



# U.S. Department of Health & Human Services

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**Food and Drug Administration**

## SAVE REQUEST

**USER:** (kml)

**FOLDER:** K974186 - 320 pages

**COMPANY:** ORTHOFIX SRL (ORTHOFIX)

**PRODUCT:** PIN, FIXATION, THREADED (JDW)

**SUMMARY:** Product: ORTHOFIX EXTERNAL FIXATION SCREW (PIN) WITH HYDROXYAPATITE COATING

**DATE REQUESTED:** Jun 26, 2016

**DATE PRINTED:** Jun 26, 2016

**Note:** Printed



K974186

**510(k) SUMMARY<sup>1</sup>**  
**Orthofix® External Fixation Screw**  
**March 3, 1998**

This summary is provided in accordance with the Safe Medical Devices Act of 1990 (SMDA). The information provided in the 510(k), premarket notification was in accordance with 21 CFR 807.87 and the SMDA.

**1. Submitter of 510(k)**

Robert L. Sheridan (Consultant)  
Vice President, Device Evaluation  
C.L. McIntosh & Associates, Inc.  
12300 Twinbrook Parkway, Suite 625  
Rockville, MD 20852

Telephone: (301) 770-9590  
Facsimile: (301) 770-9584

**2. Name of Device**

**2.1 Trade/Proprietary Name**

Orthofix® External Fixation Screw (Pin) With Hydroxyapatite Coating

**2.2 Common/Usual Name**

External fixation pin

**2.3 Classification Name**

Smooth or threaded metallic bone fixation fastener (21 CFR 888.3040).

**3. Applicant/Manufacturer**

ORTHOFIX Srl.  
Via delle Nazioni 9  
37012 Bussolengo (VR), Italy  
Attention: Rolando Stanghellini, Director of Quality Assurance

Telephone: 011-39-45-6767030  
Facsimile: 011-39-45-6767135

**4. Reason for Submitting the 510(k)**

Orthofix intends to commercially distribute a modified version of its previously 510(k)-cleared external fixation pin. Orthofix wishes to distribute its pins with a very thin plasma sprayed coating of hydroxyapatite (HA).

**5. Device Description**

The Orthofix Hydroxyapatite Coated Screws are manufactured from surgical grade stainless steel AISI 316L. The pins are available in a variety of diameters and lengths. The threaded end is gradually tapered, over approximately the last third of the pin's length. The threaded portion of the pin is coated with a very thin plasma sprayed coating of HA. The HA powder used in the plasma spray coating process conforms to ASTM F 1185. The mechanical properties of the coating conform to ASTM F 1501.

**6. Indications For Use**

The Orthofix external fixation screw (pin) with hydroxyapatite coating is indicated for use in the external fixation of bone.

**7. Substantial Equivalence**

The decision that the Orthofix HA coated pin is substantially equivalent to a legally marketed predicate device is reached through consideration of the requirements for substantial equivalence determinations. These requirements are set forth in the document entitled "Guidance on the Center for Devices and Radiological Health's Premarket Notification Review Program", which was published on June 30, 1986 by the Center for Devices and Radiological Health (CDRH),

FDA guidance documents relevant to this application were used in its preparation. In particular, the guidance document, "510(k) Information Needed for Hydroxyapatite Coated Orthopedic Implants" (revised February 20, 1997), was followed in the preparation of this 510(k). The physical, mechanical and chemical tests prescribed by FDA in its guidance document to characterize the HA coating and HA/substrate interface were conducted.

The substantial equivalence of the Orthofix HA coated pins is supported by the extensive laboratory, animal and clinical testing data presented herein. The preclinical and clinical data presented herein demonstrate that the use of the proprietary HA-coating enhances fixation at the pin/bone interface. The Orthofix HA-coated pins demonstrate statistically significantly better stability or fixation at the time of removal or extraction than do the uncoated pins.

Orthofix pins with the proprietary HA-coating were found in randomized controlled clinical and animal studies to have significantly enhanced fixation and a reduced incidence of clinical loosening. The clinical results demonstrate:

- No significant difference in the insertion torques for standard uncoated and HA-coated Orthofix pins in both metaphyseal and diaphyseal bone.
- The extraction torque is significantly greater for HA-coated Orthofix pins than for uncoated pins in both metaphyseal and diaphyseal bone.

- For the HA-coated Orthofix pins, the extraction torque is significantly greater than the insertion torque in both metaphyseal and diaphyseal bone; whereas, for the uncoated pins, the extraction torque is significantly lower than the insertion torque in both metaphyseal and diaphyseal bone.

The animal study that was conducted compared uncoated and HA-coated Orthofix pins. Radiographic, histologic, SEM and histomorphometric analyses demonstrate that osseointegration with direct contact between the bone and the screw threads of the Orthofix HA-coated pins.

As reported in the literature, complications of external fixation include pin tract infection and loosening. The enhanced fixation and improved stability at the bone-pin interface seen with the Orthofix Ha-coated pins significantly reduces the incidence of pin loosening. It is generally accepted that a loose pin provides an increased risk of infection.

In summary, the information and data provided in this submission are consistent with FDA's guidance documents for HA coated orthopedic implants and demonstrate that the Orthofix HA coated pin is substantially equivalent to legally marketed predicate devices.

