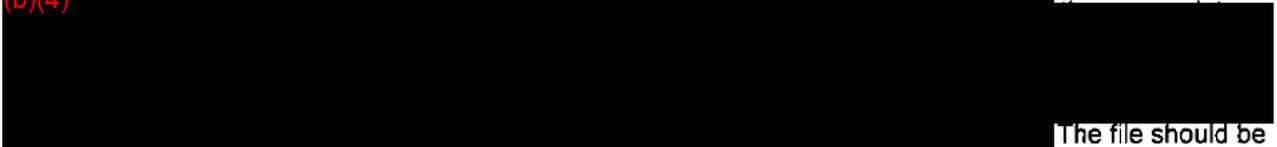
**Fax:** 239-598-5508

**Email:** [csmith@arthrex.com](mailto:csmith@arthrex.com)

**I. Purpose and Submission Summary**

The 510(k) holder would like to introduce the Arthrex Fracture System into interstate commerce. The system is a family of stainless steel plates, screws and buttons. The plates may be contoured or straight and may be available in left and right configurations. The screw family ranges from 2.0mm to 4.0mm in diameter and from 8mm to 80mm in length. The screws are solid and fully threaded and may be locking or non-locking. The button is intended to be used with suture as an adjunct in fracture repair; specifically to provide fixation during the healing process following syndesmotic trauma. The button is stainless steel and designed to fit securely in the holes of the fracture plates. The button is intended to be used with the previously cleared suture, which is provided separately. This indication is too broad since the button only fits with the clavicle plate. The sponsor will be asked to revise (b)

(b)(4)



The file should be placed on **Telephone Hold** and the sponsor should be asked to address the deficiencies at the conclusion of this memorandum.

**II. Administrative Requirements**

	Yes	No	N/A
Indications for Use page (Indicate if: <b>Prescription</b> or OTC)	X		
Truthful and Accuracy Statement	X		
510(k) Summary or 510(k) Statement	X		
Class III Summary			X
Standards Data Report for 510(k)s (Form 3654)		X	
Clinical Trials Form (Form 3674)		X	

**Reviewer Comments:** The 510(k) Summary includes contact information, device information, classification, predicate devices, device description, indications for use, substantial equivalence summary and testing summary. The sponsor will be asked to include the product code HTN.

**DEFICIENCY**

(b)(4) DEFICIENCY (b)

III. Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)?	X		
Does the device design use software?		X	
Is the device sterile?		X	
Is the device reusable (not reprocessed single use)?		X	
Are "cleaning" instructions included for the end user?		X	

The sponsor is expanding the indications for use for existing 2.7mm and 3.0mm screws. In K103705, 2.7mm and 3.0mm screws were cleared for use in the ankle, foot, hand and wrist. This indication is being expanded to include the clavicle, scapula, olecranon, humerus, radius, ulna, tibia, calcaneus, femur and fibula. The sponsor is also obtaining clearance for the Arthrex Fracture System.

The *Arthrex Fracture System* is a family of stainless steel plates, screws, and buttons. The plates may be contoured or straight and may be available in left and right configurations. The screws, which are used with the Arthrex Plates, include the solid, stainless steel locking and non-locking Low Profile Screws (K103705) with additional lengths. The additional screw lengths do not change the existing size range of the Low Profile Screws. The screw family ranges from 2.0 – 4.0mm in diameter and from 8 to 80mm in length.

The button is stainless steel and designed to fit securely in the holes of the fracture plates. The button is intended to be used with the previously cleared suture, which is provided separately.

The proposed buttress plate is designed to be used with the existing TightRope Syndesmosis Device (K043248) or TightRope Acromioclavicular (AC) Device (K052776).

Table 3: Buttons (below) specifies the subject device will be used with FiberTape (K041553). The sponsor will be asked (b)(4)  
(b)(4)

**Reviewer Comments:** (b)(4)  
(b)(4)  
(b)(4)  
DEFICIENCIES

The following tables outline the proposed and predicate devices. The proposed devices are **bolded and shaded**.

125

Table 1: Plates

Comparison Between Proposed and Predicate Plates						
510(k) Clearance	Product Numbers	Holes	Width (mm)	Length (mm)	Thickness (mm)	Material
	Central Third Clavicle Plates (AR-2650CL – AR-2655CL) (AR-2650CR – AR-2655CR)	7 – 10	9.6	76 – 120	2.3	Stainless Steel
	Distal Clavicle Plates (AR-2656DL – AR-2657DL) AR-2656DR – AR-2657DR)	10 – 13	11.2	70 – 99	2.5	Stainless Steel
	Ankle Fracture Plates (AR-8943C-04 – AR-8943C-12)	4 – 12	9.6	55 - 157	3.1	Stainless Steel
	Buttress Plate AR-8914P	2	5	22	0.5	Stainless Steel
K011335	Synthes One-Third Tubular Plates	2 - 12	9.4	81 - 117	1.0	Stainless Steel
K102998	Acumed Congruent Bone Plates	6 – 16	11	64 - 121	3.5	Titanium

Table 2: Screws

Comparison Between Proposed and Predicate Screws					
Clearance	Product Numbers	Product Description	Diameter (mm)	Total Length (mm)	Material
K103705	AR-8727-08 – AR-8727-40	Screw, Solid, FT	2.7	8 – 40	Ti
K102998	CO-27xx	Acumed Congruent Bone Screws	2.7	8-30	Ti
	<b>AR-8827L-08</b>	<b>Screw, Solid, Locking</b>	<b>2.7</b>	<b>8</b>	<b>SS</b>
K103705	AR-8827L-10 – AR-8827L-30	Screw, Solid, Locking	2.7	10 – 30	SS
K103705	AR-8730-10FT – AR-8730-50FT	Screw, Solid, FT	3.0	10 – 50	Ti
K103705	AR-8730-10PT – AR-8730-50PT	Screw, Cannulated, PT	3.0	10 – 50	Ti
K103705	AR-8830-10 – AR-8830-30	Screw, Solid, FT	3.0	10 – 30	SS
K103705	AR-8931-13 – AR-8931-20	Screw, Solid, FT	3.0	13 – 20	Ti
K103705	AR-8933-10 – AR-8933-24	Screw, Solid FT	3.0	10 – 24	Ti
K103705	AR-8933-10PT – AR-8933-50PT	Screw, Cannulated, PT	3.0	10 – 50	Ti
K103705	AR-8933L-10 – AR-8933L-24	Screw, Solid, Locking	3.0	10 – 24	Ti
	<b>AR-8835-08</b>	<b>Screw, Solid, FT</b>	<b>3.5</b>	<b>8</b>	<b>SS</b>
K103705	AR-8835-10 – AR-8835-60	Screw, Solid, FT	3.5	10 – 60	SS
K102998	CO-3xx0	Acumed Congruent Bone Screws	3.5	8-60	Ti
	<b>AR-8835-65 – AR-8835-80</b>	<b>Screw, Solid, FT</b>	<b>3.5</b>	<b>65 – 80</b>	<b>SS</b>
	<b>AR-8835L-08</b>	<b>Screw, Solid, Locking</b>	<b>3.5</b>	<b>8</b>	<b>SS</b>
K103705	AR-8835L-10 – AR-8835L-60	Screw, Solid, Locking	3.5	10 – 60	SS
	<b>AR-8835L-65 – AR-8835L-80</b>	<b>Screw, Solid, Locking</b>	<b>3.5</b>	<b>65 – 80</b>	<b>SS</b>
K111253	AR-8935L-46 – AR-8935L-80	Screw, Solid, Locking	3.5	46 – 80	Ti
K102998	CO-4xx0	Acumed Congruent Bone Screws	4.0	8-80	Ti
K103705	AR-8840-10 – AR-8840-60	Screw, Solid, FT	4.0	16 – 60	SS

Table 3: Buttons

Comparison Between Proposed and Predicate Plates						
510(k) Clearance	Product Description	Holes	Length (mm)	Width (mm)	Material	Suture
	Distal Clavicle Plate Button (AR-2658)	2	8.5	5.8	Stainless Steel	FiberTape (K041553) (provided separately)
K052776	TightRope Acromioclavicular (AC) Device	2	10	3.5	Titanium / Stainless Steel	(b) FiberWire
		4	6.5	6.5		
K043248	TightRope Syndesmosis Device	2	10	3.5	Titanium / Stainless Steel	(b) FiberWire
		4	6.5	6.5		

*Instrumentation*

The following stainless steel instruments are specific to the components listed in the tables above.

- Positioning handle, distal clavicle plate
- Drill guide, 2.0mm distal clavicle plate, L and R

**Reviewer Comments:**

(b)(4) DEFICIENCY (b)(4)

**IV. Indications for Use**

The Arthrex *Fracture System* is intended to be used for internal bone fixation for bone fractures, fusions, and osteotomies and non-unions in the ankle, foot, hand, wrist, clavicle and scapula, olecranon, humerus, radius, ulna, tibia, calcaneous, femur and fibula.

The button is intended to be used with suture as an adjunct in fracture repair; specifically, to provide fixation during the healing process following syndesmotoc trauma.

The Arthrex *Low Profile Screws (2.7mm and larger, solid)* are intended to be used as stand-alone bone screws, or in a plate-screw system for internal bone fixation for bone fractures, fusions, osteotomies and non-unions in the ankle, foot, hand, wrist, clavicle, scapula, olecranon, humerus, radius, ulna, tibia, calcaneous, femur, and fibula. When used with a plate, the screws may be used with the Arthrex Fracture System, Distal Extremity Plates, Low Profile and Small Fragment Plates, Humeral Fracture Plates, and Osteotomy Plates.

**Reviewer Comment:** (b)(4)

(b)(4) DEFICIENCY (b)(4)

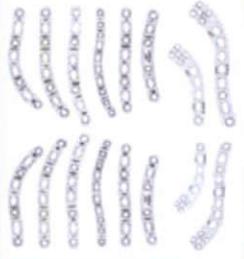
**V. Predicate Device Comparison**

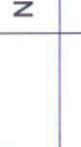
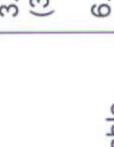
The sponsor provided a predicate device comparison in Table 4.

Table 4: Predicate Device Comparison

Manufacturer	Arthrex	Synthes	Acumed	Arthrex	Arthrex
<b>Device Name</b>	<b>Fracture System</b>	<b>One-Third Tubular Plate</b>	<b>Congruent Bone Plate System</b>	<b>Low Profile Screws</b>	<b>TightRope Syndesmosis and Acromioclavicular (AC) Devices</b>
<b>510(k) Number</b>	<b>Subject</b>	<b>K011335</b>	<b>K102998</b>	<b>K103705/K111253</b>	<b>K043248/K052776</b>
<b>Product Code</b>	HRS, HWC	HRS	HRS	HRS, HWC	HTN
<b>Classification</b>	888.3030, 888.3040	888.3030	888.3030	888.3040	888.3030
<b>Intended Use</b>	Intended to be used for internal bone fixation for bone fractures, fusions, osteotomies and non-unions. Intended to be used for internal bone fixation for bone fractures, fusions, and osteotomies and non-unions in the ankle, foot, hand, wrist, clavicle and scapula, olecranon, humerus, radius, ulna, tibia, calcaneus, femur and fibula. The button is intended to be used with suture as an adjunct in fracture repair; specifically, to provide fixation during the healing process following syndesmosis trauma.	Intended for fixation of fractures, osteotomies, and nonunions.  Intended for fixation of fractures, osteotomies, and non-unions of the clavicle, scapula, olecranon, humerus, radius, ulna, pelvis, distal tibia and fibula, particularly in osteopenic bone.	Provides fixation for fractures, fusions, or osteotomies.  Fixation for fractures, fusions, or osteotomies for the clavicle, humerus, radius, ulna, metacarpal, metatarsal, malleolus, tibia, and fibula.	Intended to be used for internal bone fixation for bone fractures, fusions or osteotomies.  Intended to be used as stand-alone bone screws, or in a plate-screw system for internal bone fixation for bone fractures, fusions, osteotomies and non-unions in the ankle, foot, hand, wrist, clavicle, scapula, olecranon, humerus, radius, ulna, tibia, calcaneus, femur and fibula.	Intended as an adjunct in fracture repair and as an adjunct in fixation systems.  The Arthrex TightRope Syndesmosis Device is intended as an adjunct in fracture repair involving metaphyseal and periarticular small bone fragments where screws are not indicated, and as an adjunct in external and intramedullary fixation systems involving plates and rods, with fracture braces and casting.  Specifically, the Arthrex TightRope Syndesmosis Device is intended to provide fixation during the healing process following a syndesmosis trauma, such as fixation of syndesmosis
<b>Indications for Use</b>					

128

	<p>The Arthrex Low Profile Screws (2.7mm and larger, solid) are intended to be used as stand-alone bone screws, or in a plate-screw system for internal bone fixation for bone fractures, fusions, osteotomies and non-unions in the ankle, foot, hand, wrist, clavicle, scapula, olecranon, humerus, radius, ulna, tibia, calcaneus, femur, and fibula.</p>		<p>Various sized contoured bone plates and screws.</p> 	<p>Fully or partially threaded screws, and solid or cannulated.</p>	<p>(syndesmosis disruptions) in connection with Weber B and C ankle fractures.</p> <p>Specifically, the Arthrex TightRope AC Device is intended to provide fixation during the healing process following a syndesmosis trauma, such as fixation of acromioclavicular separations due to coracoclavicular ligament disruptions.</p>
<p><b>Description</b></p>	<p>Various sized contoured plates, screws and buttons.</p> 	<p>Various sized contoured bone plates with both locking and compression holes.</p> 	<p>Two metal buttons (stainless steel or titanium) and a #5 suture.</p>	<p>Not applicable</p>	<p>Not applicable</p>
<p><b>Plates</b></p>	<p>Stainless Steel</p>	<p>Stainless Steel</p>	<p>Titanium</p>	<p>Not applicable</p>	<p>Not applicable</p>
<p><b>Plate Material</b></p>	<p>22 – 121mm</p>	<p>81 – 117mm</p>	<p>Clavicle Plates: 64-121mm</p>	<p>Not applicable</p>	<p>Not applicable</p>
<p><b>Plate Range</b></p>				<p>Not applicable</p>	<p>Not applicable</p>

Screws					Not applicable
<b>Screw Material</b>	Stainless Steel	Titanium	Titanium	Stainless Steel Titanium	Not applicable
<b>Screw Diameters</b>	2.7 – 4.0mm	Clavicle Screws: 2.7-4.0mm	2.7 – 3.5mm	2.0 – 4.0mm	Not applicable
<b>Screw Lengths</b>	8, 65 – 80mm	8 – 80mm	Not applicable	8 – 60mm	Not applicable
<b>Button Description</b>	Designed to fit securely in the holes of the fracture plates. Length: 8.5mm, Width: 5.8mm 2 holes	Not applicable	Not applicable	Not applicable	3.5mm button is oblong (3.5x10) with 2 holes. 6.5mm button is circular with 4 holes. Pre-threaded with #5 FiberWire suture.
<b>Buttons</b>		Not applicable	Not applicable	Not applicable	
<b>Button Material</b>	Stainless Steel	Not applicable	Not applicable	Not applicable	Stainless Steel Titanium

Reviewer Comments: Please see the Indications for Use comparison in the Indications for Use section. The specifications of the proposed plates and screws

(b)(4)

**VI. Labeling**

Package Insert

The sponsor includes a package insert in Appendix 2 of their submission. The sponsor describes the plates, screws and distal clavicle plate button and indications for use. The indications for use are listed for the fracture plate, low profile screw (2.0-2.4mm solid), low profile screws (2.0-3.0mm cannulated), low profile screws (2.7mm and larger, solid) and low profile screws (3.55mm and larger, cannulated). The button is listed under the fracture plate as "The button is intended to be used with suture an adjunct in fracture repair, specifically to provide fixation during the healing process following syndesmotic trauma."

The package insert includes relevant contraindications, adverse effects, warnings, including the device not being evaluated in an MR environment, precautions and sterilization instructions. The sterilization instructions match the recommended sterilization parameters in AAMI ST79 and the sponsor differentiates between sterilization parameters for inside the US and outside the US.

**Reviewer Comments:** (b)(4)

(b)(4)  
(b)(4)  
**DEFICIENCIES**

(b)(4)

(b)(4)

**DEFICIENCY**

Package Labels

The package labels include the device name, manufacturer information, lot number, non-sterile, single use only and see Instructions for Use. A separate package label defines the symbols.

**Reviewer's Comments:** *The package labels include the relevant information.*

**VII. Sterilization**

The devices included in the Fracture System are provided non-sterile and are single use only. The devices should be cleaned and sterilized prior to use. The sponsor provides the following sterilization

(b)(4)

(b)(4)

**Reviewer's Comment:** *The sponsor has clearly outlined the sterilization parameters. The*

*sterilization information is adequate.*

**VIII. Biocompatibility**

The Arthrex Fracture System components in this submission are composed of stainless steel.

*Reviewer Comment: Stainless steel is commonly used in orthopedic implants. The identified predicate devices are composed of the same materials.*

**IX. Software – Not Applicable**

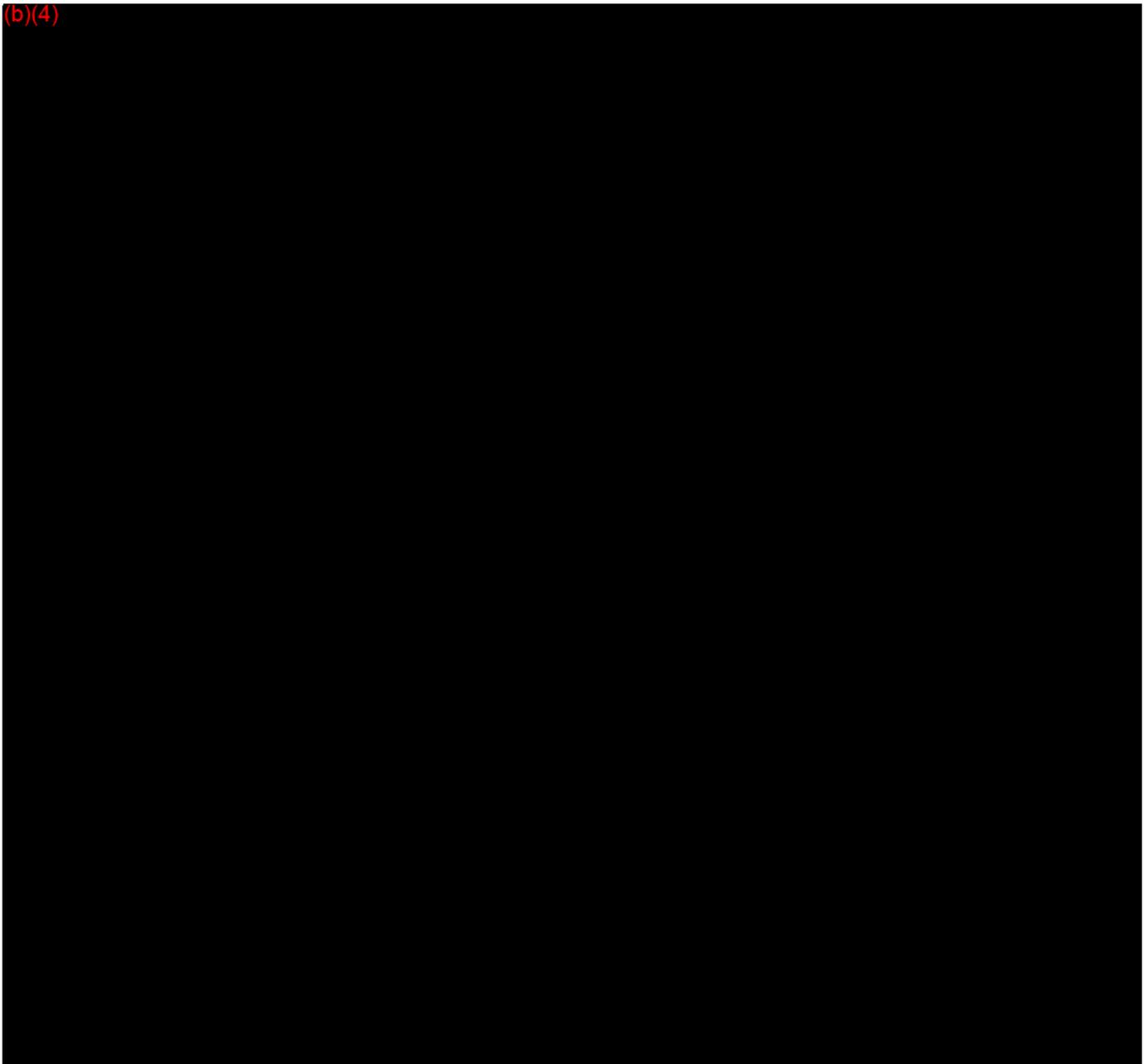
There is no software component with the subject device.

**X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety – Not Applicable**

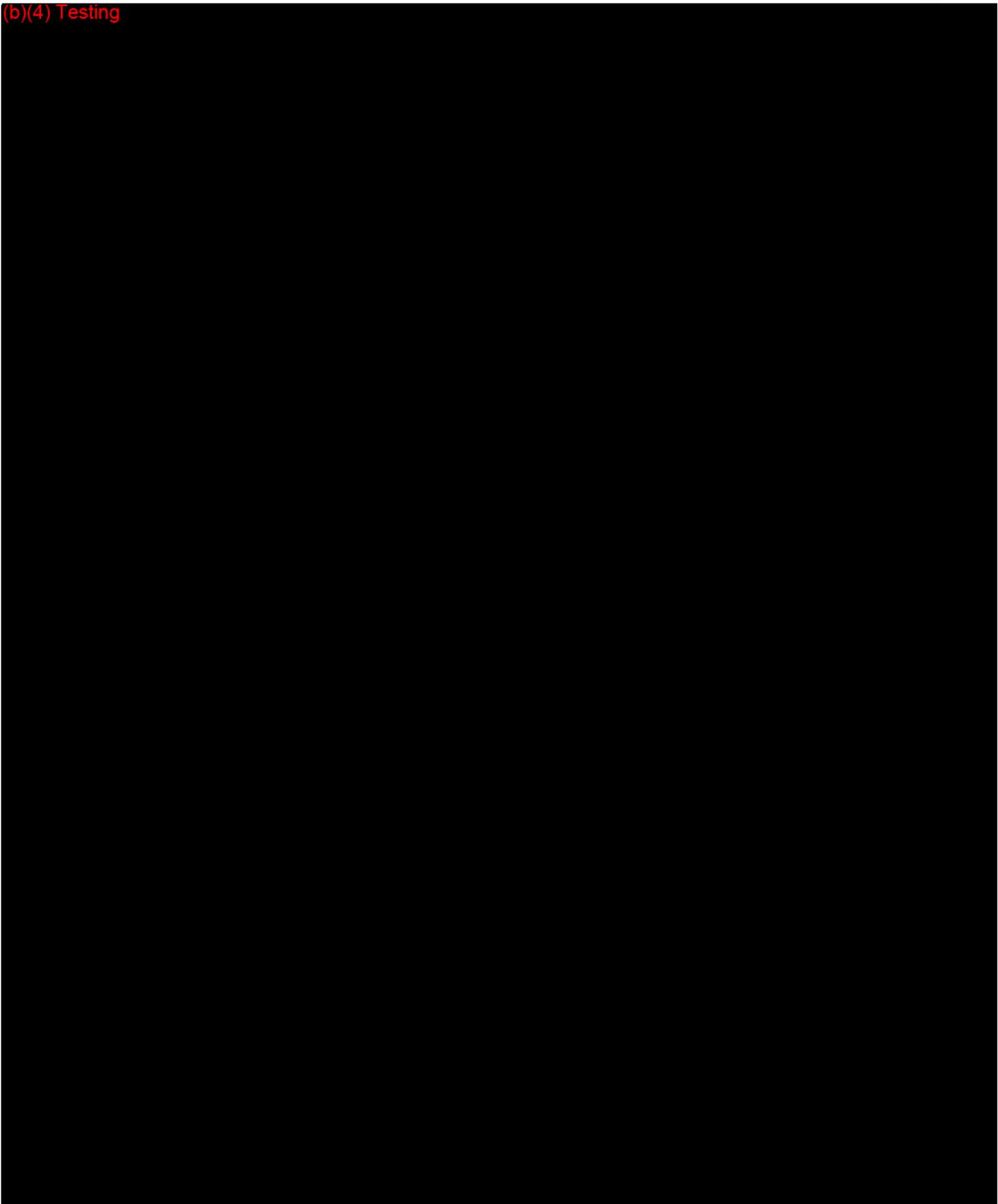
The sponsor has addressed MR compatibility with a warning in the package insert.

**XI. Performance Testing – Bench**

(b)(4)



(b)(4) Testing



**XII. Performance Testing – Animal – Not Applicable**

Animal Testing is not necessary to demonstrate the substantial equivalence of the Arthrex Fracture System.

**XIII. Performance Testing – Clinical – Not Applicable**

Clinical data is not necessary to demonstrate the substantial equivalence of the Arthrex Fracture System.

**XIV. Substantial Equivalence Discussion**

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

Note: See

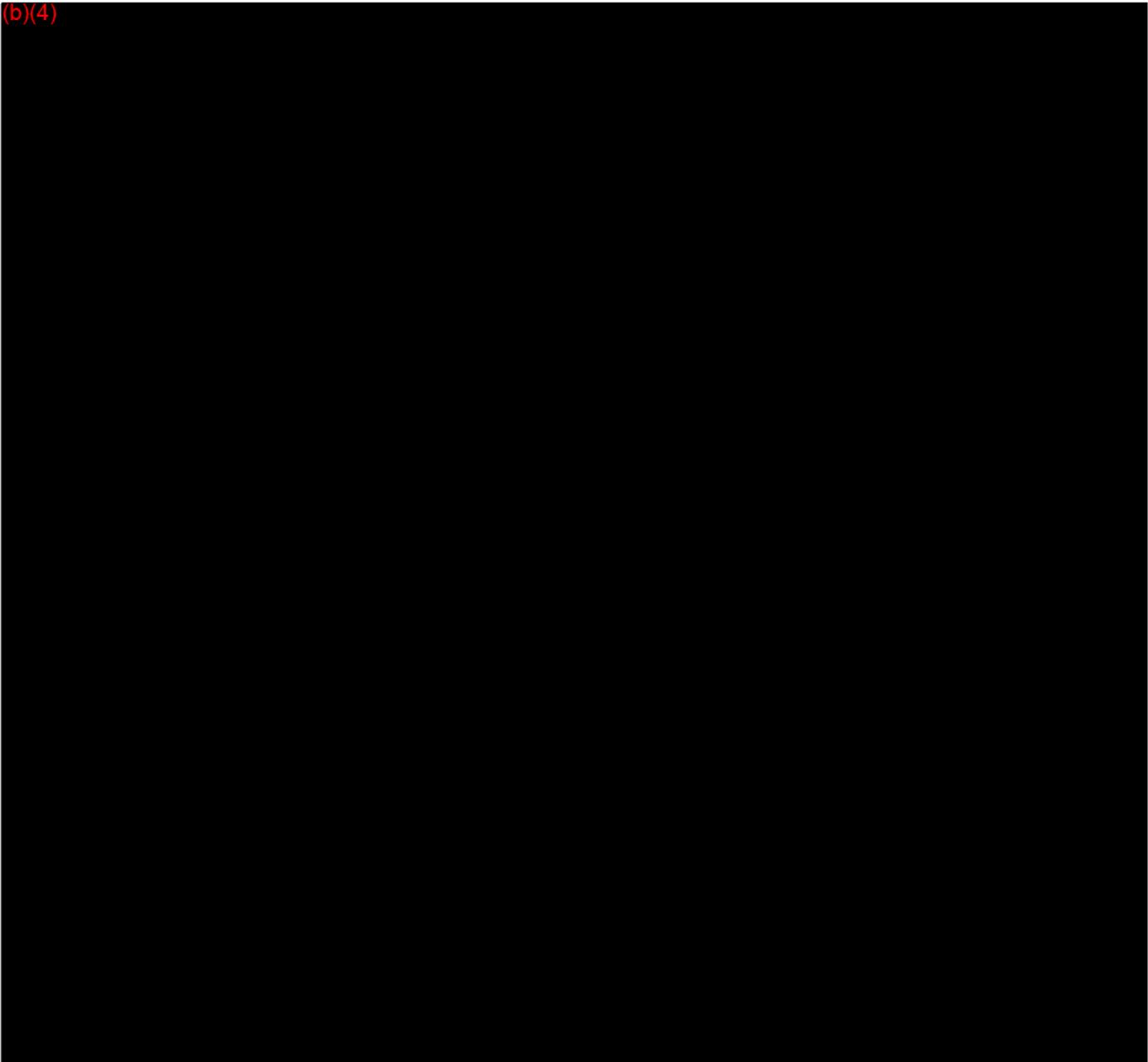
[http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0\\_4148/FLOWCART%20DECISION%20TREE%20.DOC](http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4148/FLOWCART%20DECISION%20TREE%20.DOC) for Flowchart to assist in decision-making process. Please complete the above table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

- 1. Explain how the new indication differs from the predicate device's indication:**  
*The proposed indications are broader than the actual device appears to be intended to be used, i.e. intended for acromioclavicular (AC) repair, but indicated for syndesmotic trauma.*
- 2. Explain why there is or is not a new effect or safety or effectiveness issue:**  
*There are legally marketed predicate devices intended for AC repair.*
- 3. Describe the new technological characteristics:**  
*The proposed device is a button that snaps into a plate where the predicate is not designed to fit into a plate.*
- 4. Explain how new characteristics could or could not affect safety or effectiveness:**  
*It is not clear how the button and plate will perform, as the plate is intended to fix a clavicle fracture, while the button and sutures are for AC repair.*
- 5. Explain how descriptive characteristics are not precise enough:**

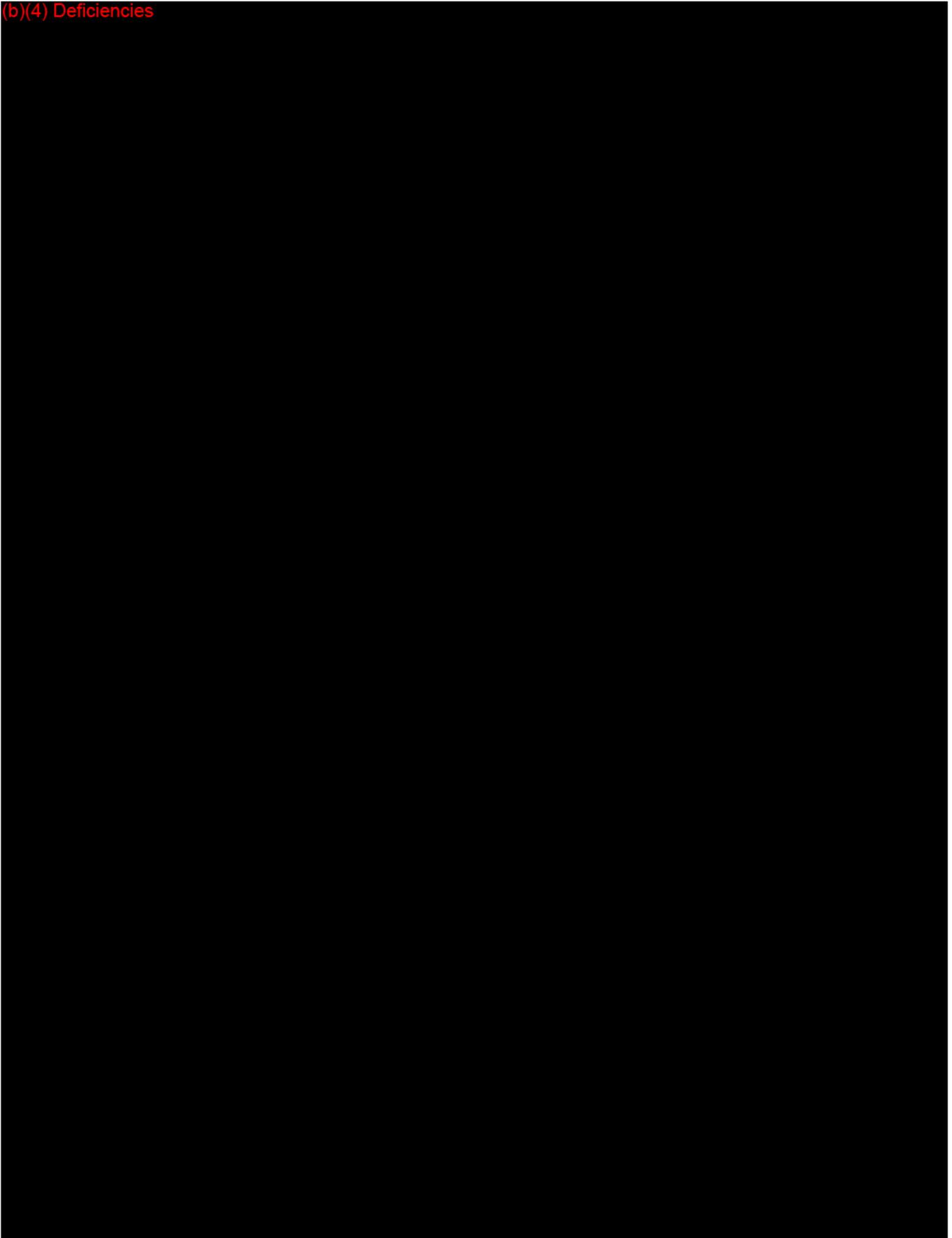
6. **Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:**  
*Clavicle fracture healing and AC joint repair are not new questions, this is only a new method repairing them together.*
7. Explain why existing scientific methods can not be used:
8. **Explain what performance data is needed.**  
*The sponsor must clarify their intended use and provide fatigue testing of the construct.*
9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

**XV. Deficiencies and Contact History**

(b)(4)



(b)(4) Deficiencies



(b)(4) Deficiencies

**XVI. Recommendation**

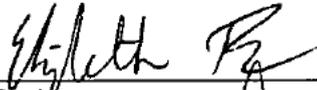
I recommend the Arthrex Fracture System be placed on **Telephone Hold** and the sponsor be sent the deficiencies outlined above.

**Regulation Number:** 21 CFR 888.3030

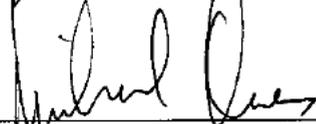
**Regulation Name:** Single/multiple component metallic bone fixation appliances and accessories

**Regulatory Class:** Class II

**Product Code:** HTN, HWC, HRS

  
\_\_\_\_\_  
Reviewer

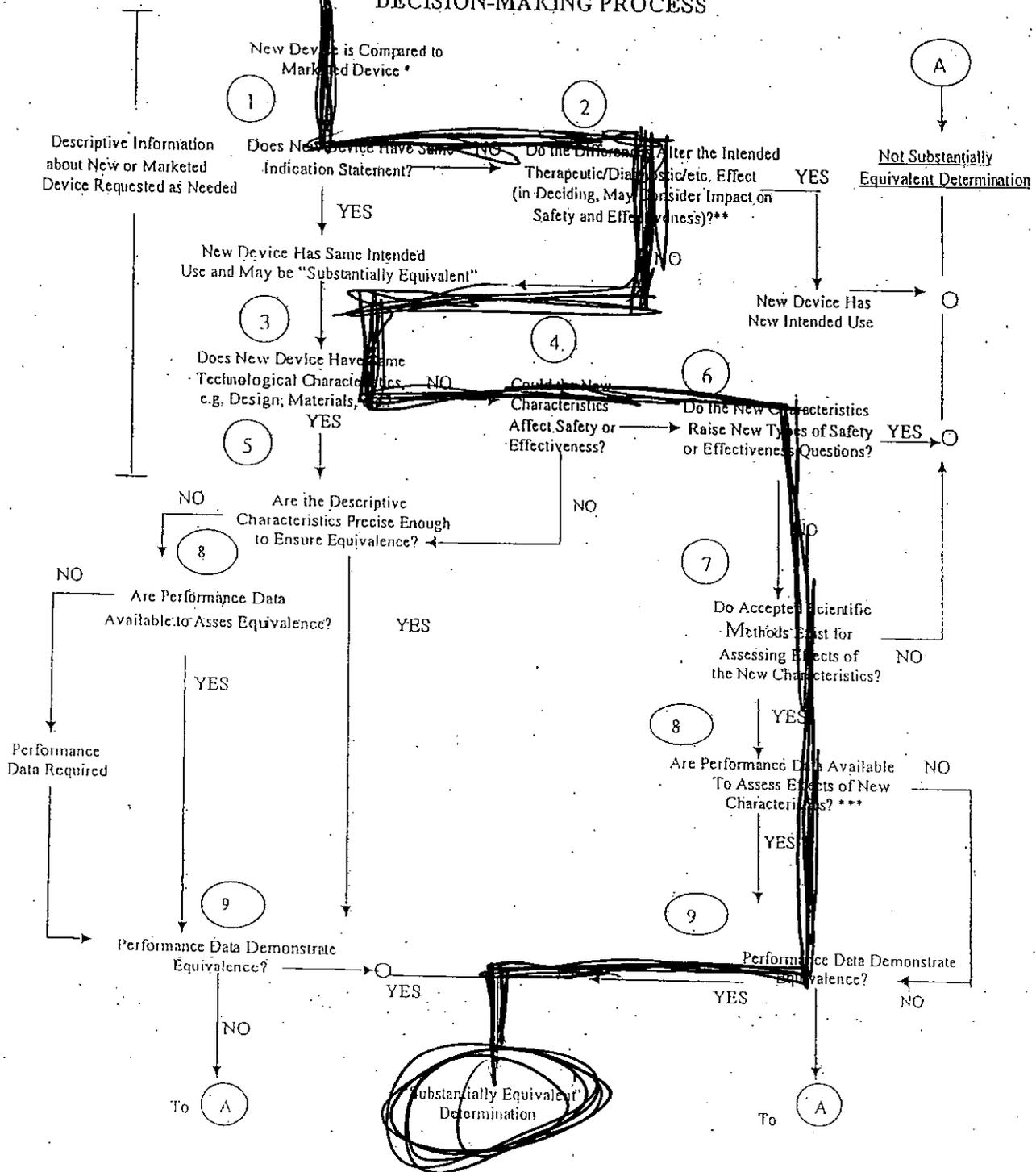
10/27/11  
Date

  
\_\_\_\_\_  
Branch Chief

10/28/11  
Date

137

### 510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



§10(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

\*\* This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

\*\*\* Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.