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<sup>1</sup> Any statement made in conjunction with this submission regarding a determination of substantial equivalence to any other product is intended only to refer to whether the product can be lawfully marketed without pre-market approval or reclassification and is not intended to be interpreted as an admission or any other type of evidence in patent infringement litigation. (Establishment Registration and Pre-market Notification Procedures, Final Regulation, Preamble, August 23, 1977, FR 42520 (Docket No. 76N-0355))



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAR 18 1998

ORTHOFIX Srl.  
c/o Mr. Robert L. Sheridan  
Vice President, Device Evaluation  
C.L. McIntosh & Associates, Inc.  
12300 Twinbrook Parkway, Suite 625  
Rockville, Maryland 20852

Re: K974186  
Trade Name: Orthofix® External Fixation Screw (Pin)  
with Hydroxyapatite Coating  
Regulatory Class: II  
Product Code: JDW  
Dated: March 3, 1998  
Received: March 4, 1998

Dear Mr. Sheridan:

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

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

Page 2 - Mr. Robert L. Sheridan

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



*for* Celia M. Witten, Ph.D., M.D.  
Director  
Division of General and  
Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

### Indications For Use

**Device Name:** Orthofix External Fixation Screw (Pin) With Hydroxyapatite Coating

**Indications For Use:** The Orthofix external fixation screw (pin) with hydroxyapatite coating is indicated for use in the external fixation of bone.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use:  
(Per 21 CFR 801.109)

X

OR

Over-The-Counter: \_\_\_\_\_

(Optional Format 1-2-96)

*Russell A. Rayson*  
\_\_\_\_\_  
Division Sign-Off  
Division of General Restorative Devices

11/5/9711:11

STU(k) Number K974186



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAR 18 1998

ORTHOFIX Srl.  
c/o Mr. Robert L. Sheridan  
Vice President, Device Evaluation  
C.L. McIntosh & Associates, Inc.  
12300 Twinbrook Parkway, Suite 625  
Rockville, Maryland 20852

Re: K974186  
Trade Name: Orthofix® External Fixation Screw (Pin)  
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Regulatory Class: II  
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Sincerely yours,



*for* Celia M. Witten, Ph.D., M.D.  
Director  
Division of General and  
Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure



### Indications For Use

**Device Name:** Orthofix External Fixation Screw (Pin) With Hydroxyapatite Coating

**Indications For Use:** The Orthofix external fixation screw (pin) with hydroxyapatite coating is indicated for use in the external fixation of bone.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: \_\_\_\_\_  
(Per 21 CFR 801.109)

X

OR

Over-The-Counter: \_\_\_\_\_

(Optional Format 1-2-96)

*Russell D. Ryan*  
\_\_\_\_\_  
for Division Sign-Off  
Division of General Restorative Devices  
11/5/97 11:11 510(k) Number K974186

3



MA  
3/10/98

Memorandum

Reviewer(s) - Name(s) Peter Allen

Subject: 510(k) Number K974186/51

To: The Record - It is my recommendation that the subject 510(k) Notification:

- Refused to accept.
- Requires additional information (other than refuse to accept).
- Accepted for review \_\_\_\_\_.
- Is substantially equivalent to marketed devices.
- NOT substantially equivalent to marketed devices.

De Novo Classification Candidate?  YES  NO

Other (e.g., exempt by regulation, not a device, duplicate, etc.)

- Is this device subject to Postmarket Surveillance?  YES  NO
- Is this device subject to the Tracking Regulation?  YES  NO
- Was clinical data necessary to support the review of this 510(k)?  YES  NO
- Is this a prescription device?  YES  NO
- Was this 510(k) reviewed by a Third Party?  YES  NO
- Special 510(k)?  YES  NO
- Abbreviated 510(k)?  YES  NO

This 510(k) contains:

Truthful and Accurate Statement  Requested  Enclosed  
(required for originals received 3-14-95 and after)

A 510(k) summary OR  A 510(k) statement

The required certification and summary for class III devices

The indication for use form (required for originals received 1-1-96 and after)

Animal Source Material  Human Tissue Product  Human Cell Product  Human Extraction Product  
(Please Check All That Apply)

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

No Confidentiality  Confidentiality for 90 days  Continued Confidentiality exceeding 90 days

Predicate Product Code with class:

Additional Product Code(s) with panel (optional):