K112437/31

December 12, 2011

Elizabeth Frank  
CDRH/ODE/DSORD/OJDB  
Food and Drug Administration  
WO66-G609  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

FDA CDRH DMC  
DEC 14 2011  
Received

**510(k) Pre-market Notification: K112437 – Arthrex Fracture System - RESPONSE**

**ATTN: Elizabeth Frank**

Dear Ms. Frank,

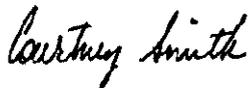
The attached responses and documents are submitted to address your request, received via e-mail on October 28, 2011, for additional information regarding the 510(k) Pre-market Notification *Arthrex Fracture System – K112437*.

Pursuant to 21 CFR 807.95 (c) (3) Arthrex, Inc. considers this pre-market submission to be confidential commercial information.

We trust you will find that these responses and documents will address the concerns in your request.

Questions regarding this submission response may be directed to me by e-mail at [Courtney.smith@arthrex.com](mailto:Courtney.smith@arthrex.com) or telephone at 239.643.5553 at extension 1720, and by facsimile at 239.598.5508.

Sincerely,



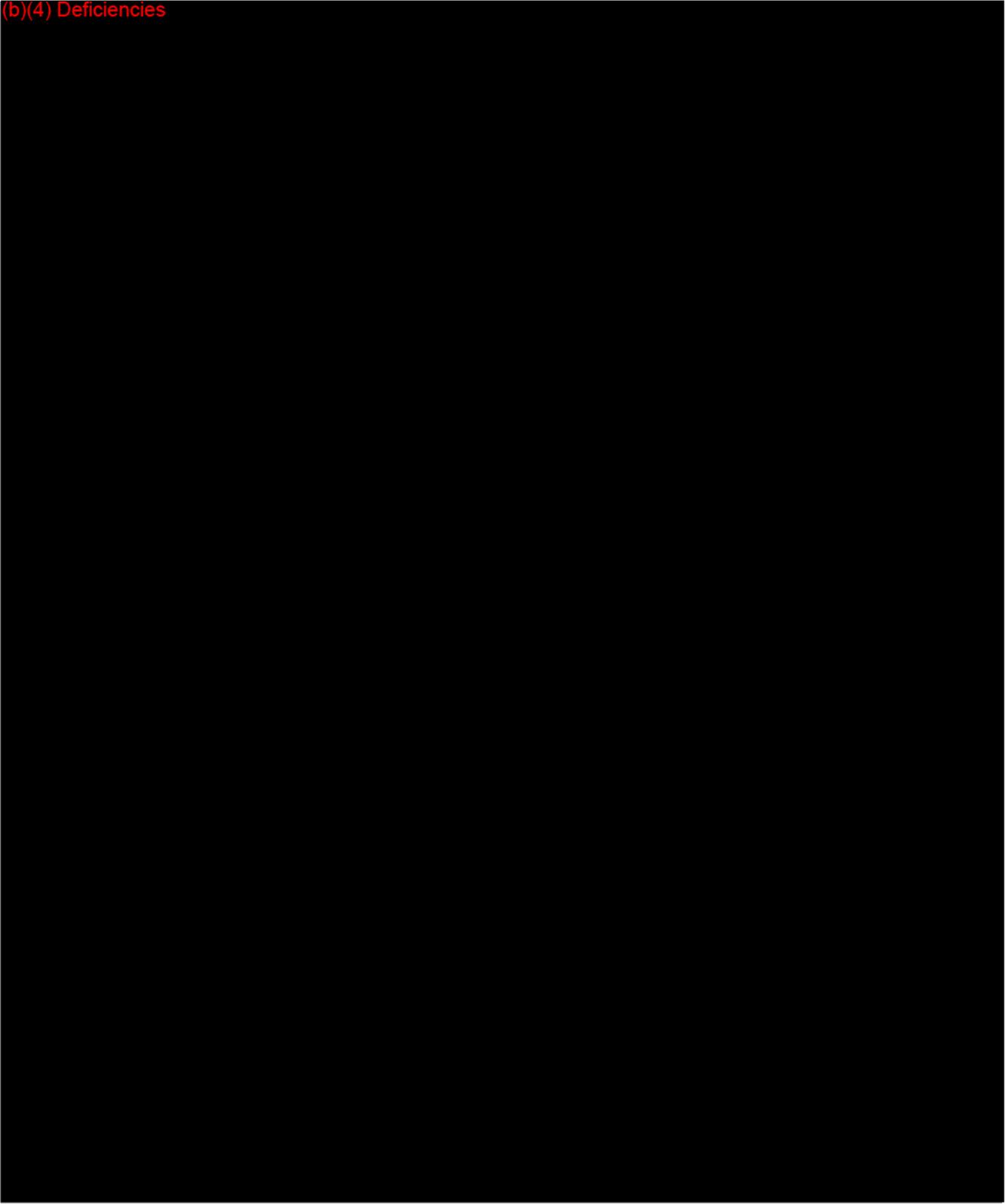
Courtney Smith  
Regulatory Affairs Associate

53

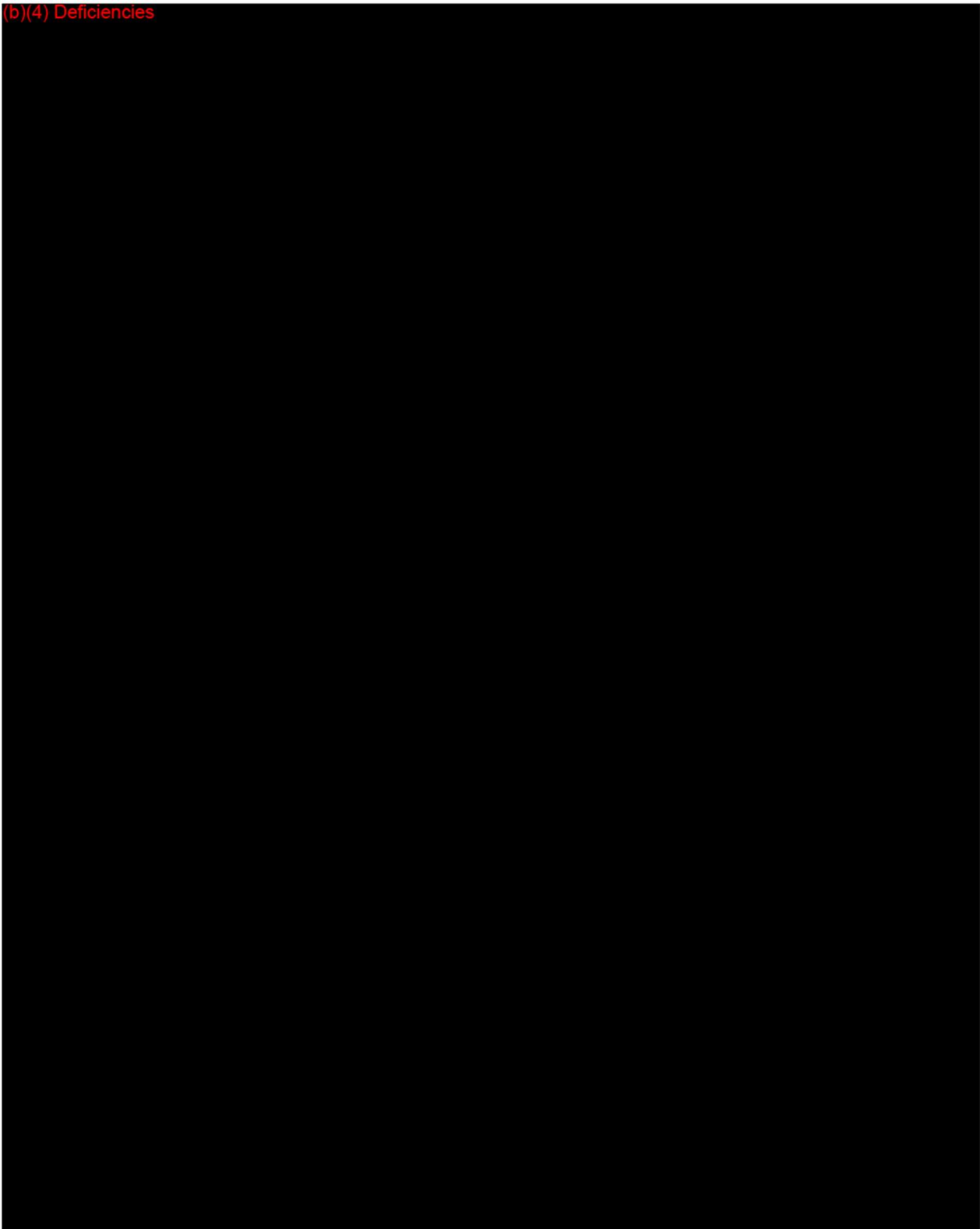
KO

**Arthrex, Inc. responses to the FDA request for additional information for K112437 are provided below following each item text. This request was received via e-mail on October 28, 2011. Responses are shown in blue font.**