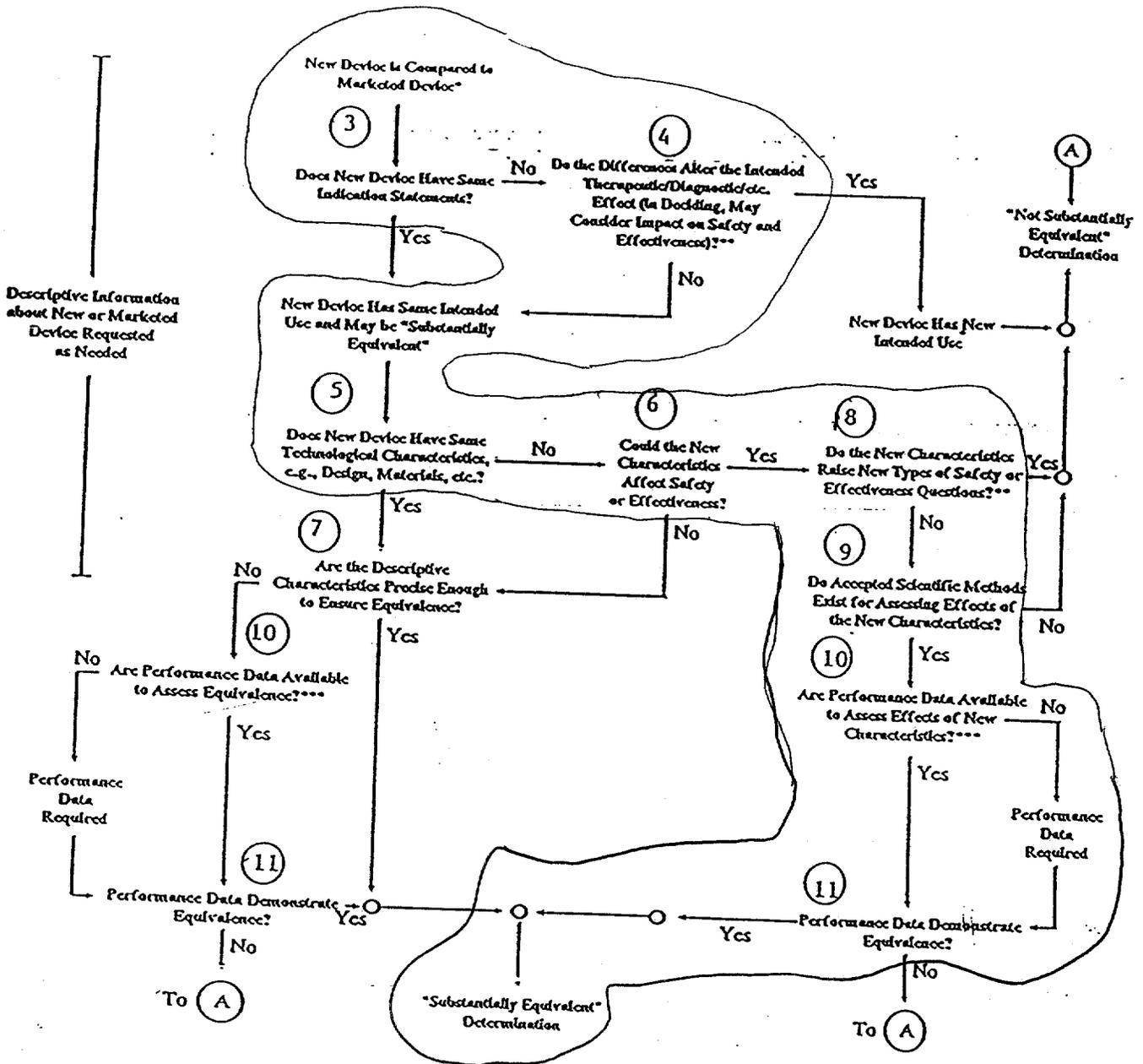
JDW, II

Review: Mark A. Melker ORDB 3/18/98  
(Branch Chief) (Branch Code) (Date)

Final Review: Samuel P. Payer 3/18/98  
(Division Director) (Date)

h

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



- 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.

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THE 510(K) DOCUMENTATION FORMS ARE AVAILABLE ON THE LAN UNDER 510(K) BOILERPLATES TITLED "DOCUMENTATION" AND MUST BE FILLED OUT WITH EVERY FINAL DECISION (SE, NSE, NOT A DEVICE, ETC.).

"SUBSTANTIAL EQUIVALENCE". (SE) DECISION MAKING DOCUMENTATION .....

Reviewer: Peter Allen <sup>K 974186/s'</sup>

Division/Branch: DGRD/ORDB

Device Name: Orthofix External Fixation Screw(Pin) with HA coating

Product To Which Compared (510(K) Number If Known): K955848

	YES	NO	
1. Is Product A Device	X		If NO = Stop
2. Is Device Subject To 510(k)?	X		If NO = Stop
3. Same Indication Statement?	X	<del>X</del>	If YES = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?		X	If YES = Stop NE
5. Same Technological Characteristics?		X	If YES = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?	X		If YES = Go To 8
7. Descriptive Characteristics Precise Enough?			If NO = Go To 10 If YES = Stop SE
8. New Types Of Safety Or Effectiveness Questions?		X	If YES = Stop NE
9. Accepted Scientific Methods Exist?	X		If NO = Stop NE
10. Performance Data Available?	X	X	If NO = Request Additional Data
11. Data Demonstrate Equivalence?	X		Final Decision: <del>NE</del> SE

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

JK  
3/17/98

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510(k) MEMORANDUM

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**TO:** K974186  
**FROM:** Peter G. Allen, Biomedical Engineer, M.S.  
FDA/CDRH/ODE/DGRD/Orthopedic Devices Branch  
**DATE:** March 12, 1998  
**SUBJ:** Orthofix External Fixation Screw (Pin) with Hydroxyapatite Coating  
Product Code: JDW(87), CFR 888.3040; Class II  
Company: Orthofix, Srl. (Italy)  
Contact: Robert L. Sheridan, Vice President Device Evaluation, C.L. McIntosh & Associates  
Phone: (301) 770-9590 Fax: (301) 770-9584

---

**Recommendation:**

I recommend that the subject device be found **SE**, substantially equivalent to other legally marketed predicate devices based on similarities in materials, design, intended use, and method of fixation.

**Review:**

1. **Administrative Requirements:**

This submission included a 510(k) Summary, Indications for Use page, and a Truthful and Accuracy statement. The Summary and Indications for Use page will need to be revised to reflect any claims the sponsor can support based on the additional information provided to FDA.