(b)(4) Deficiencies

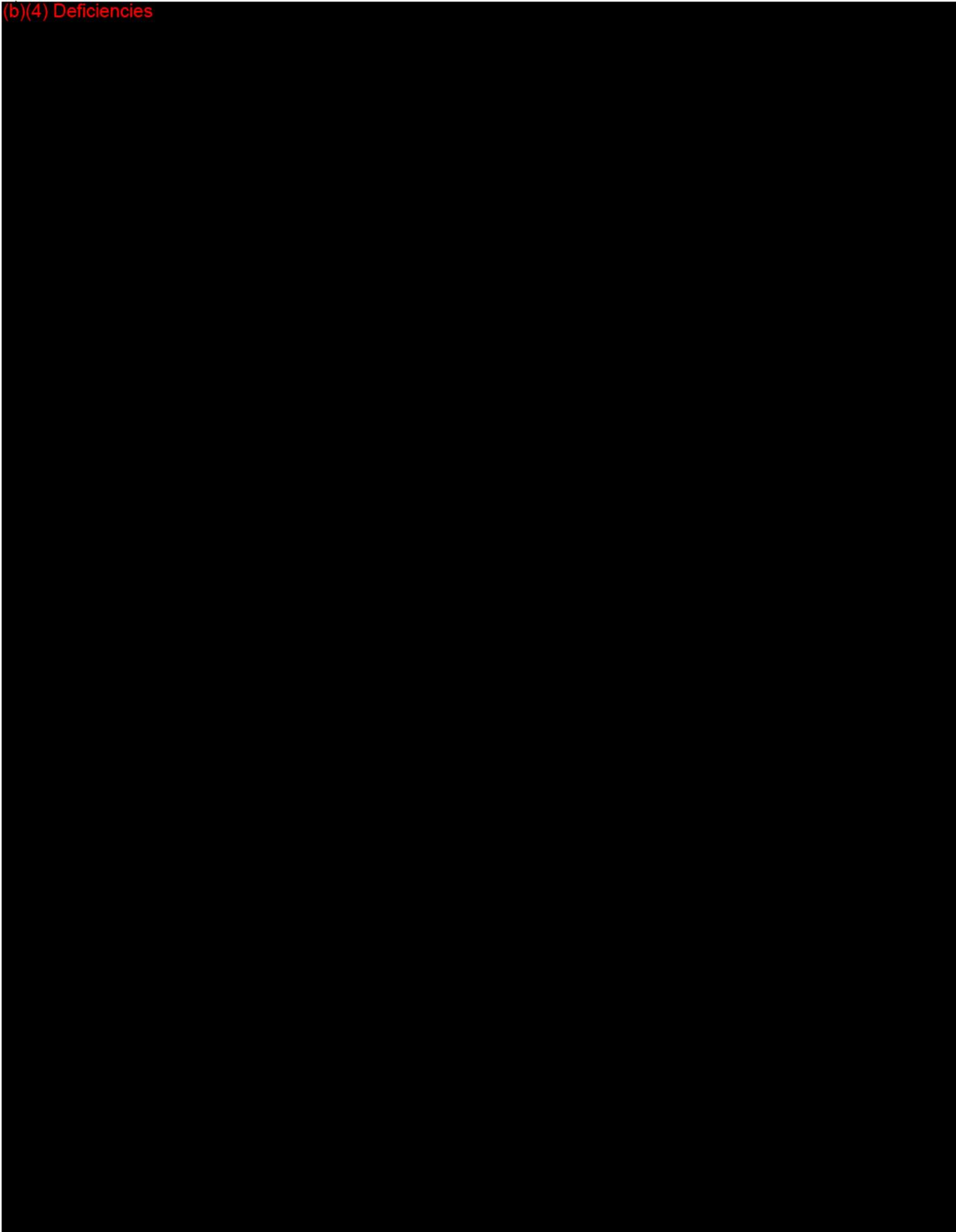


(b)(4) Deficiencies

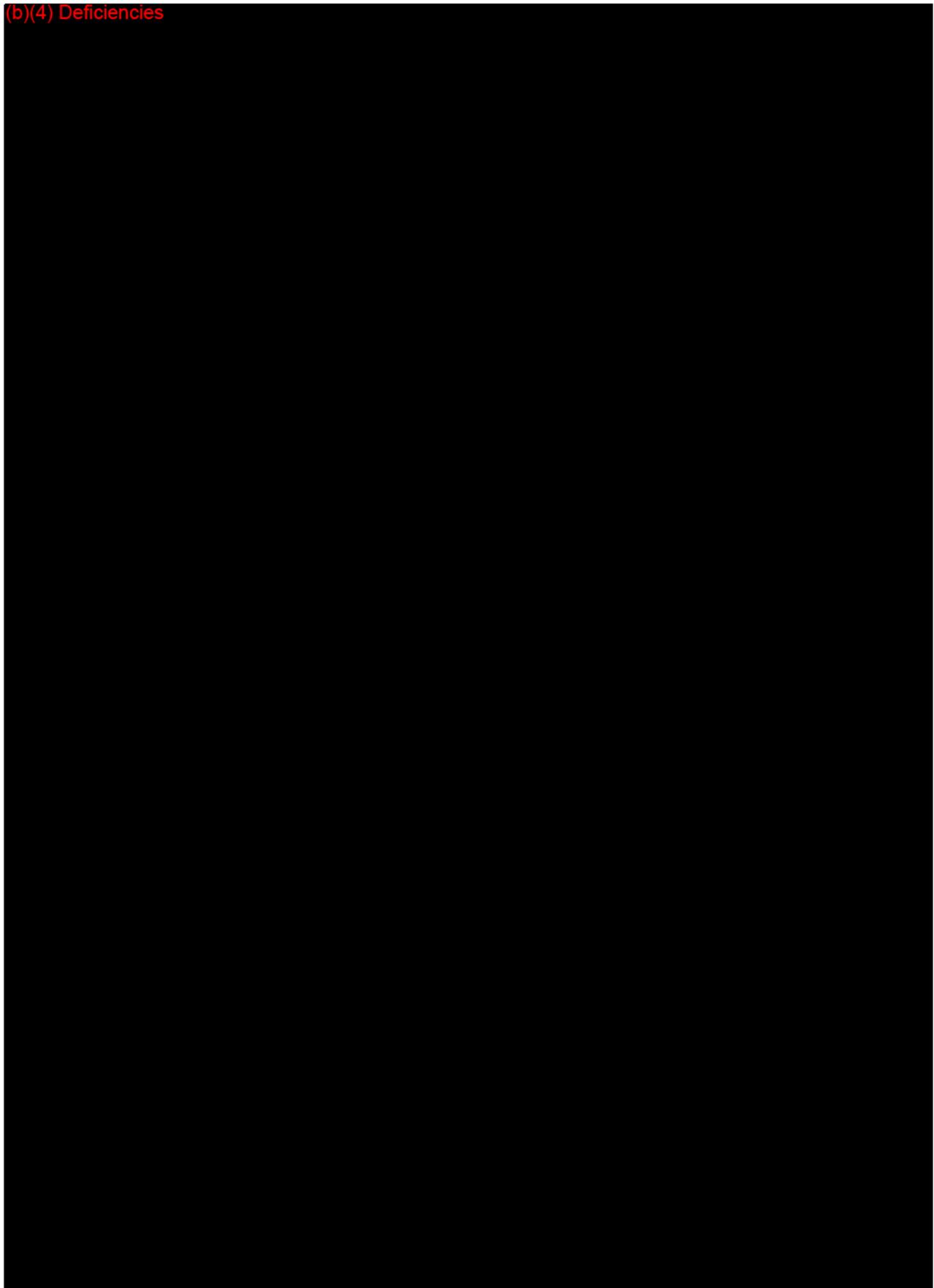


55

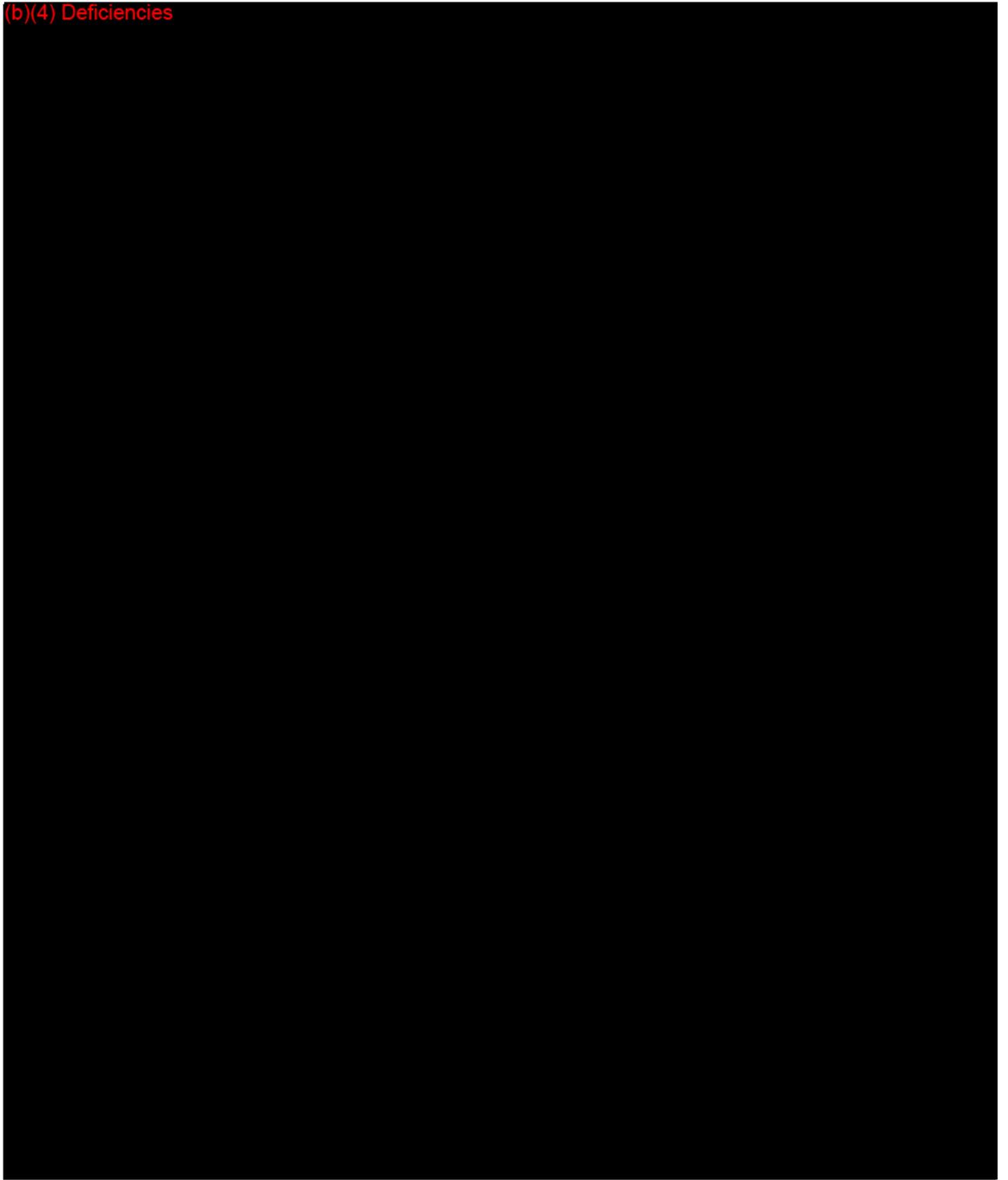
(b)(4) Deficiencies



(b)(4) Deficiencies



(b)(4) Deficiencies







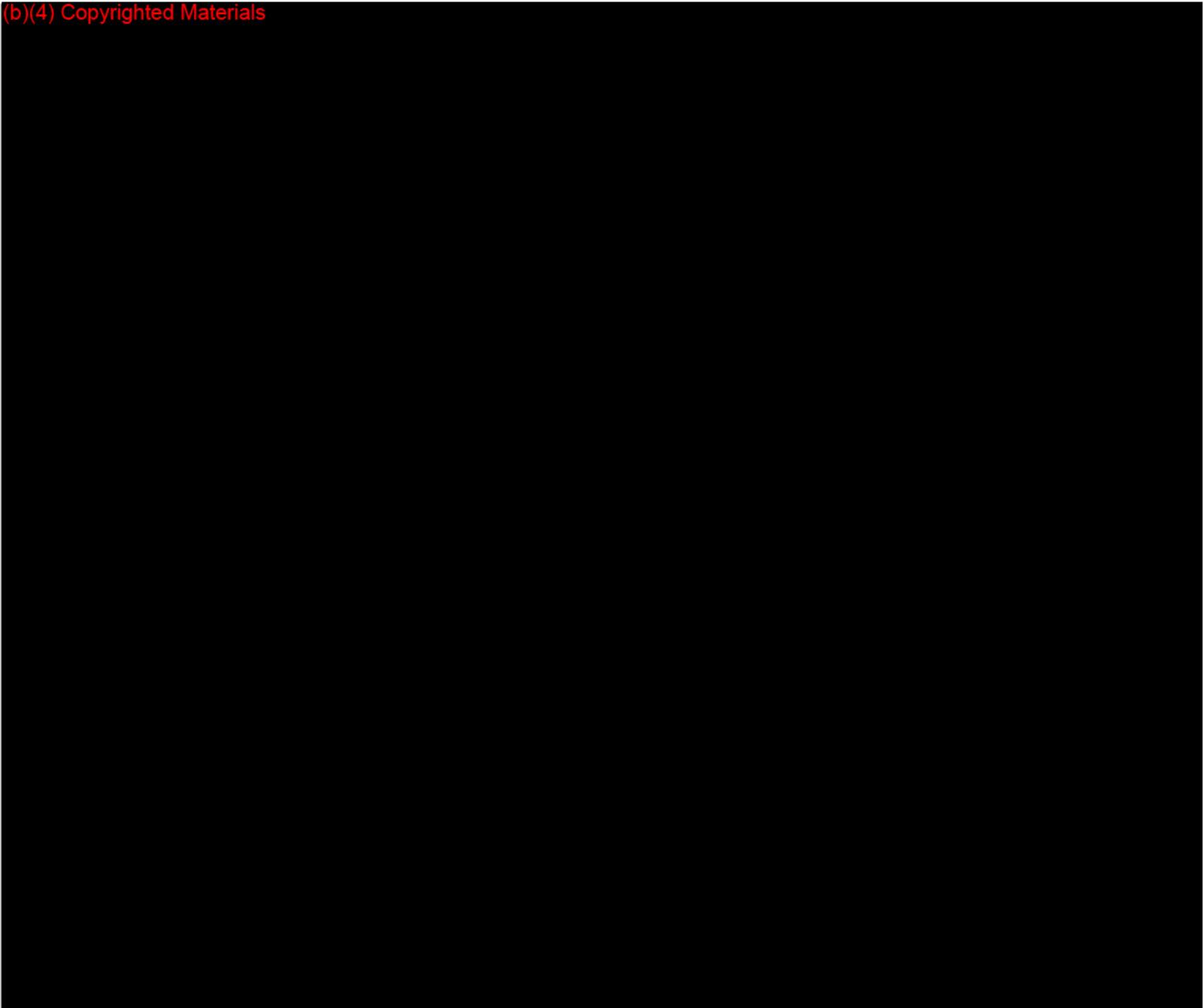




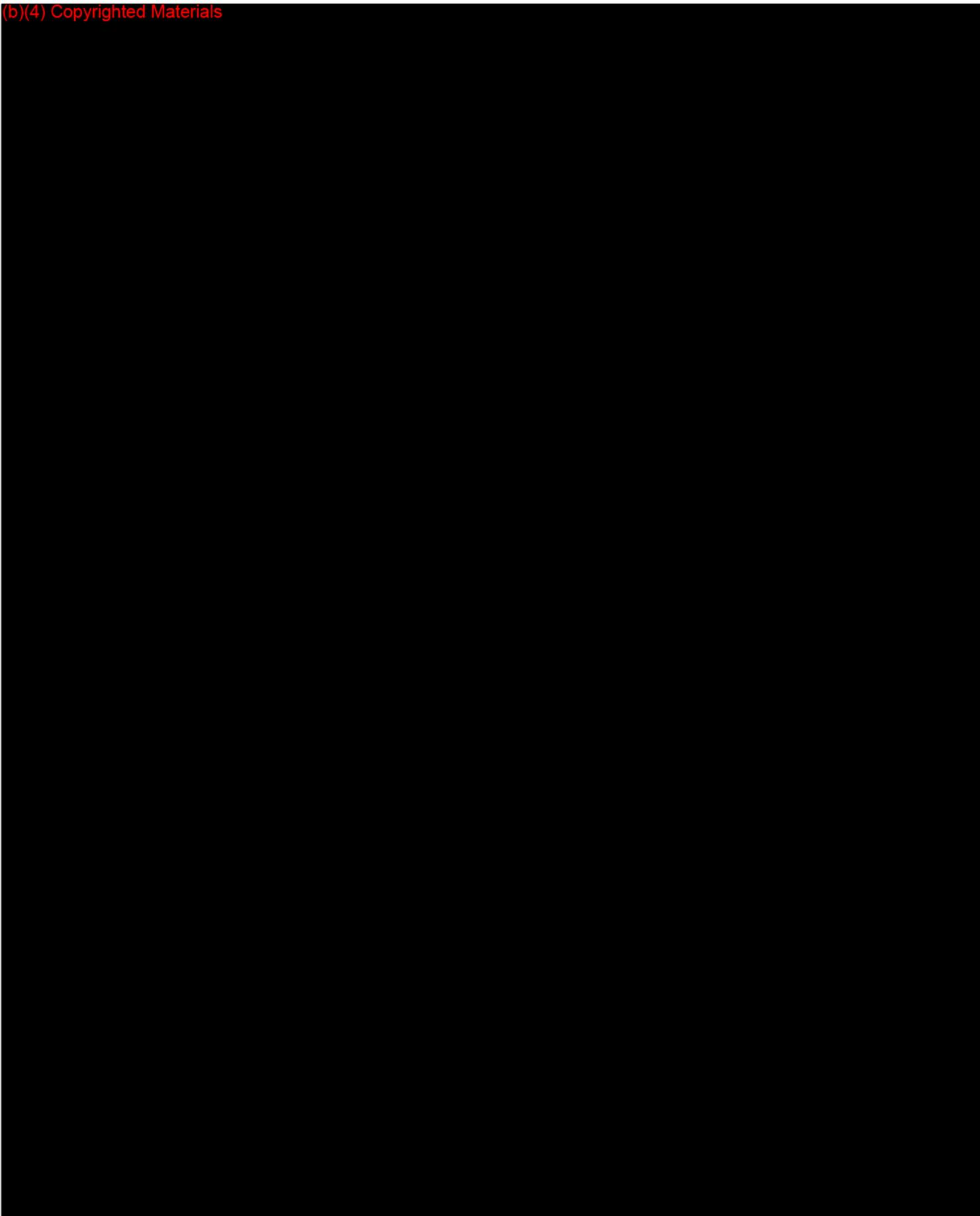
# A Biomechanical Evaluation of an Anatomical Coracoclavicular Ligament Reconstruction

Augustus D. Mazzocca,\* MD, Stephen A. Santangelo, Sean T. Johnson, MD, Clifford G. Rios, MD, Mark L. Dumonski, MD, and Robert A. Arciero, MD  
*From the University of Connecticut Health Center, Farmington, Connecticut*