(b) (4)



2. **Device Description:**

The Orthofix External Fixation Pin (without HA) is a component of the Orthofix Dynamic Axial Fixation System, which received FDA clearance under K831576 and K955848. These pins are a

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cortical, self-tapping, tapered design, manufactured from surgical grade stainless steel. The current submission seeks to add an additional pin option to this system. The 'new' pin is identical to the previous pin, with the exception that the distal threads have a very thin (b) (4) plasma sprayed coating of hydroxyapatite (HA).

The stainless steel, AISI 316L, conforms to ISO 5832-1 and ASTM F 138. The HA powder conforms to ASTM F 1185. The mechanical properties of the powder conform to ASTM F 1501.

The Orthofix HA coated pins are available in a variety of lengths and diameters. The shank or shaft diameter is either 4 or 6 mm. Lengths range from 50 to 250 mm. The threaded end (inserted into the bone) is gradually tapered, over approximately the last third of the pin's length. The threaded end is coated with HA. The exact length of the taper and coating surface are dependent on the pin's length and are given on the engineering drawing of Appendix 2 as A (mm) and L (mm), respectively.

The pins are coated for Orthofix (b) (4)



No special tools are needed to insert or remove the HA coated pins. They use the same surgical instrumentation as the predicate uncoated pins and are to be used with the same external fixator system.

**3. Intended Use:**

The Orthofix External Fixation Screw (Pin) with Hydroxyapatite Coating is indicated for use in the external fixation of bone.

**4. Sterilization:**

The device is provided sterile.

Method: 2.5 Mrads (25 kGy) of gamma radiation

Sterility Validation Method: Guideline for Gamma Radiation Sterilization, ANSI/AAMI/ISO 11137.

Sterility Assurance Level:  $10^{-6}$

Description of packaging: polyethylene terephthalate glycol (PETG) modified thermoform inner tray, heat sealed with a Tyvek lid. The inner tray will be enclosed in an outer PETG tray also heat sealed with a Tyvek lid.

Is device labeled "pyrogen free"? No

Recommended re-sterilization method: none recommended

**5. Labeling:**

Labeling in the form of draft package labels were provided. A statement was provided that information (see fax of 3/12) on the HA coated screws would be added to the General Application Instructions for the Orthofix Dynamic Axial Fixator system. This instruction manual provides information on surgical technique and proper use of system components. This additional information includes a description of the HA coated screws and the claim of enhanced fixation. The information provided for these components is equivalent to what is typically provided for these types of systems.

**6. Testing:**

Physical, mechanical, and chemical tests to characterize the HA coating and HA/substrate interface were conducted by the sponsor as outlined in the FDA guidance document, 510(k) Information Needed

2

for Hydroxyapatite Coated Orthopedic Implants (revised 2/20/97).

( [REDACTED]

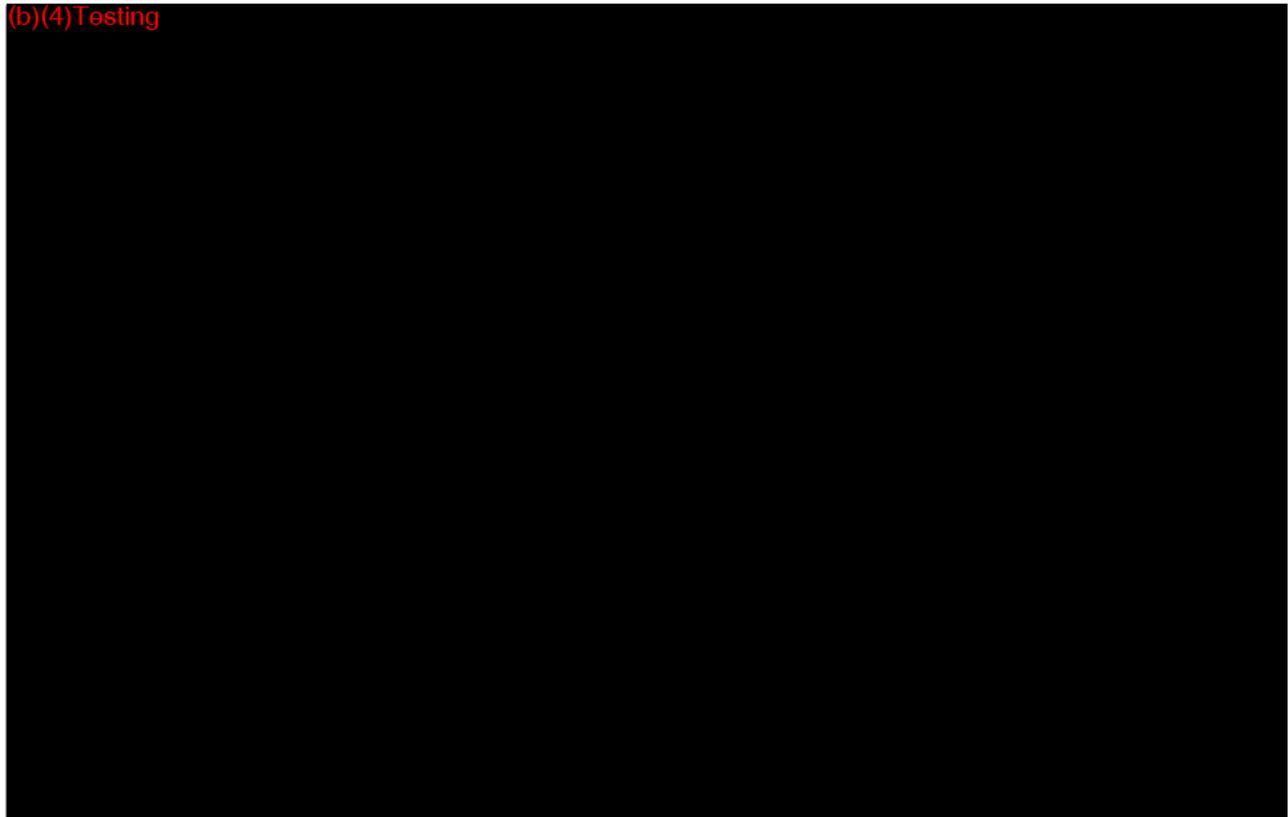
[REDACTED]

b

(b)(4) Testing

[REDACTED]

(b)(4)Testing



7. **Sponsor's Information in Support of SE:**  
K955848, K831576, Orthofix Srl., Orthofix Dynamic Axial Fixation System  
K896047, Osteonics Corp., Omnifit EPF Hip Joint Femoral Stem  
K912369, Biomet, HAP Bio-Groove Total Hip Prosthesis  
K910156, DePuy, Hydroxyapatite Coated Profile Hip Stem  
K961433, Electro-Biology, Inc., EBI X Fix Dynafix System - SC Bone Screws

8. **Review of other 510(k)s for SE:**  
See number 7, above.

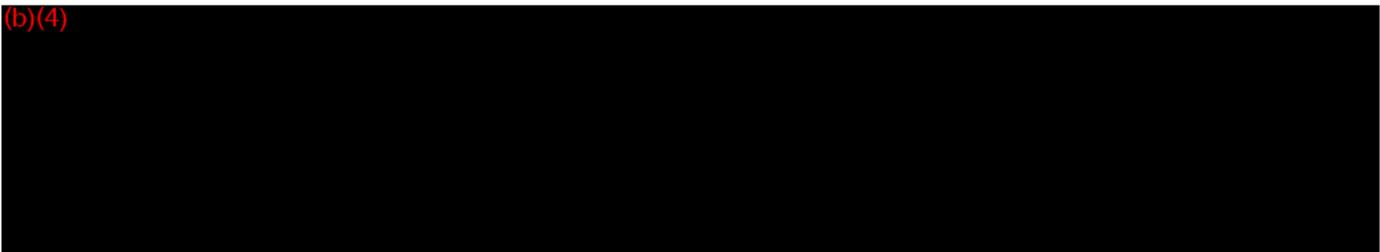
9. **Summary of Sponsor's Information in Support of SE:**

(b)(4)