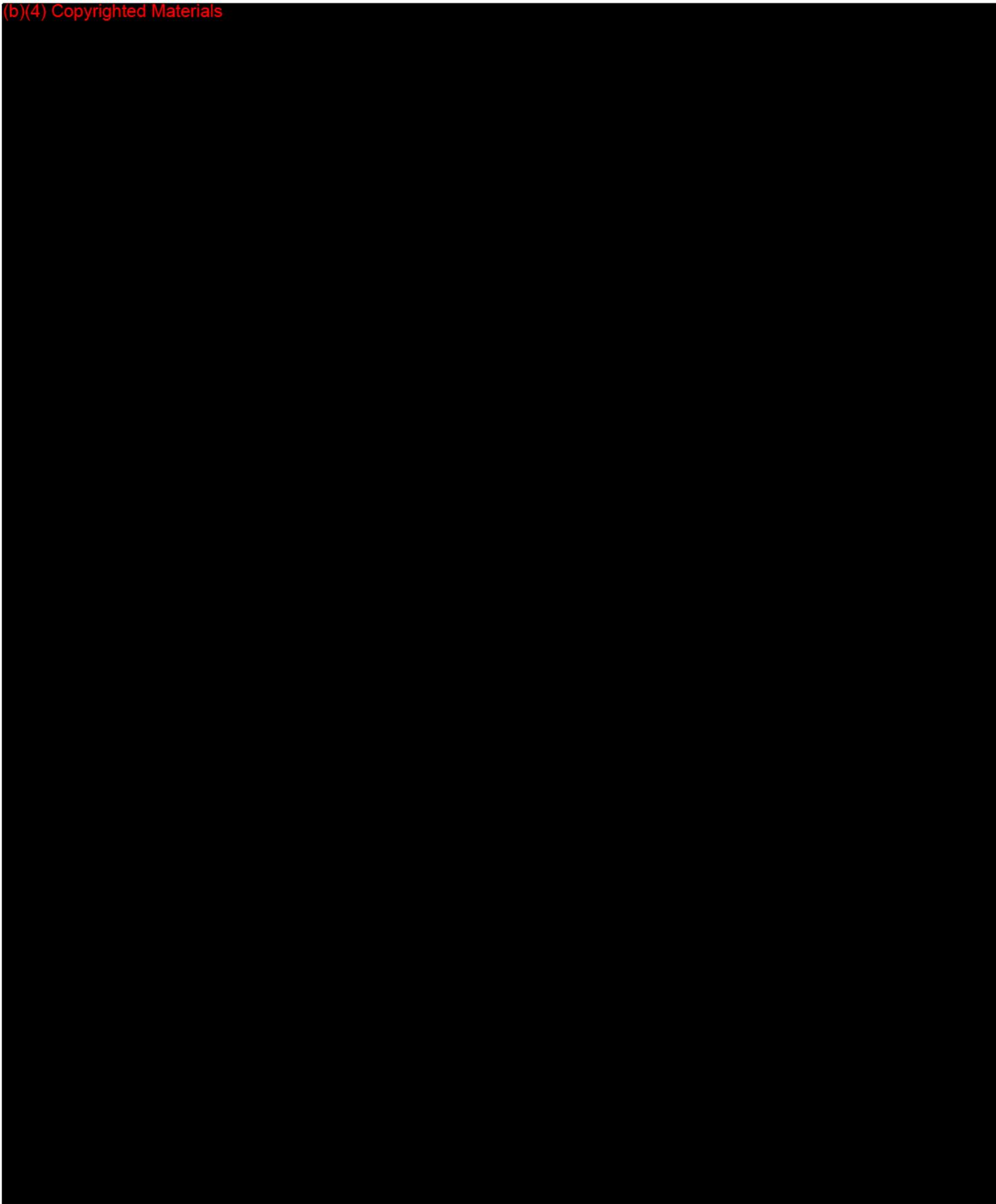
(b)(4) Copyrighted Materials



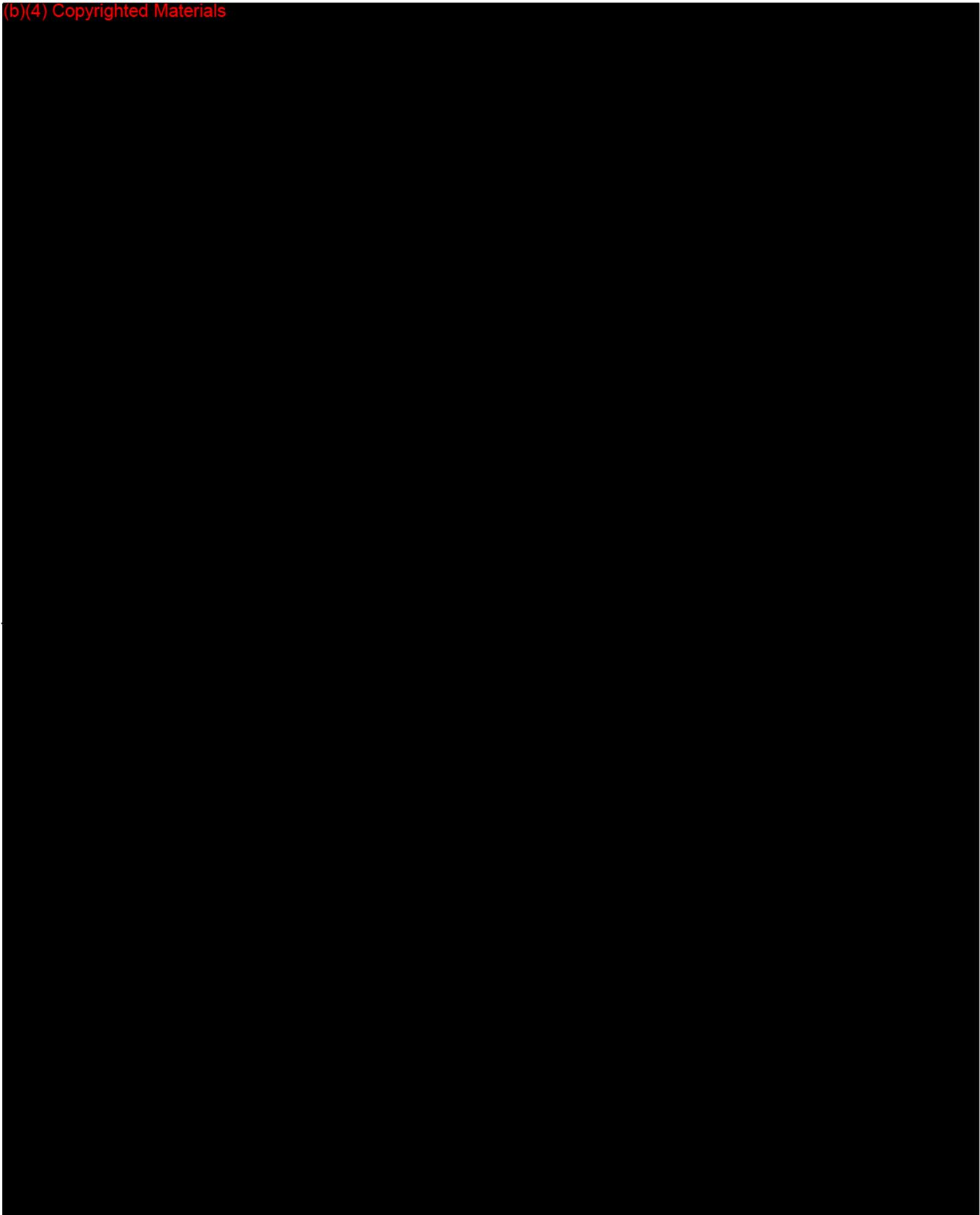
(b)(4) Copyrighted Materials



(b)(4) Copyrighted Materials

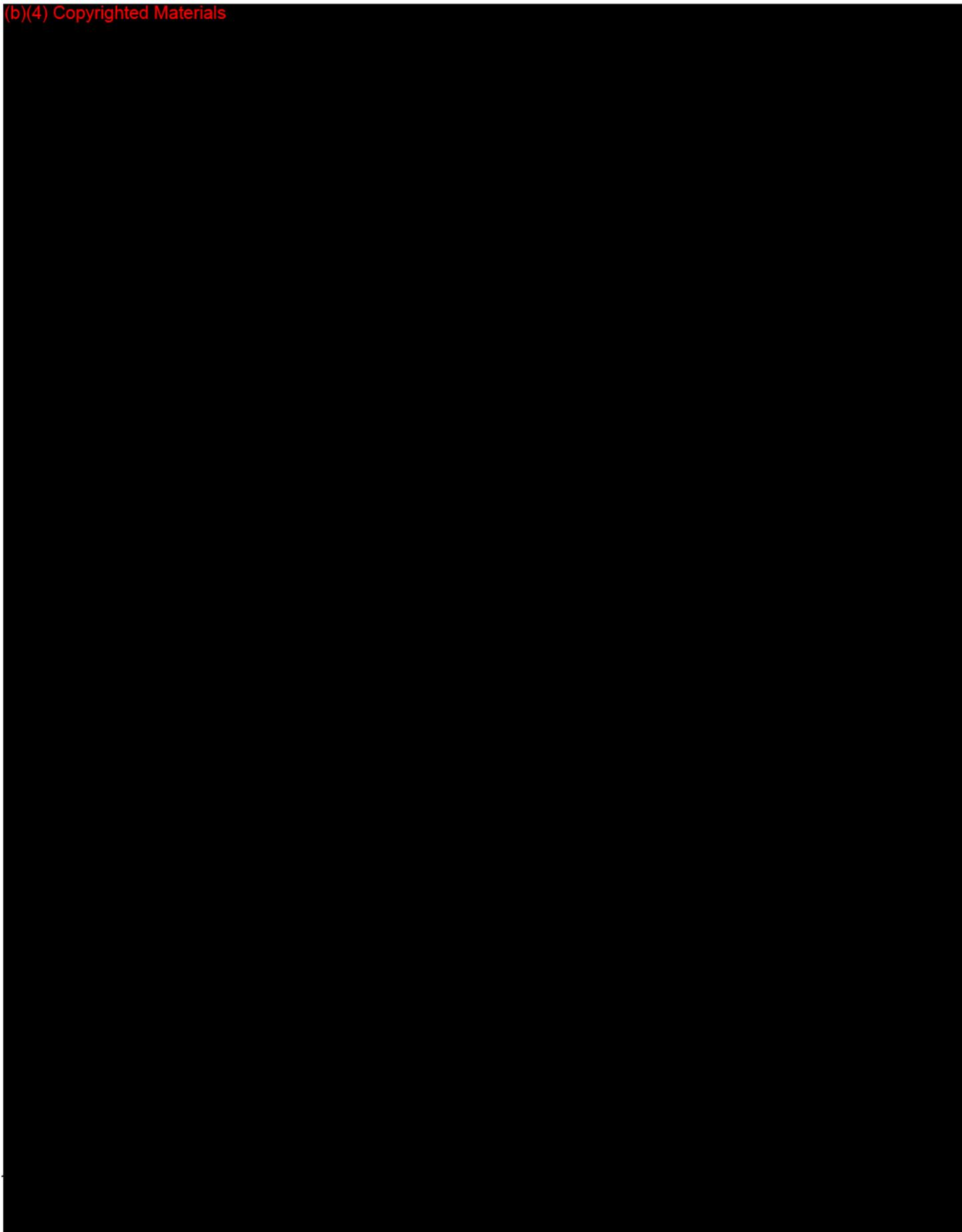


(b)(4) Copyrighted Materials

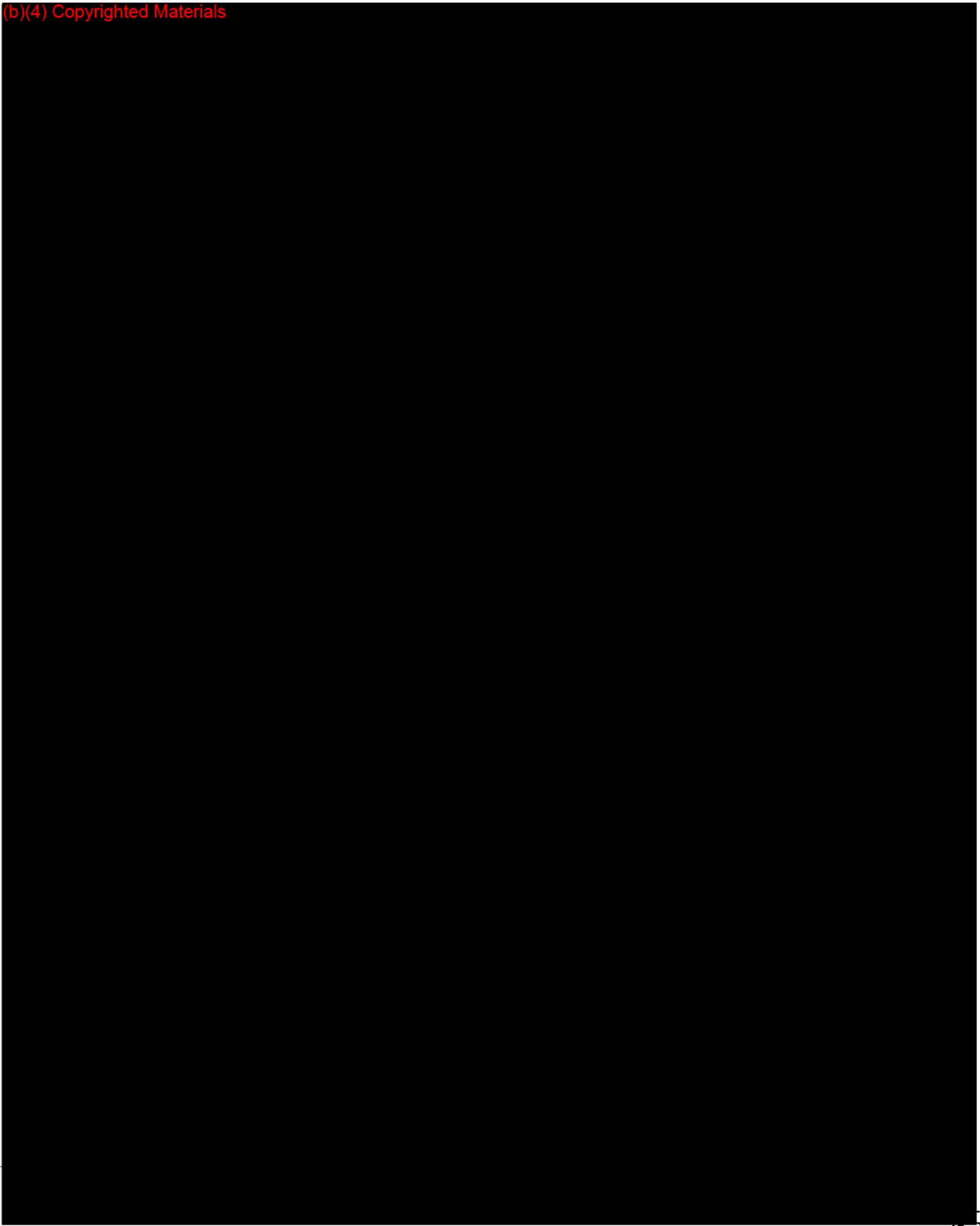


66

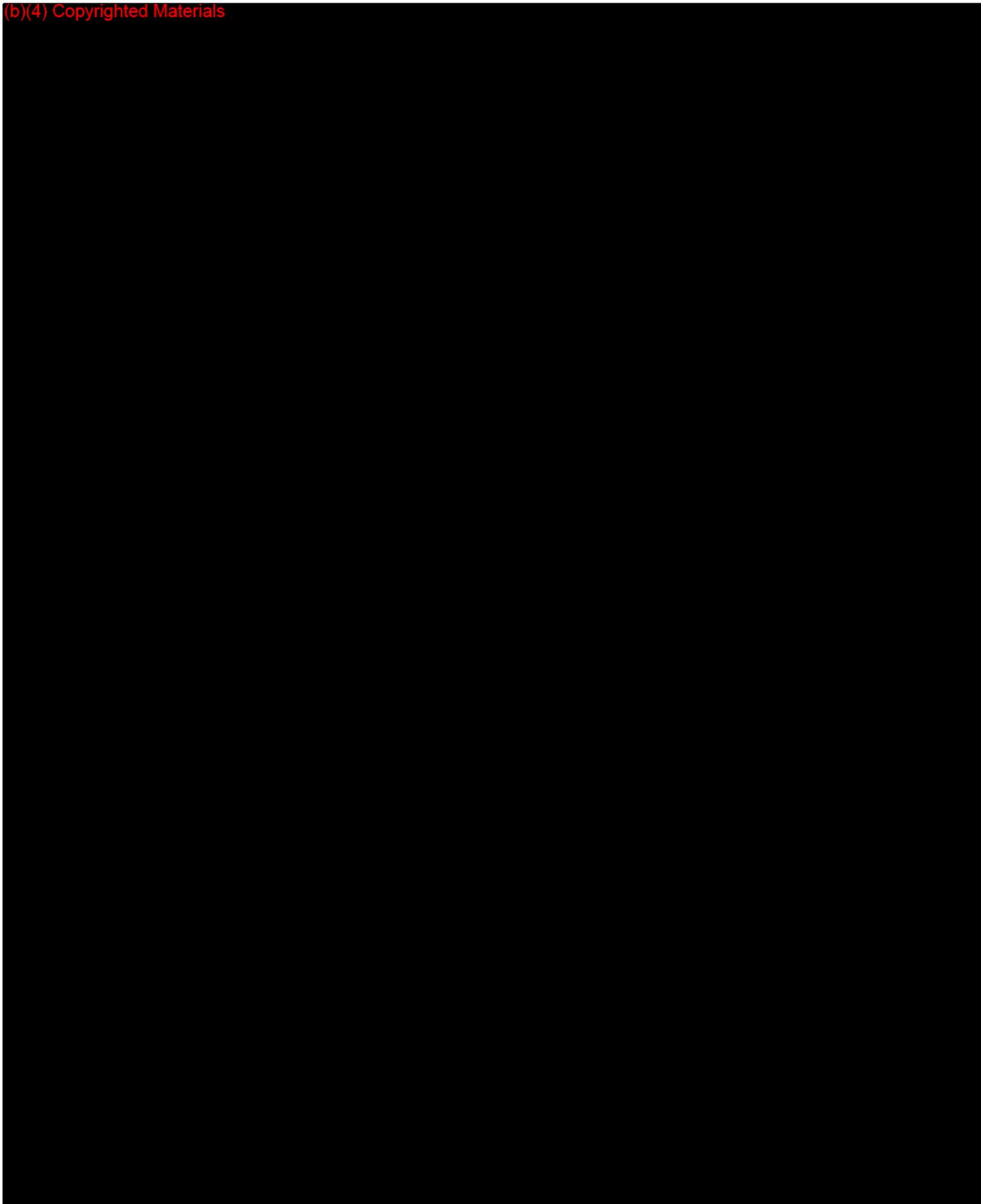
(b)(4) Copyrighted Materials



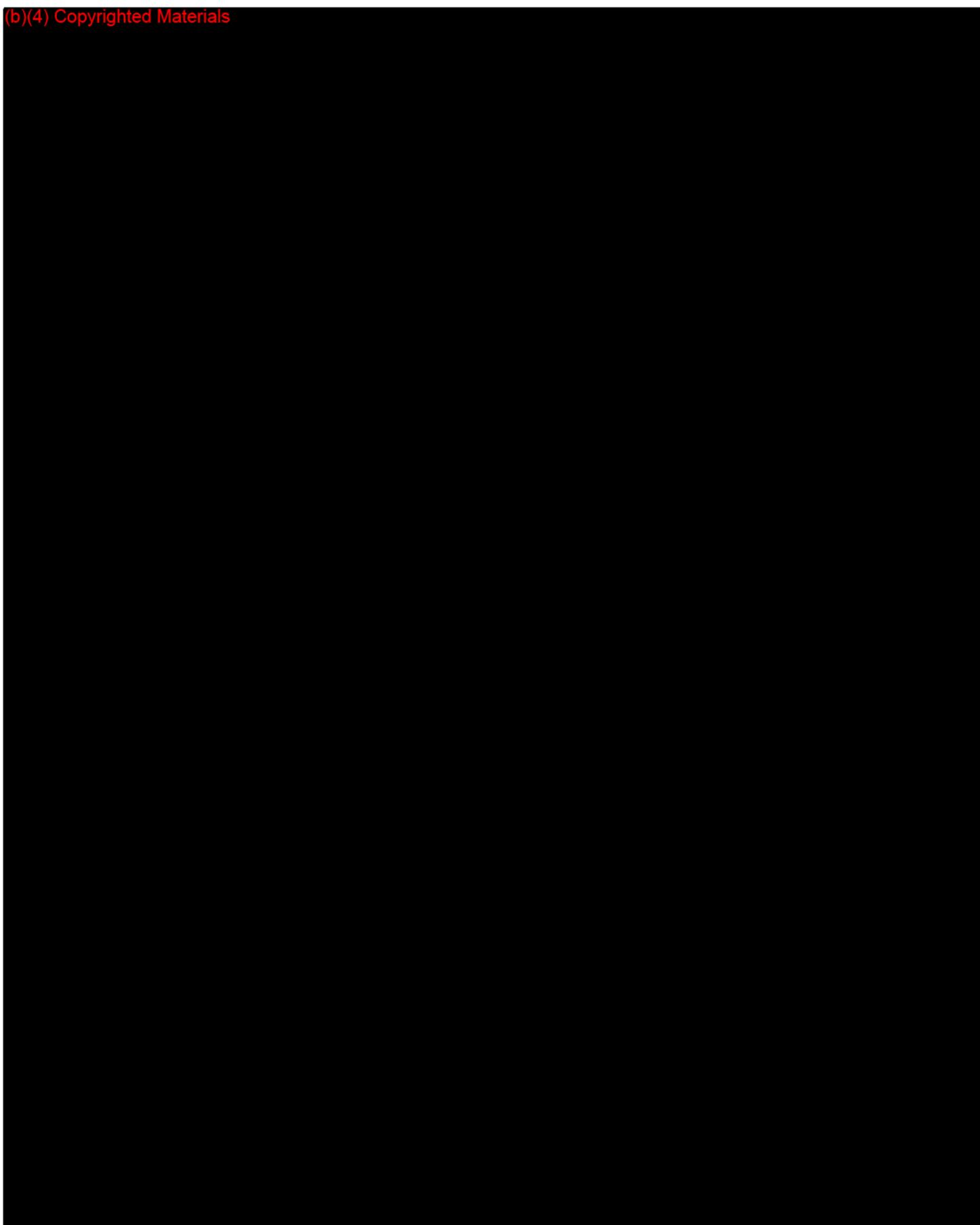
(b)(4) Copyrighted Materials



(b)(4) Copyrighted Materials



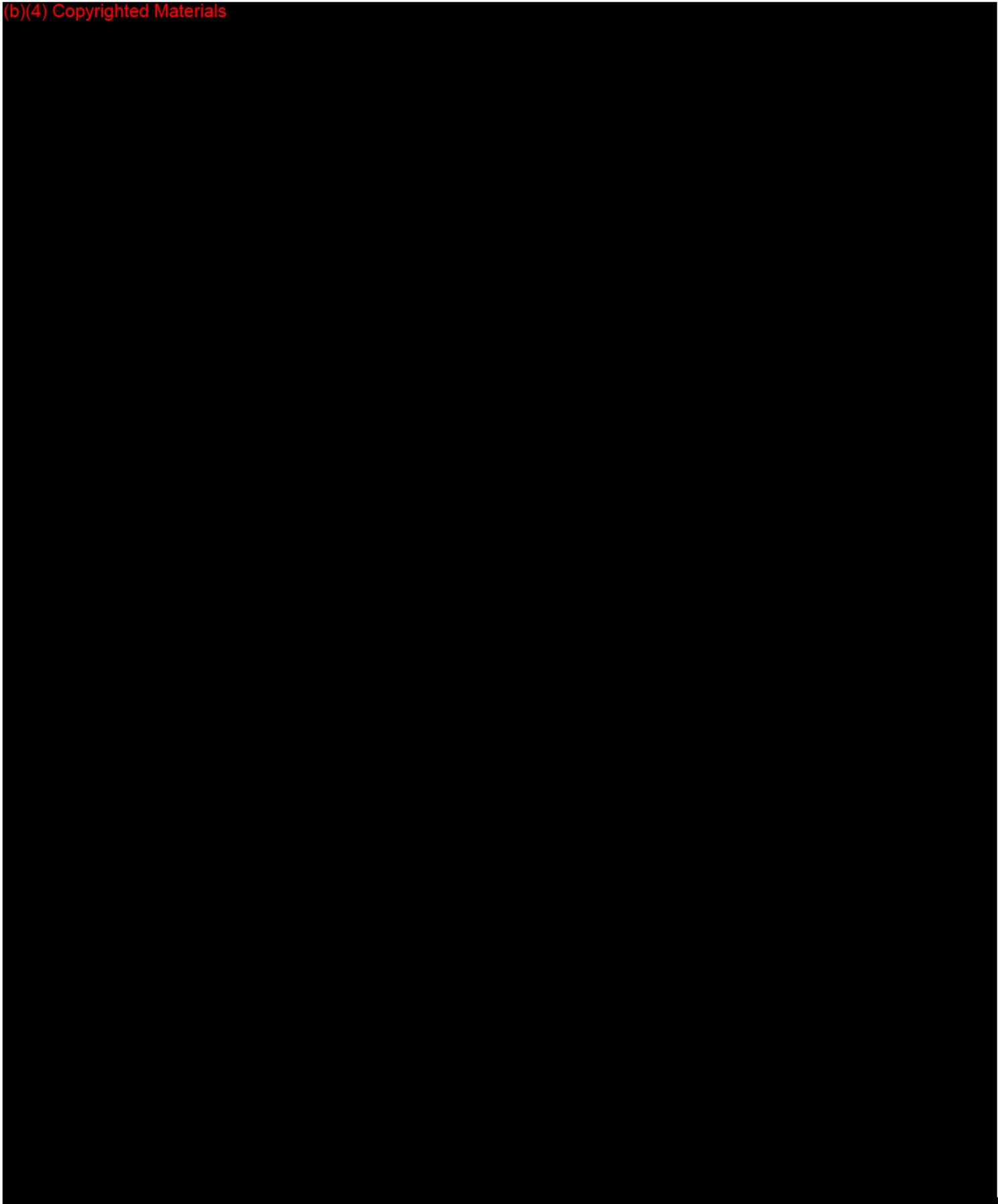
69



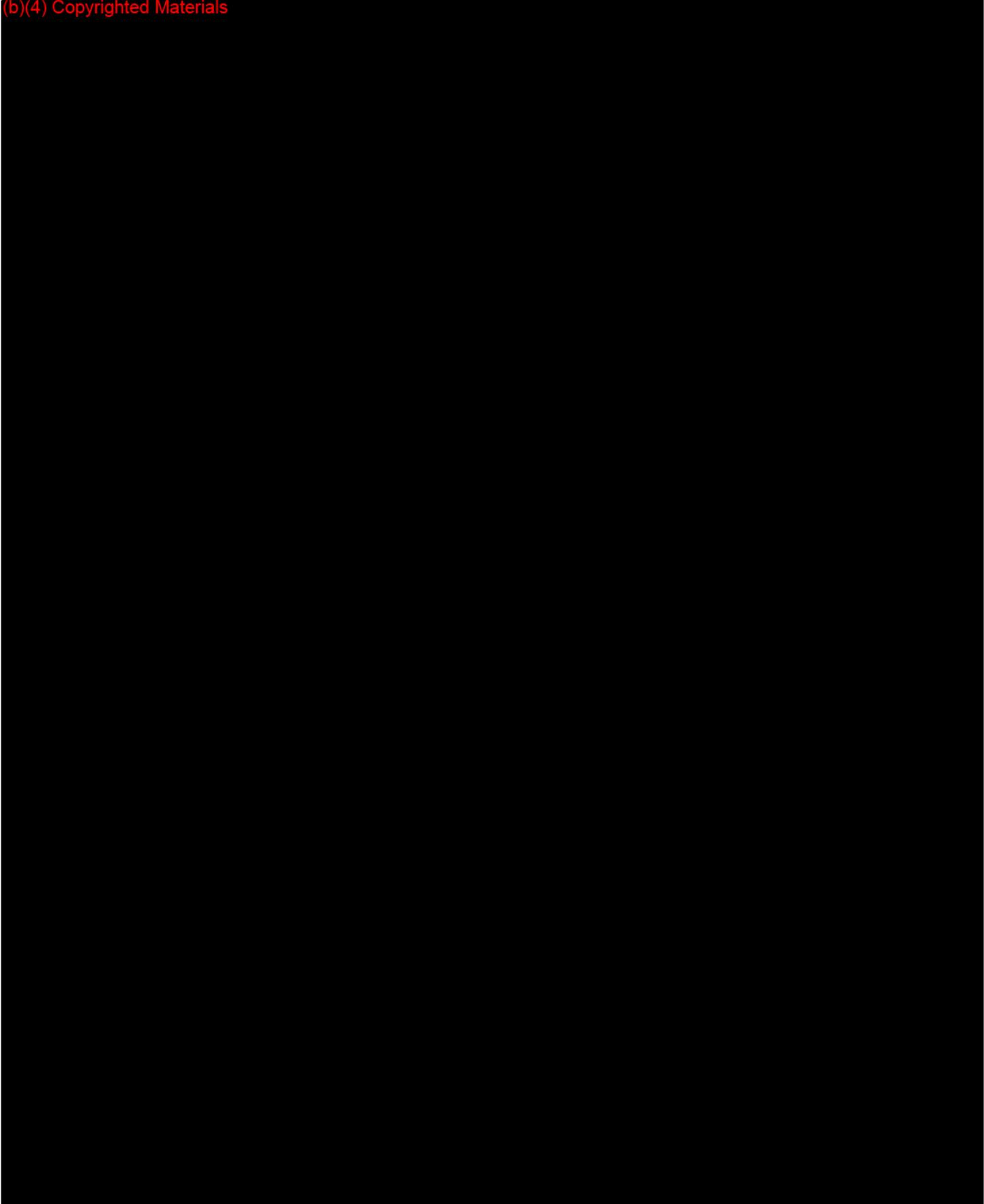
(b)(4) Copyrighted Materials

10

(b)(4) Copyrighted Materials



(b)(4) Copyrighted Materials



(b)(4) Copyrighted Materials



# The American Journal of Sports Medicine

<http://ajs.sagepub.com/>

---

## TightRope Versus Fiber Mesh Tape Augmentation of Acromioclavicular Joint Reconstruction : A Biomechanical Study

Chad C. Zooker, Brent G. Parks, Kacey L. White and Richard Y. Hinton  
*Am J Sports Med* 2010 38: 1204 originally published online April 14, 2010  
DOI: 10.1177/0363546509359064