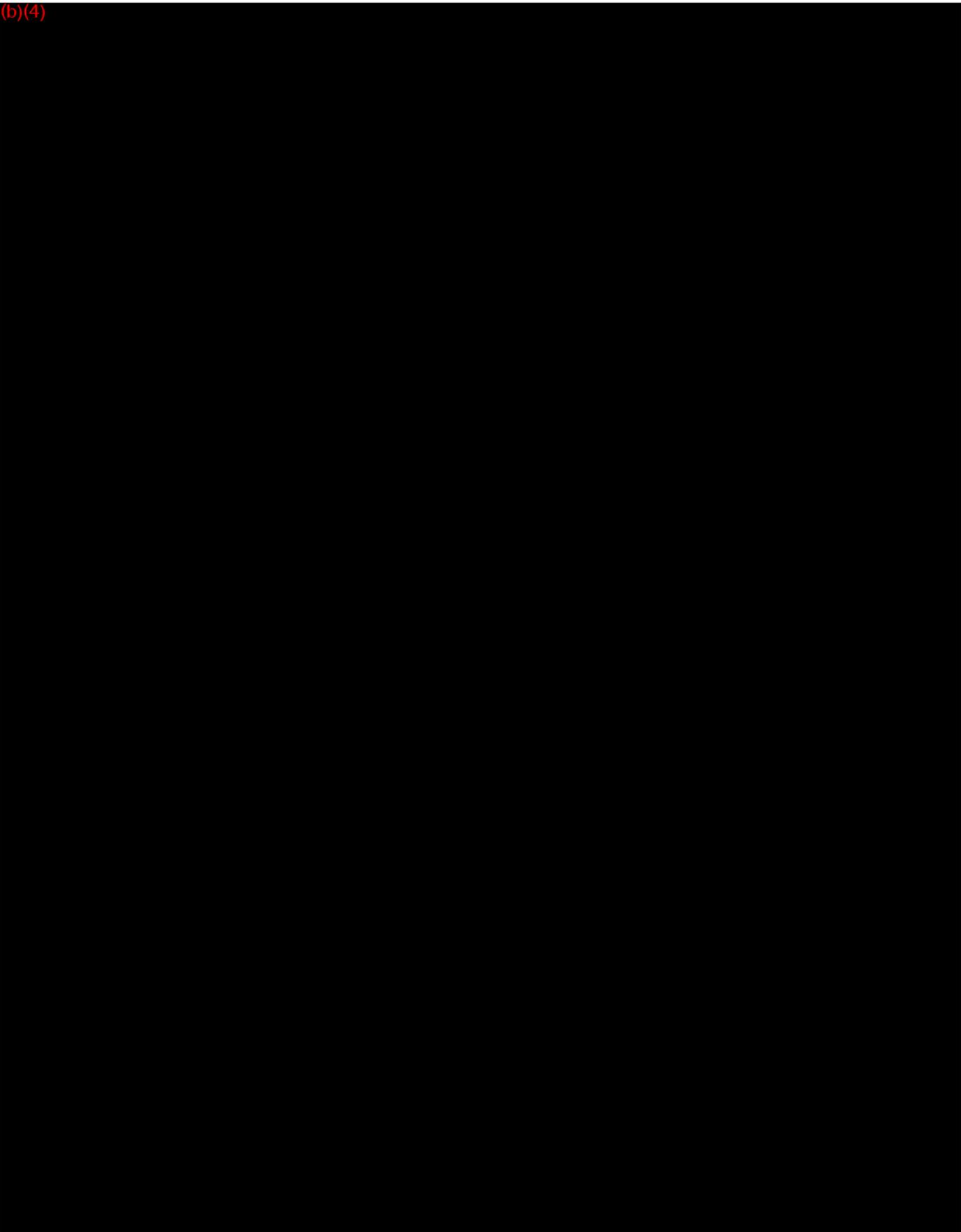


10. **Contact History/Requests for More Information:**

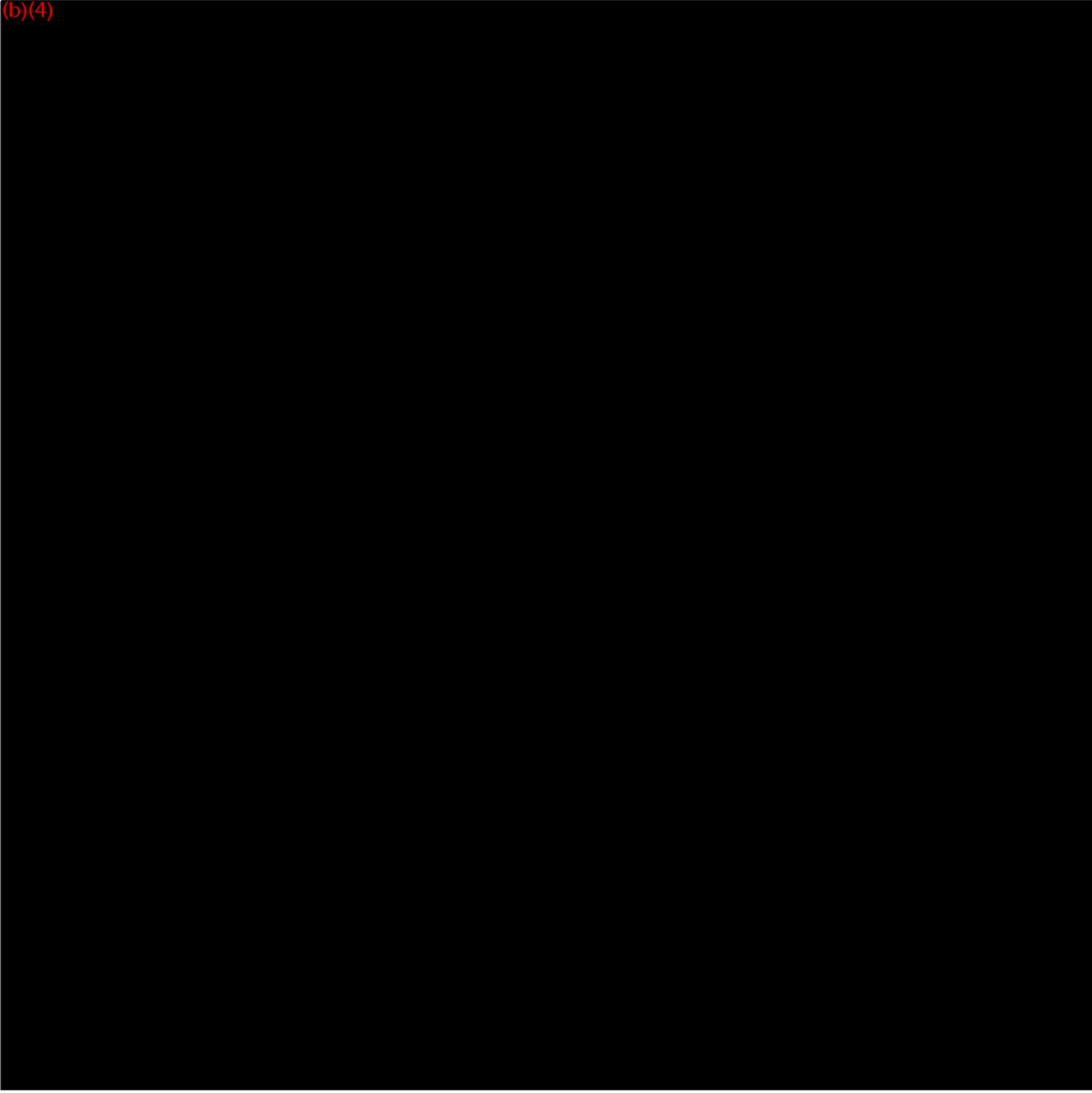
(b)(4)



(b)(4)



(b)(4)



Peter G. Allen, Biomedical Engineer/Reviewer  
DGRD/ORDB  
March 12, 1998

Peter G. Allen

12

**C.L. McIntosh**

& ASSOCIATES, INC.

K974186/A1

Medical and Regulatory Affairs Services

12300 Twinbrook Parkway, Suite 625  
Rockville, Maryland 20852

Tel: (301) 770-9590  
Fax: (301) 770-9584

March 12, 1998

Document Mail Center  
Center for Devices and Radiological Health  
Food and Drug Administration  
9200 Corporate Boulevard  
Rockville, MD 20850

Attn: Peter Allen, M.S., Orthopedic Devices Branch  
Division of General and Restorative Devices, HF-410

Re: K974186 Orthofix® External Fixation Screw/Pin  
Additional Information

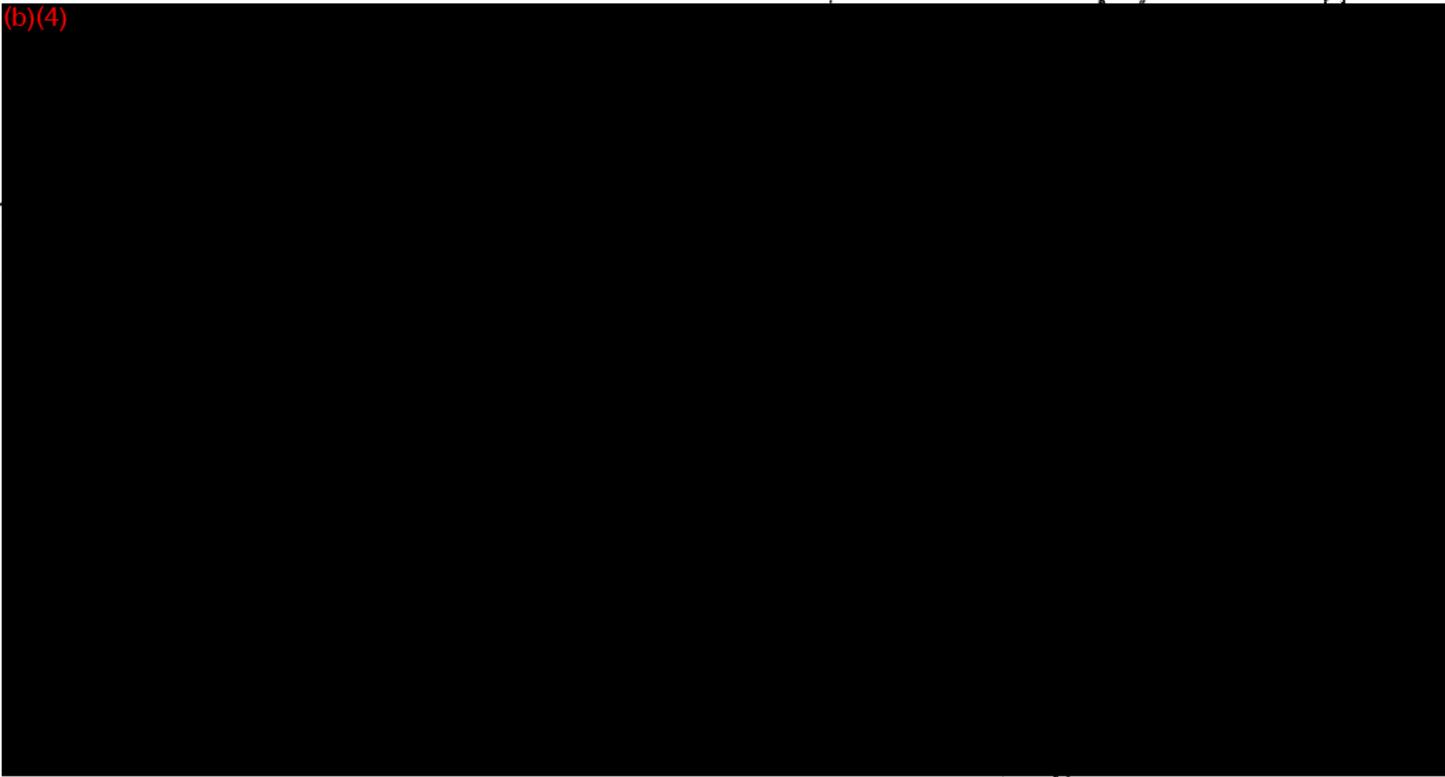
Dear Mr. Allen:

RECEIVED

13 MAR 98 16 07

FDA/CDRH/ODE/DMD

(b)(4)



Sincerely,



Robert L. Sheridan  
Vice President for Marketing  
Submissions

SK-42

B

**C.L. Macintosh & Associates, Inc.**  
12300 Twinbrook Parkway, Suite 625  
Rockville, Maryland 20852

Phone: 301-770-9590 - Fax: 301-770-9584

**Fax Transmission Form**

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Date: 3/12/98 Time: \_\_\_\_\_  
To: Mr. Peter Allen  
Company: DGRD  
Fax No. 301-827-4350  
From: Bob Sheridan  
Code na

Number of pages transmitted (including this cover page): 2

**Additional Notes:**

Mr. Allen: Enclosed is a copy of a letter which we are forwarding in hard copy to the DMC (three copies to be hand delivered today). Thank you for your help in this matter.

See Enclosure

Bob Sheridan  


lh

# *C.L. McIntosh*

& ASSOCIATES, INC.