The online version of this article can be found at:  
<http://ajs.sagepub.com/content/38/6/1204>

---

Published by:



<http://www.sagepublications.com>

On behalf of:



American Orthopaedic Society for Sports Medicine

**Additional services and information for *The American Journal of Sports Medicine* can be found at:**

**Email Alerts:** <http://ajs.sagepub.com/cgi/alerts>

**Subscriptions:** <http://ajs.sagepub.com/subscriptions>

**Reprints:** <http://www.sagepub.com/journalsReprints.nav>

**Permissions:** <http://www.sagepub.com/journalsPermissions.nav>

>> Version of Record - May 28, 2010

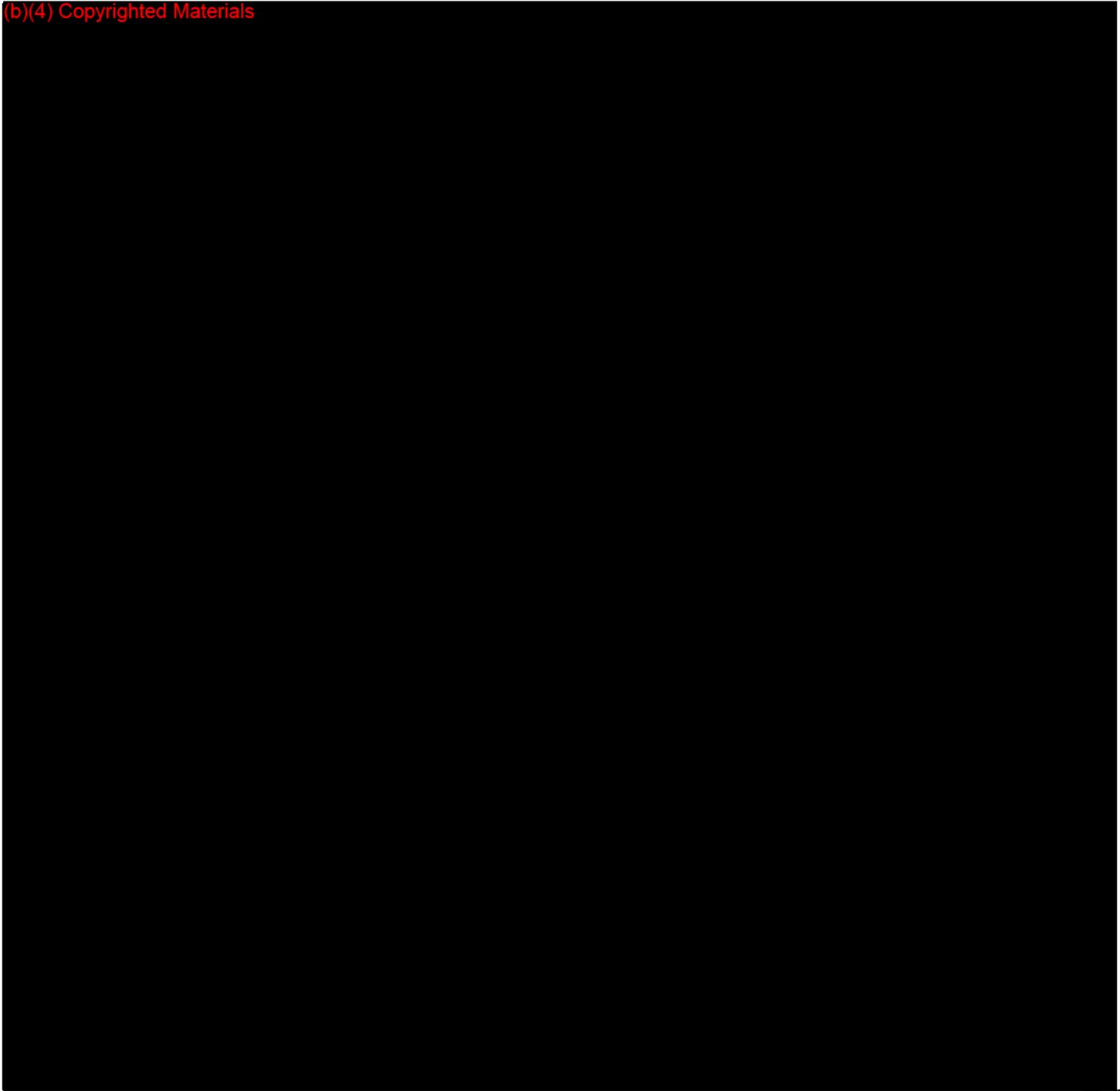
Proof - Apr 14, 2010

What is This?

# TightRope Versus Fiber Mesh Tape Augmentation of Acromioclavicular Joint Reconstruction

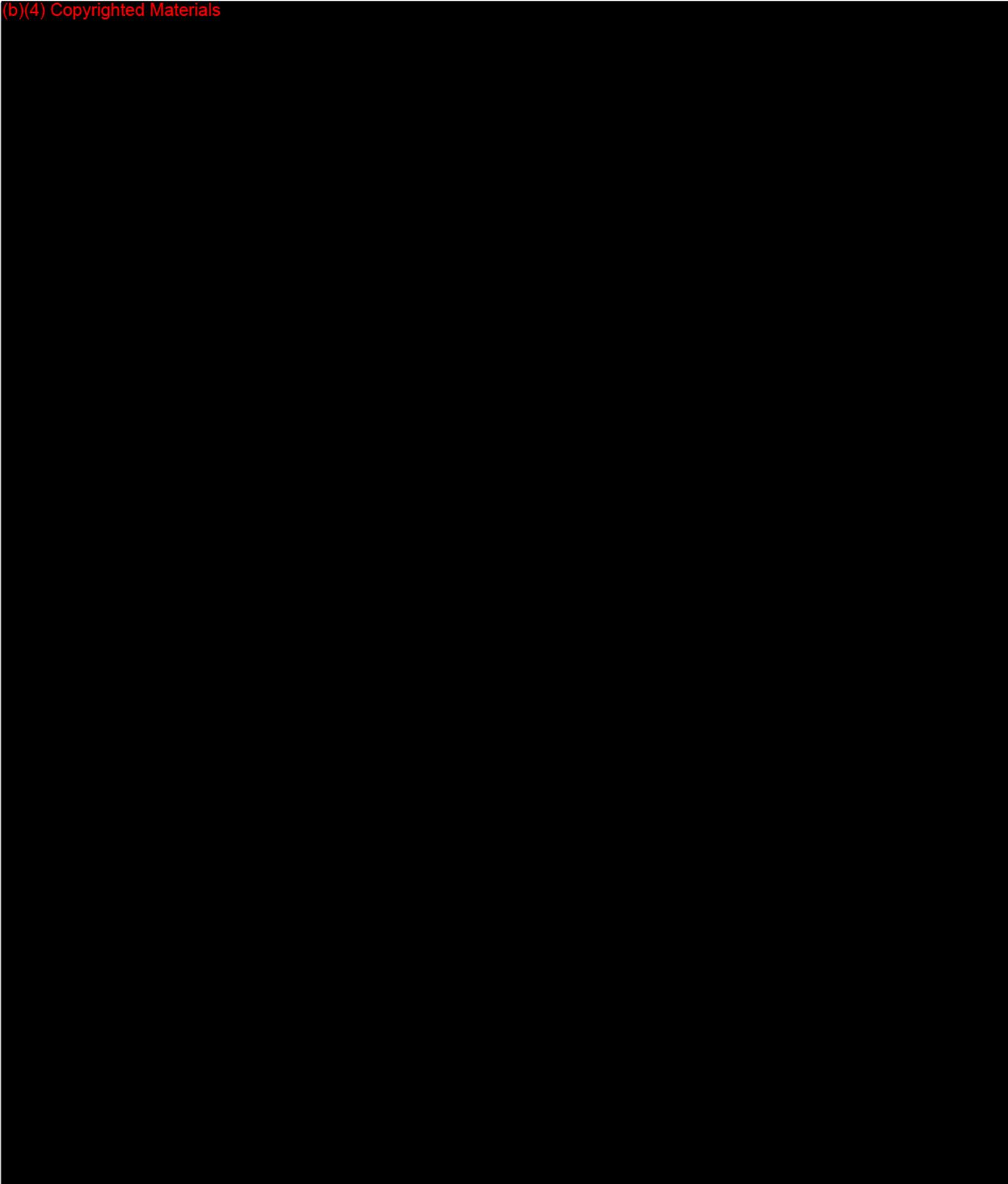
## A Biomechanical Study

(b)(4) Copyrighted Materials

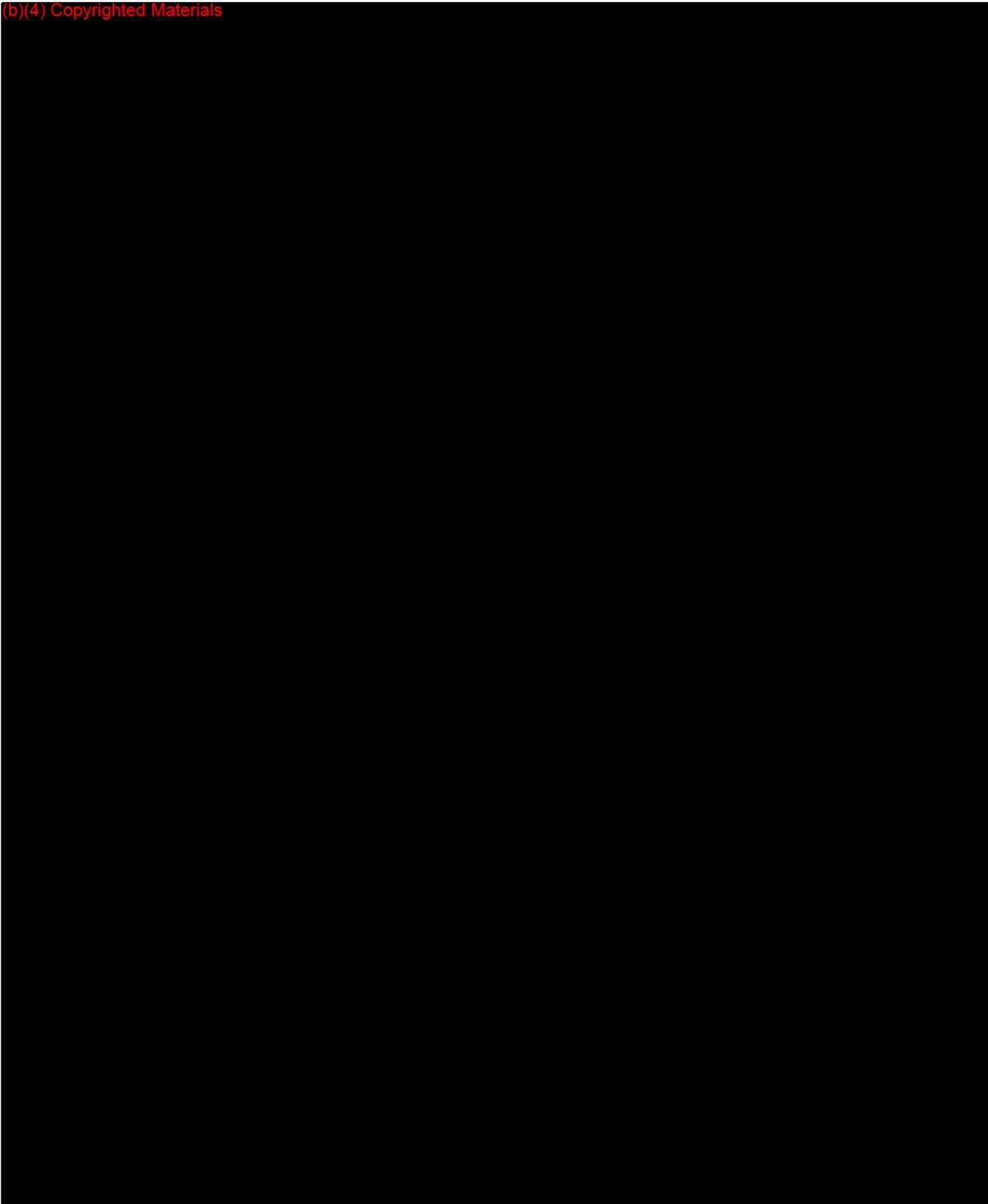


15

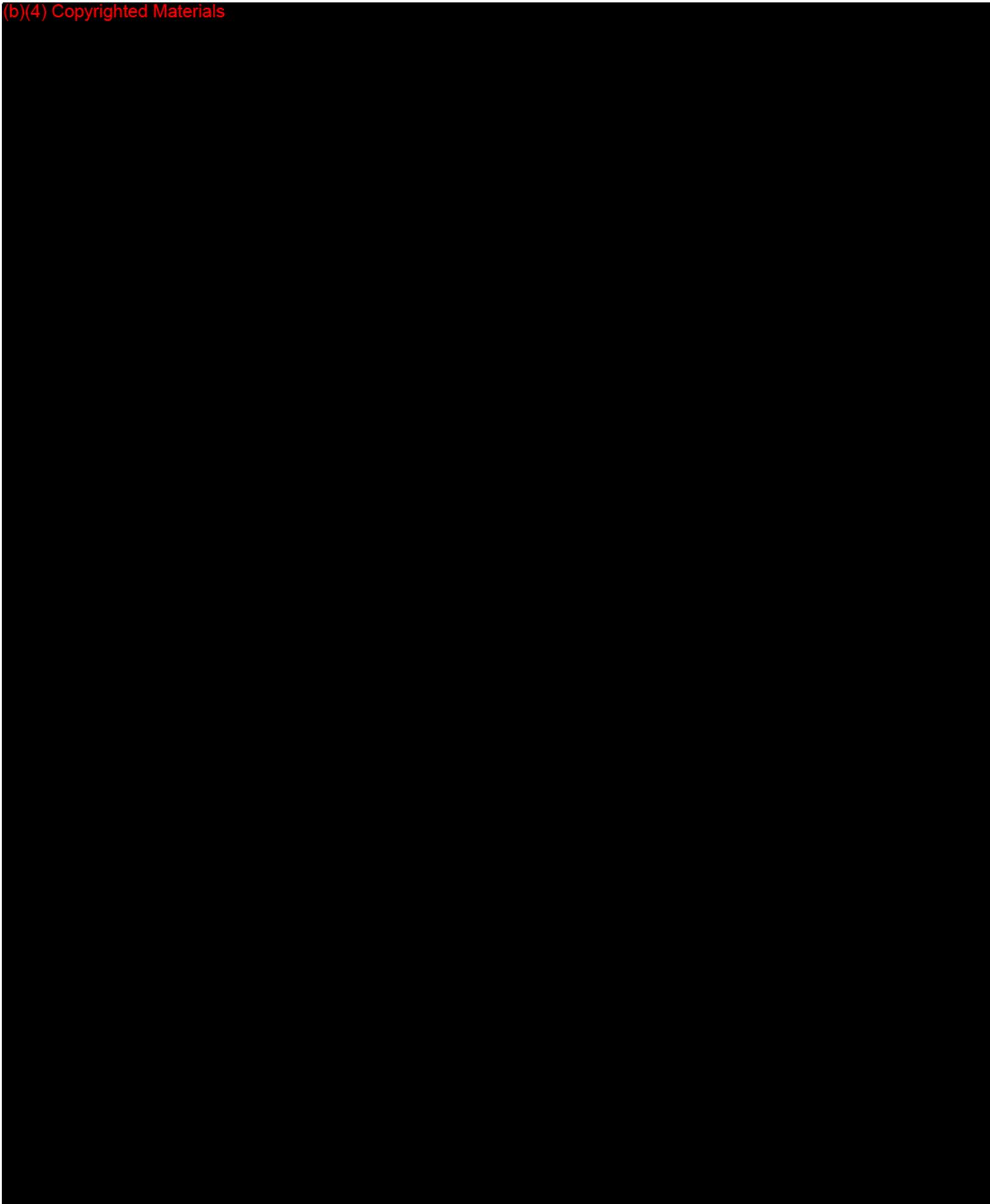
(b)(4) Copyrighted Materials



(b)(4) Copyrighted Materials

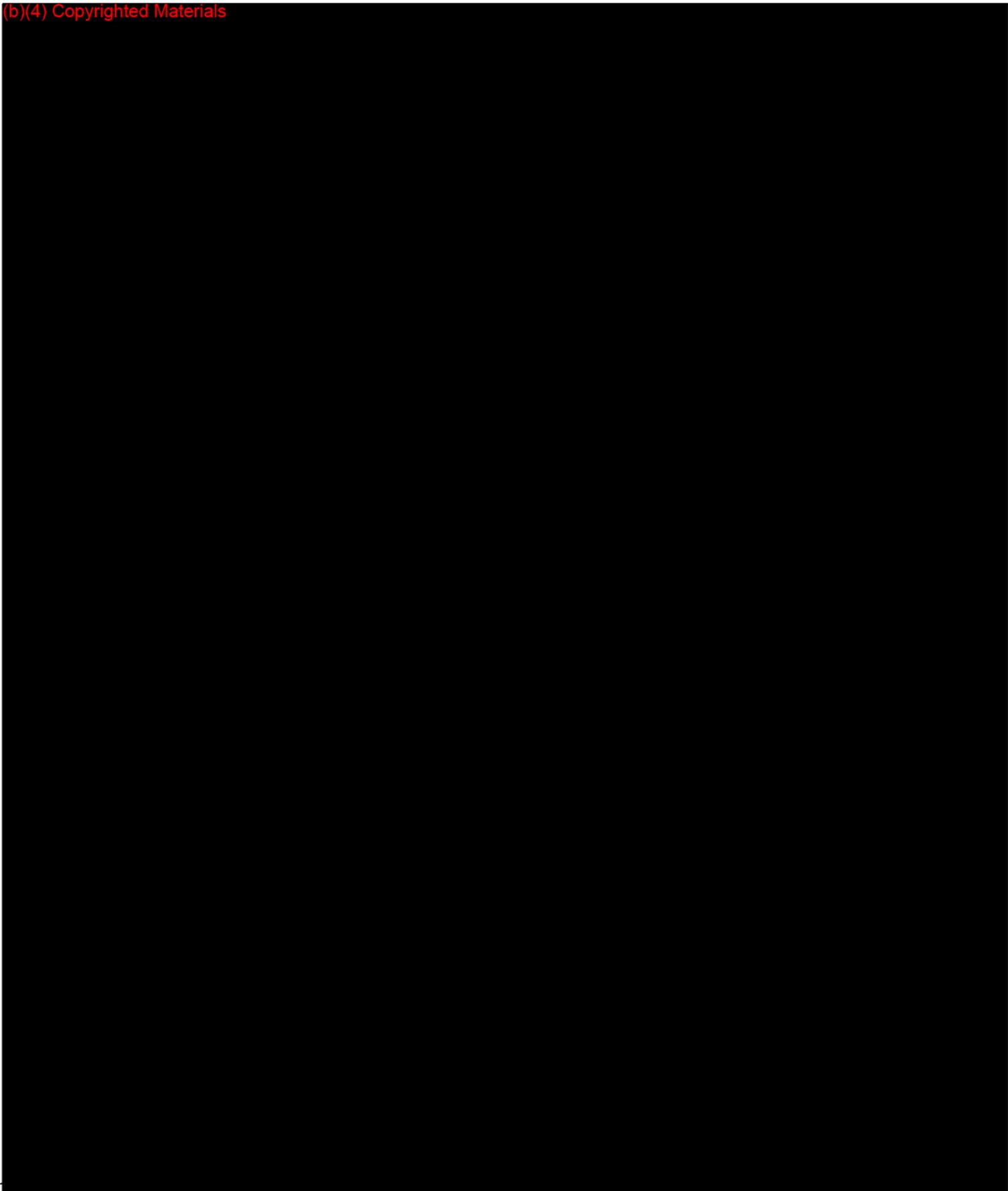


(b)(4) Copyrighted Materials



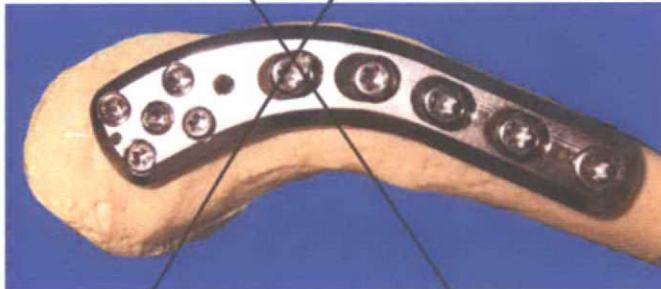
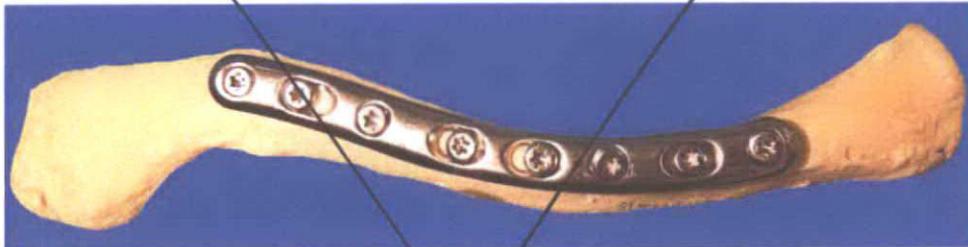
78

(b)(4) Copyrighted Materials



*Please see A1  
ECF*

# Arthrex Clavicle Plate and Screw System



## Technique Guide

80

Please see All  
1/1/15

K112437, Arthrex Fracture System, Response to Deficiency - December 13, 2015 Appendix 2

## Indications

The **Arthrex Fracture System** is intended to be used for internal bone fixation for bone fractures, fusions, osteotomies and non-unions in the ankle, foot, hand, wrist, clavicle, scapula, olecranon, humerus, radius, ulna, tibia, calcaneus, femur and fibula. The Arthrex Fracture Plates are to be used with the 2.7mm-4.0mm Arthrex Low Profile Screws.

The **Clavicle Plate Button** is intended for use with the clavicle plates for clavicle indications such as for the treatment of syndesmotic trauma, such as acromioclavicular and/or coracoclavicular ligament disruption, and this button may not be used alone. The button is intended to be used with #5 FiberWire or FiberTape.

## Patient Positioning

The patient is placed on the OR table. The beach chair position is recommended. The affected extremity is prepped and draped free in the normal sterile fashion. A roll or pad placed between the shoulder blades allows retraction to aid in reduction. An arm holder can also be very helpful to maintain the position of the injured extremity.

## Surgical Approach

Make a 3-5 cm horizontal incision over the superior clavicle. Subcutaneous dissection allows for identification of supraclavicular nerve branches.

Please see A  
SLP

K112437, Arthrex Fracture System, Response to Deficiency - December 13, 2011 Appendix 2

## Fracture Reduction

Reduce the fracture and use fluoroscopy to confirm reduction. Using reduction forceps can be very helpful in maintaining reduction.

## Plate Selection

Select the appropriate plate to match the patient anatomy. The plates are pre-contoured to reduce the need to bend. If contouring the plate is necessary, use the appropriate plate benders.

## Plate Placement

Place the plate onto the reduced clavicle and temporarily attach it to the bone using K-wires, BB-Taks or plate holding forceps.



*Please see A1*

K112437, Arthrex Fracture System, Response to Deficiency - December 13, 2011 Appendix 2

## Screw Insertion

### Nonlocking Screw Insertion

Place the 3.5/ 2.5 mm Drill Guide into the appropriate plate slot and prepare a hole using the 2.5 mm Drill Bit. If drilling bicortically, place a retractor under the clavicle to protect the neurovascular structures.



Measure for screw length using the Screw Depth Gauge.



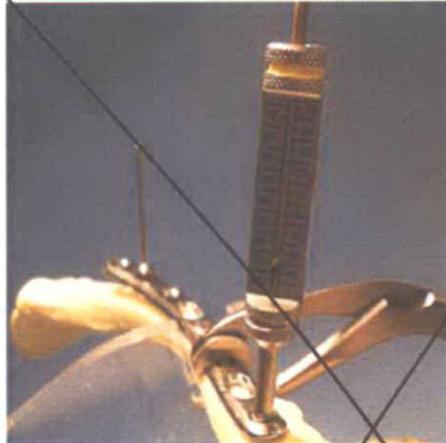
Select appropriate 3.5 mm or 4.0 mm screw and insert using the hexalobe screwdriver.



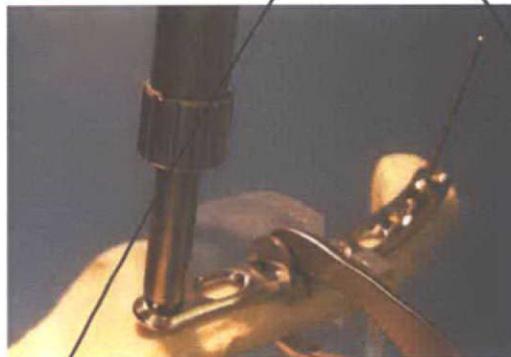
*Please see A1*

## Locking Screw Insertion

Place the 3.5 mm Threaded Drill Guide into the appropriate locking hole and prepare a hole using the 2.5 mm Calibrated Drill Bit. Read the corresponding screw length from the line on the drill bit.



Alternately the Screw Depth Gauge may be used to determine screw length.



Select appropriate 3.5 mm locking screw and insert using the hexalobe screwdriver.

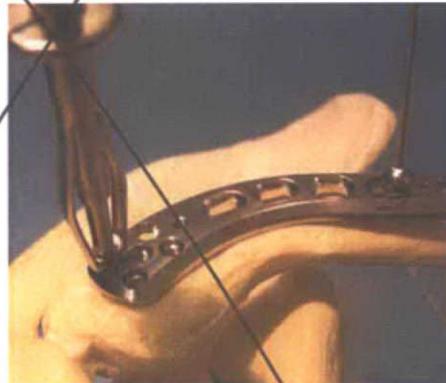
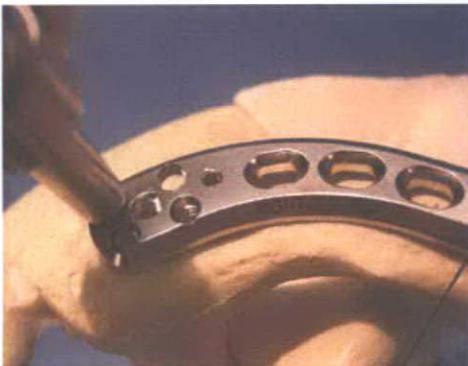


*Please see A1*

K112437, Arthrex Fracture System, Response to Deficiency - December 13, 2015 Appendix 2

## Locking Screw Insertion for 2.7mm Screws

Place a K-wire in the distal end of the plate. Slide the appropriate Drill Guide over the K-wire and thread it into the locking hole. Use the 2.0 mm Calibrated Drill and drill to the desired depth. Use the Depth Gauge to determine the screw length. Select the appropriate 2.7 mm screw and insert using the hexalobe screwdriver.



### Alternate Method:

Thread the 2.7 mm Threaded Drill Guide into a 2.7 mm locking hole until fully seated. Use the 2.0 mm Calibrated Drill and drill to the desired depth. Read the corresponding screw length from the line on the drill bit. Select the appropriate 2.7 mm screw and insert using the hexalobe screwdriver.



*85*

Please see A1.

K112437, Arthrex Fracture System, Response to Deficiency - December 13, 2015 Appendix 2

## Distal Clavicle Plate Button Fixation

Insert screws as previously described. Determine which plate slot will be used for the Distal Clavicle Plate Button. This slot should be left vacant of any screws.

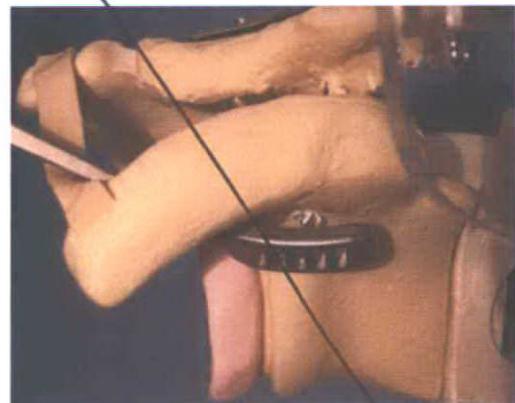
Use an elevator or a radio-frequency device to define the lateral and medial aspect of the coracoid process. Place the appropriate AC Guide underneath the lateral side of the coracoid, seating it as close to the base of the coracoid as possible.



### Alternate Method

Place blunt retractors medially and laterally under the coracoid process to protect the neurovascular structures. A nemostat or other blunt instrument can be placed on the lateral side underneath the coracoid process to feel the transition to the neck of the glenoid and the anterior scapula. The 3 mm Cannulated Reamer should exit underneath the coracoid at the identified transition zone.

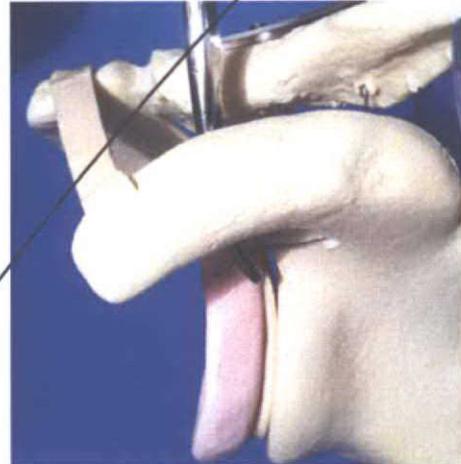
Place the 3 mm Drill Guide in the identified plate slot and using the 3 mm Cannulated Reamer, drill through all four cortices, exiting underneath the coracoid. Fluoroscopy may be used to verify tunnel placement.



*Please see A1.*

K112437, Arthrex Fracture System, Response to Deficiency - December 13, 2011 Appendix 2

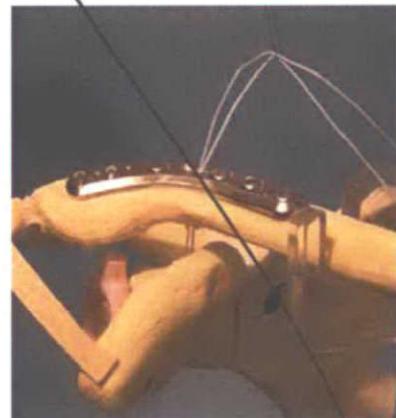
Remove the guide arm or retractors from under the coracoid. Remove the trocar from the cannulated reamer. Pass a Nitinol wire through the cannulation and using a hemostat or other grasping instrument, retrieve the wire from under the coracoid.



Attach a Dog Bone Button to a strand of FiberTape or FiberWire, making sure that the concavity of the button will seat against the base of the coracoid.



Shuttle the suture limbs retrograde through the coracoid and clavicle.

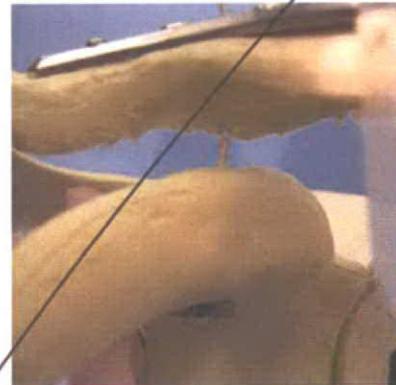


*87*

*Please see AL  
ELF*

K112437, Arthrex Fracture System, Response to Deficiency - December 13, 2011 Appendix 2

Pull suture limbs so the Dog Bone Button seats at the base of the coracoid. Confirm placement under the coracoid using fluoroscopy.



Insert both suture limbs through the Distal Clavicle Plate Button and reduce the button to the plate. The button should seat flush with the plate.



Tie a knot over the button with the suture limbs. Cut the excess limbs, making sure to leave a sufficient tail.



### Confirm Reduction and Fixation

Confirm the final reduction and plate and screw fixation both visually and with fluoroscopy.

*88*

*Please see A1  
SLP*

K112437, Arthrex Fracture System, Response to Deficiency - December 13, 2011 Appendix 2

## **Plate and Screw Removal**

If the plate and screws need to be removed, make an incision over the clavicle. Use the appropriate screw driver to remove each screw.

To remove the Distal Clavicle Plate Button, cut the sutures and remove the button from the plate slot. Reach under the coracoid laterally with a hemostat or other grasping instrument to remove the Dog Bone Button.

*89*

AI

plea

# 1 Indications for Use Form

## Indications for Use

510(k) Number (if known): \_\_\_\_\_

Device Name: *Arthrex Fracture System*

### Indications For Use:

The *Arthrex Fracture System* is intended to be used for internal bone fixation for bone fractures, fusions, osteotomies and non-unions in the ankle, foot, hand, wrist, clavicle, scapula, olecranon, humerus, radius, ulna, tibia, calcaneous, femur and fibula. The Arthrex Fracture Plates are to be used with the 2.7mm-4.0mm Arthrex Low Profile Screws.

The *Clavicle Plate Button* is intended for use with the clavicle plates for clavicle indications such as for the treatment of syndesmotic trauma, such as acromioclavicular and/or coracoclavicular ligament disruption, and this button may not be used alone. The button is intended to be used with #5 FiberWire or FiberTape.

Prescription Use  AND/OR Over-The-Counter Use \_\_\_\_\_  
(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

PAGE 1 of 1

90

Please see A1

## 2 510(k) Summary of Safety and Effectiveness

<b>Date Summary Prepared</b>	November 29, 2011
<b>Manufacturer/Distributor/Sponsor</b>	Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA
<b>510(k) Contact</b>	Courtney Smith Manager, Regulatory Affairs Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA Telephone: 239/643.5553, ext. 1720 Fax: 239/598.5508 Email: <a href="mailto:csmith@arthrex.com">csmith@arthrex.com</a>
<b>Trade Name</b>	<b>Arthrex Fracture System</b>
<b>Common Name</b>	Plate, fixation, bone
<b>Product Code -Classification Name CFR</b>	HWC, HRS, HTN 21 CFR 888.8030: Single/multiple component metallic bone fixation appliances and accessories 21/CFR 888.3040: Smooth or threaded metallic bone fixation fastener.
<b>Predicate Device</b>	<i>K011335</i> : Synthes One-Third Tubular Plates <i>K102998</i> : Acumed Congruent Bone Plate System <i>K043248 / K052776</i> : Arthrex TightRope Syndesmosis and Acromioclavicular (AC) Devices <i>K103705 / K111253</i> : Arthrex Low Profile Screws
<b>Device Description and Intended Use</b>	<p>The <b>Arthrex Fracture System</b> is a family of stainless steel plates, screws, and buttons. The plates may be contoured or straight and may be available in left and right configurations. The plates are to be used with the 2.7mm-4.0mm Low Profile Screws. The screws are solid and fully threaded and may be locking or non-locking. The button is stainless steel and designed to fit securely in the holes of the fracture plates. The button is intended to be used with the previously cleared suture, which is provided separately.</p> <p>The <b>Arthrex Fracture System</b> is intended to be used for internal bone fixation for bone fractures, fusions, osteotomies and non-unions in the ankle, foot, hand, wrist, clavicle, scapula, olecranon, humerus, radius, ulna, tibia, calcaneous, femur and fibula. The Arthrex Fracture Plates are to be used with the 2.7mm-4.0mm Arthrex Low Profile Screws.</p> <p>The <b>Clavicle Plate Button</b> is intended for use with the clavicle</p>

Please see A1

	<p>plates for clavicle indications such as for the treatment of syndesmotic trauma, such as acromioclavicular and/or coracoclavicular ligament disruption, and this button may not be used alone. The button is intended to be used with #5 FiberWire or FiberTape.</p>
<p><b>Substantial Equivalence Summary</b></p>	<p>The Arthrex Fracture System is substantially equivalent to the predicate Synthes One-Third Tubular Plates (K011335), Acumed Congruent Bone Plate System (K102998), Arthrex TightRope Syndesmosis and Acromioclavicular (AC) Devices (K043248 / K052776), and the cleared Arthrex Low Profile Screws (K103705, K111253) in which the basic features and intended uses are the same. Any differences between the <b>Fracture System</b> and the predicates are considered minor and do not raise questions concerning safety and effectiveness.</p> <p>The proposed devices are composed of Stainless Steel which is substantially equivalent to the predicate devices.</p> <p>The submitted mechanical testing data demonstrated that the bending and pull-out strength of the proposed devices are substantially equivalent to the bending and pull-out strength of the predicate devices.</p> <p>Based on the indication for use, technological characteristics, and the comparison to the predicate devices, Arthrex, Inc. has determined that the <b>Fracture System</b> is substantially equivalent to currently marketed predicate devices.</p>

A1

# Arthrex Fracture Plates

DFU-0xxx

Draft 0

## A. DEVICE DESCRIPTION

Plates are available in different shapes, sizes and orientations (e.g. left and right types). The plates have specific sized holes for screws to provide fixation.

The Distal Clavicle Plate Button is designed to fit securely in the holes of the fracture plates. i

## B. INDICATIONS

The **Arthrex Fracture Plates** are s intended to be used for internal bone fixation for bone fractures, fusions, osteotomies and non-unions in the ankle, foot, hand, wrist, clavicle, scapula, olecranon, humerus, radius, ulna, tibia, calcaneous, femur and fibula. The Arthrex Fracture Plates are to be used with the 2.7mm-4.0mm Arthrex Low Profile Screws.

The **Clavicle Plate Button** is intended for use with the clavicle plates for clavicle indications such as for the treatment of syndesmotic trauma, such as acromioclavicular and/or coracoclavicular ligament disruption, and this button may not be used alone. The button is intended to be used with FiberWire or FiberTape.

## C. CONTRAINDICATIONS

1. Insufficient quantity or quality of bone.
2. Blood supply limitations and previous infections, which may retard healing.
3. Foreign-body sensitivity. Where material sensitivity is suspected, appropriate tests should be made and sensitivity ruled out prior to implantation.
4. Any active infection or blood supply limitations.
5. Conditions that tend to limit the patient's ability or willingness to restrict activities or follow directions during the healing period.
6. The use of this device may not be suitable for patients with insufficient or immature bone. The physician should carefully assess bone quality before performing orthopedic

93

A1

surgery on patients who are skeletally immature. The use of this medical device and the placement of hardware or implants must not bridge, disturb or disrupt the growth plate.

7. Do not use for surgeries other than those indicated.

#### **D. ADVERSE EFFECTS**

1. Infections, both deep and superficial.
2. Foreign body reactions.

#### **E. WARNINGS**

1. An internal fixation device must never be reused.
2. All metallic implant devices used for this surgical procedure should have the same metallurgical composition.
3. Postoperatively and until healing is complete, fixation provided by this device should be considered as temporary and may not withstand weight bearing or other unsupported stress. The fixation provided by this device should be protected. The postoperative regimen prescribed by the physician should be strictly followed to avoid adverse stresses applied to the device.
4. Pre-operative and operating procedures, including knowledge of surgical techniques and proper selection and placement of the device, are important considerations in the successful utilization of this device. The appropriate Arthrex delivery system is required for proper implantation of the device.
5. Any decision to remove the device should take into consideration the potential risk to the patient of a second surgical procedure. Device removal should be followed by adequate postoperative management.
6. Detailed instructions on the use and limitations of this device should be given to the patient.
7. This is a single use device. Reuse of this device could result in failure of the device to perform as intended and could cause harm to the patient and/or user.
8. The device has not been evaluated for safety and compatibility in the magnetic resonance (MR) environment. The device has not been tested for heating or migration in the MR environment. If the implant is manufactured from a metallic material, surgeons can expect that MR artifacts will be present during routine MR Imaging.

AM

9. Removal of supplemental fixation after healing. If the supplemental fixation is not removed following the completion of its intended use, any of the following complications may occur: (1) Corrosion, with localized tissue reaction or pain; (2) Migration of implant position resulting in injury; (3) Risk of additional injury from postoperative trauma; (4) Bending, loosening, and/or breakage, which could make removal impractical or difficult; (5) Pain, discomfort, or abnormal sensations due to the presence of the device; (6) Possible increased risk of infection; and (7) Bone loss due to stress shielding. The surgeon should carefully weigh the risks versus benefits when deciding whether to remove the implant. Implant removal should be followed by adequate postoperative management to avoid re-fracture.

## F. PRECAUTIONS

1. Surgeons are advised to review the product-specific surgical technique prior to performing any surgery. Arthrex provides detailed surgical techniques in print, video, and electronic formats. The Arthrex website also provides detailed surgical technique information and demonstrations. Or, contact your Arthrex representative for an onsite demonstration.
2. Do not bend the plate near the locking hole. Bending the plate near the locking hole can distort the holes threading, which prohibits insertion of the screw
3. Repeated bending of the plate at the same location, or by creating excessive acute angles may potentially lead to premature plate fatigue, failure and or breakage in situ.
4. Screws should be inserted by hand and not with powered equipment.

## G. PACKAGING AND LABELING

1. Arthrex devices should be accepted only if the factory packaging and labeling arrive intact.
2. Contact Customer Service if the package has been opened or altered.

## H. STERILIZATION

This device is provided sterile or non-sterile. Refer to the package label for the sterilization method.

This device can be resterilized. It must be adequately cleaned, then sterilized using one of the following sterilization parameters.

Follow your country-specific guidelines, standards, and requirements.

**STERILIZATION PARAMETERS: FOR THE USA ONLY:**

A1

	Exposure Temperature	Exposure Time	Drying Time
<b>Gravity-Displacement Steam Sterilization Cycle</b>	121°C (250°F)	30 Minutes	15 to 30 Minutes
	132°C (270°F)	15 Minutes	15 to 30 Minutes
	135°C (275°F)	10 Minutes	30 Minutes
<b>Pre-vacuum Cycle</b>	132°C (270°F)	4 Minutes	20 to 30 Minutes
	135°C (275°F)	3 Minutes	16 Minutes

**STERILIZATION PARAMETERS: FOR OUTSIDE THE USA ONLY:**

	Exposure Temperature	Exposure Time	Drying Time
<b>Gravity-Displacement Steam Sterilization Cycle</b>	132°C – 135°C (270°F – 275°F)	18 Minutes	15 to 30 Minutes
	121°C (250°F)	30 Minutes	15 to 30 Minutes
<b>Pre-vacuum Cycle</b>	132°C - 135°C (270°F - 275°F)	4 Minutes	20 to 30 Minutes

Certain Arthrex devices that may be used during this procedure are provided non-sterile and must be adequately cleaned and sterilized prior to use or re-use. Please refer to DFU-0023 and ANSI/AAMI ST79, "Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities" for specific information.

Sterilizers vary in design and performance characteristics. Cycle parameters and the load configuration should always be verified against the sterilizer manufacturer's instructions.

Cooling – The device must be adequately cooled, after being removed from the sterilizer.

**I. MATERIAL SPECIFICATIONS**

Refer to the package label for the materials. This device is made of stainless steel.

**J. STORAGE CONDITIONS**

Sterile devices must be stored in the original unopened packaging, away from moisture and should not be used after the expiration date.

Non-sterile metal devices should be stored in a clean, dry environment. The shelf life of non-sterile devices is not limited; the devices are manufactured from non-degradable material, which does not raise any question of device stability when stored under recommended conditions.

96

AI

**K. INFORMATION**

Surgeons are advised to review the product specific surgical technique prior to performing any surgery. Arthrex provides detailed surgical techniques in print, video, and electronic formats. The Arthrex website also provides detailed surgical technique information and demonstrations. Or, contact your Arthrex representative for an onsite demonstration.

97

# Arthrex Low Profile Screws

## DFU-0125

### Draft 0

#### A. DEVICE DESCRIPTION

The **Arthrex Low Profile Screws** are headed and self-tapping. They are available as fully or partially threaded, and solid or cannulated. The screw family ranges from 2.0 mm to 6.7 mm in diameter and from 8 mm to 120 mm in length (in 1, 2 or 5 mm increments).

#### B. INDICATIONS

The **Arthrex Low Profile Screws (2.0-2.4mm solid)** are intended to be used as stand-alone bone screws, or in a plate-screw system for internal bone fixation for bone fractures, fusions, osteotomies and non-unions in the ankle, foot, hand, and wrist. When used with a plate, the screw may be used with the Arthrex Low Profile and Small Fragment Plates.

The **Arthrex Low Profile Screws (2.0-3.0mm cannulated)** are intended to be used as stand-alone bone screws for internal bone fixation for bone fractures, fusions, osteotomies and non-unions in the ankle, foot, hand, and wrist.

The **Arthrex Low Profile Screws (2.7mm and larger, solid)** are intended to be used as stand-alone bone screws, or in a plate-screw system for internal bone fixation for bone fractures, fusions, osteotomies and non-unions in the ankle, foot, hand, wrist, clavicle, scapula, olecranon, humerus, radius, ulna, tibia, calcaneous, femur and fibula. When used with a plate, the screws may be used with the Arthrex Low Profile and Small Fragment Plates, Fracture Plates, Humeral Fracture Plates, and Osteotomy Plates.

The **Arthrex Low Profile Screws (3.5mm and larger, cannulated)** are intended to be used as stand-alone bone screws for internal bone fixation for bone fractures, fusions, osteotomies and non-unions in the ankle, foot, hand, wrist, clavicle, scapula, olecranon, humerus, radius, ulna, tibia, calcaneous, femur and fibula.

#### C. CONTRAINDICATIONS

1. Insufficient quantity or quality of bone.

2. Blood supply limitations and previous infections, which may retard healing.
3. Foreign-body sensitivity. Where material sensitivity is suspected, appropriate tests should be made and sensitivity ruled out prior to implantation.
4. Any active infection or blood supply limitations.
5. Conditions that tend to limit the patient's ability or willingness to restrict activities or follow directions during the healing period.
6. The use of this device may not be suitable for patients with insufficient or immature bone. The physician should carefully assess bone quality before performing orthopedic surgery on patients who are skeletally immature. The use of this medical device and the placement of hardware or implants must not bridge, disturb or disrupt the growth plate.
7. Do not use for surgeries other than those indicated.

#### **D. ADVERSE EFFECTS**

1. Infections, both deep and superficial.
2. Foreign body reactions.

#### **E. WARNINGS**

1. An internal fixation device must never be reused.
2. All metallic implant devices used for this surgical procedure should have the same metallurgical composition.
3. Postoperatively and until healing is complete, fixation provided by this device should be considered as temporary and may not withstand weight bearing or other unsupported stress. The fixation provided by this device should be protected. The postoperative regimen prescribed by the physician should be strictly followed to avoid adverse stresses applied to the device.
4. Pre-operative and operating procedures, including knowledge of surgical techniques and proper selection and placement of the device, are important considerations in the successful utilization of this device. The appropriate Arthrex delivery system is required for proper implantation of the device.
5. Any decision to remove the device should take into consideration the potential risk to the patient of a second surgical procedure. Device removal should be followed by adequate postoperative management.

6. Detailed instructions on the use and limitations of this device should be given to the patient.
7. This is a single use device. Reuse of this device could result in failure of the device to perform as intended and could cause harm to the patient and/or user.
8. The device has not been evaluated for safety and compatibility in the magnetic resonance (MR) environment. The device has not been tested for heating or migration in the MR environment. If the implant is manufactured from a metallic material, surgeons can expect that MR artifacts will be present during routine MR Imaging.
9. Removal of supplemental fixation after healing. If the supplemental fixation is not removed following the completion of its intended use, any of the following complications may occur: (1) Corrosion, with localized tissue reaction or pain; (2) Migration of implant position resulting in injury; (3) Risk of additional injury from postoperative trauma; (4) Bending, loosening, and/or breakage, which could make removal impractical or difficult; (5) Pain, discomfort, or abnormal sensations due to the presence of the device; (6) Possible increased risk of infection; and (7) Bone loss due to stress shielding. The surgeon should carefully weigh the risks versus benefits when deciding whether to remove the implant. Implant removal should be followed by adequate postoperative management to avoid re-fracture.

## **F. PRECAUTIONS**

1. Surgeons are advised to review the product-specific surgical technique prior to performing any surgery. Arthrex provides detailed surgical techniques in print, video, and electronic formats. The Arthrex website also provides detailed surgical technique information and demonstrations. Or, contact your Arthrex representative for an onsite demonstration.
2. Use the appropriately sized drill bit for the screw.
3. Damage to the driver or screw may result from failure to seat the driver fully into the screw or to align the driver properly with the screw.
4. Screws should be inserted by hand and not with powered equipment.

## **G. PACKAGING AND LABELING**

1. Arthrex devices should be accepted only if the factory packaging and labeling arrive intact.
2. Contact Customer Service if the package has been opened or altered.

**H. STERILIZATION**

This device is provided sterile or non-sterile. Refer to the package label for the sterilization method.

This device can be resterilized. It must be adequately cleaned, then sterilized using one of the following sterilization parameters.

Follow your country-specific guidelines, standards, and requirements.

<b>STERILIZATION PARAMETERS: FOR THE USA ONLY:</b>			
	<b>Exposure Temperature</b>	<b>Exposure Time</b>	<b>Drying Time</b>
<b>Gravity-Displacement Steam Sterilization Cycle</b>	121°C (250°F)	30 Minutes	15 to 30 Minutes
	132°C (270°F)	15 Minutes	15 to 30 Minutes
	135°C (275°F)	10 Minutes	30 Minutes
<b>Pre-vacuum Cycle</b>	132°C (270°F)	4 Minutes	20 to 30 Minutes
	135°C (275°F)	3 Minutes	16 Minutes

<b>STERILIZATION PARAMETERS: FOR OUTSIDE THE USA ONLY:</b>			
	<b>Exposure Temperature</b>	<b>Exposure Time</b>	<b>Drying Time</b>
<b>Gravity-Displacement Steam Sterilization Cycle</b>	132°C – 135°C (270°F – 275°F)	18 Minutes	15 to 30 Minutes
	121°C (250°F)	30 Minutes	15 to 30 Minutes
<b>Pre-vacuum Cycle</b>	132°C - 135°C (270°F - 275°F)	4 Minutes	20 to 30 Minutes

Certain Arthrex devices that may be used during this procedure are provided non-sterile and must be adequately cleaned and sterilized prior to use or re-use. Please refer to DFU-0023 and ANSI/AAMI ST79, "Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities" for specific information.

Sterilizers vary in design and performance characteristics. Cycle parameters and the load configuration should always be verified against the sterilizer manufacturer's instructions.

Cooling – The device must be adequately cooled, after being removed from the sterilizer.

**I. MATERIAL SPECIFICATIONS**

Refer to the package label for the materials. This device is made of titanium or stainless steel.

## **J. STORAGE CONDITIONS**

Sterile devices must be stored in the original unopened packaging, away from moisture and should not be used after the expiration date.

Non-sterile metal devices should be stored in a clean, dry environment. The shelf life of non-sterile devices is not limited; the devices are manufactured from non-degradable material, which does not raise any question of device stability when stored under recommended conditions.

## **K. INFORMATION**

Surgeons are advised to review the product specific surgical technique prior to performing any surgery. Arthrex provides detailed surgical techniques in print, video, and electronic formats. The Arthrex website also provides detailed surgical technique information and demonstrations. Or, contact your Arthrex representative for an onsite demonstration.













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 <sup>1</sup>

AAMI / ANSI ST79:2006 and A1:2008, A2:2009 Comprehensive guide to steam sterilization and sterility assurance in health care

**Please answer the following questions**

Yes      No

Is this standard recognized by FDA <sup>2</sup>? .....      

FDA Recognition number <sup>3</sup> ..... #

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

Is a summary report <sup>4</sup> describing the extent of conformance of the standard used included in the 510(k)? .....         
 If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? .....      

Does this standard include acceptance criteria? .....         
 If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests? .....         
 If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard? .....         
 If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) <sup>5</sup>? .....      

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 <sup>6</sup> that is associated with this standard? .....         
 If yes, was the guidance document followed in preparation of this 510(k)? .....      

Title of guidance: \_\_\_\_\_

<sup>1</sup> The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

<sup>2</sup> Authority [21 U.S.C. 360d], [www.fda.gov/cdrh/stdsprog.html](http://www.fda.gov/cdrh/stdsprog.html)

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

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

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

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

<sup>6</sup> The online search for CDRH Guidance Documents can be found at [www.fda.gov/cdrh/guidance.html](http://www.fda.gov/cdrh/guidance.html)

109

**EXTENT OF STANDARD CONFORMANCE  
 SUMMARY REPORT TABLE**

STANDARD TITLE  
 AAMI / ANSI ST79:2006 and A1:2008, A2:2009 Comprehensive guide to steam sterilization and sterility assurance in health care

**CONFORMANCE WITH STANDARD SECTIONS\***

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

TYPE OF DEVIATION OR OPTION SELECTED \*

DESCRIPTION

JUSTIFICATION

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

TYPE OF DEVIATION OR OPTION SELECTED \*

DESCRIPTION

JUSTIFICATION

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

TYPE OF DEVIATION OR OPTION SELECTED \*

DESCRIPTION

JUSTIFICATION

\* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.  
 \* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

**Paperwork Reduction Act Statement**

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to:

Center for Devices and Radiological Health  
 1350 Piccard Drive  
 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.*

110

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 <sup>1</sup>  
 ISO 14971:2007, Medical devices - Application of risk management to medical devices

**Please answer the following questions** Yes    No

Is this standard recognized by FDA <sup>2</sup>? .....    

FDA Recognition number <sup>3</sup> ..... # 5-40

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

Is a summary report <sup>4</sup> describing the extent of conformance of the standard used included in the 510(k)? .....       
 If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? .....    

Does this standard include acceptance criteria? .....       
 If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests? .....       
 If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard? .....       
 If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) <sup>5</sup>? .....    

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 <sup>6</sup> that is associated with this standard? .....       
 If yes, was the guidance document followed in preparation of this 510k? .....       
 Title of guidance: \_\_\_\_\_

<sup>1</sup> The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

<sup>2</sup> Authority [21 U.S.C. 360d], [www.fda.gov/cdrh/stdsprog.html](http://www.fda.gov/cdrh/stdsprog.html)

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

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

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

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

<sup>6</sup> The online search for CDRH Guidance Documents can be found at [www.fda.gov/cdrh/guidance.html](http://www.fda.gov/cdrh/guidance.html)

**EXTENT OF STANDARD CONFORMANCE  
 SUMMARY REPORT TABLE**

STANDARD TITLE  
 ISO 14971:2007, Medical devices - Application of risk management to medical devices

**CONFORMANCE WITH STANDARD SECTIONS\***

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

TYPE OF DEVIATION OR OPTION SELECTED \*

DESCRIPTION

JUSTIFICATION

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

TYPE OF DEVIATION OR OPTION SELECTED \*

DESCRIPTION

JUSTIFICATION

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

TYPE OF DEVIATION OR OPTION SELECTED \*

DESCRIPTION

JUSTIFICATION

\* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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

**Paperwork Reduction Act Statement**

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to:

Center for Devices and Radiological Health  
 1350 Piccard Drive  
 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.*

112