*Medical and Regulatory Affairs Services*

12300 Twinbrook Parkway, Suite 625 Tel: (301) 770-9590  
Rockville, Maryland 20852 Fax: (301) 770-9584

March 12, 1998

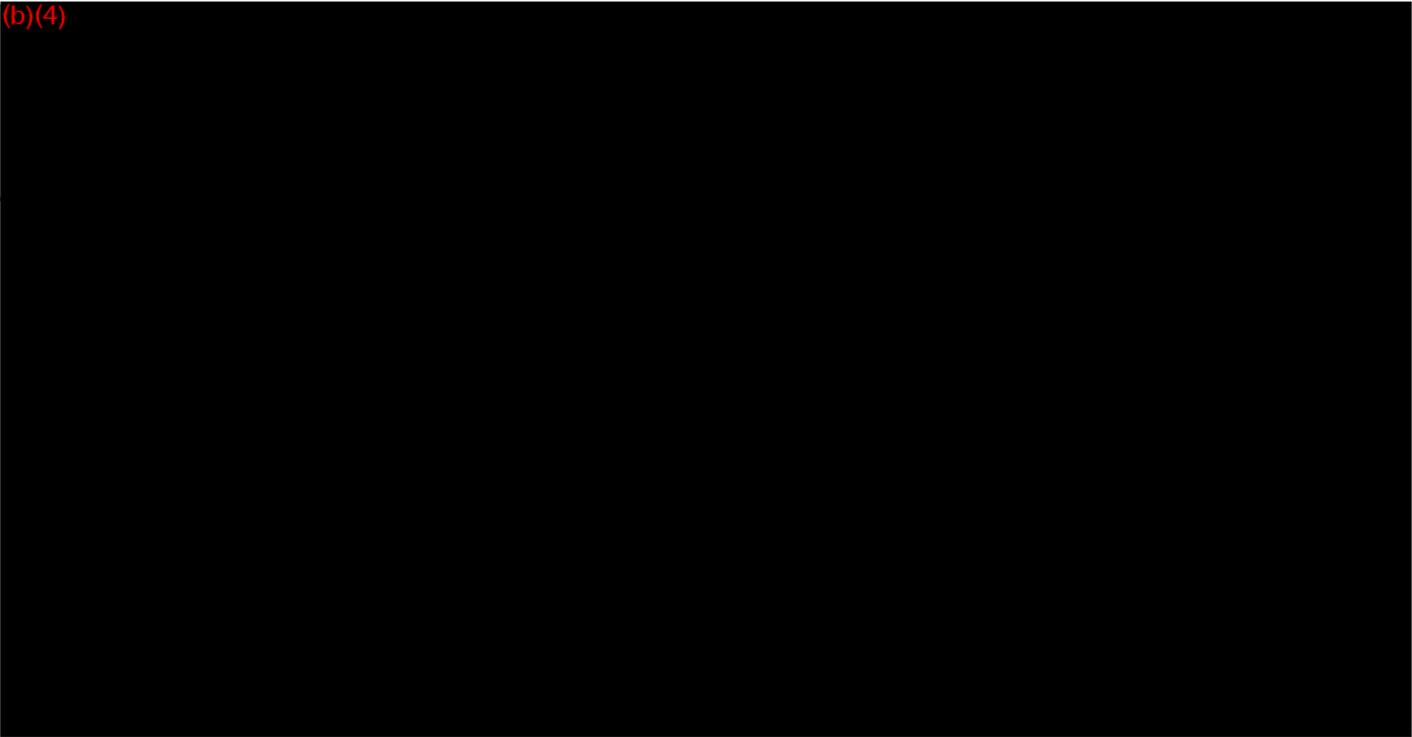
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Food and Drug Administration  
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Rockville, MD 20850

Attn: Peter Allen, M.S., Orthopedic Devices Branch  
Division of General and Restorative Devices, HF-410

Re: K974186 Orthofix® External Fixation Screw/Pin  
Additional Information

Dear Mr. Allen:

(b)(4)



Sincerely,



Robert L. Sheridan  
Vice President for Marketing  
Submissions

15

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

March 05, 1998

ORTHOFIX SRL	510(k) Number: K974186
C/O C.L. MCINTOSH & ASSOCIATES, INC	Product: ORTHOFIX
12300 TWINBROOK PARKWAY,	EXTERNAL
SUITE 625	FIXATION SCREW
ROCKVILLE, MD 20852	(PIN) WITH
ATTN: ROBERT L. SHERIDAN	

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 (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official.

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 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.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

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

16

K974186/S1

12300 Twinbrook Parkway, Suite 625  
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Tel: (301) 770-9590  
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March 3, 1998

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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville, MD 20850

RECEIVED

4 MAR 98 16 05

FDA/CDRH/ODE/DHC

Attn: Peter Allen, M.S., Orthopedic Devices Branch  
Division of General and Restorative Devices, HFZ-410

Re: K974186 Orthofix® External Fixation Screw/Pin  
Additional Information

Dear Mr. Allen:

Provided herein is the additional information you requested. Per your request we have provided a tabulation and summary of our clinical data, a revised 510(k) Summary and a list of the claims we propose to make in future promotional materials. We believe that the indications for use of our coated pin remain the same as for our uncoated pin. That is, the Orthofix external fixation pins, whether coated or uncoated are simply indicated for use in the external fixation of bone.

To facilitate your review, preceding each of our responses, we have restated your request in italics.

Thank you for your consideration of this matter. If you require any additional information or clarification, please call Joel S. Faden, Ph.D. at 301- 881-9139 or the undersigned at (301) 770-9590.

Sincerely,



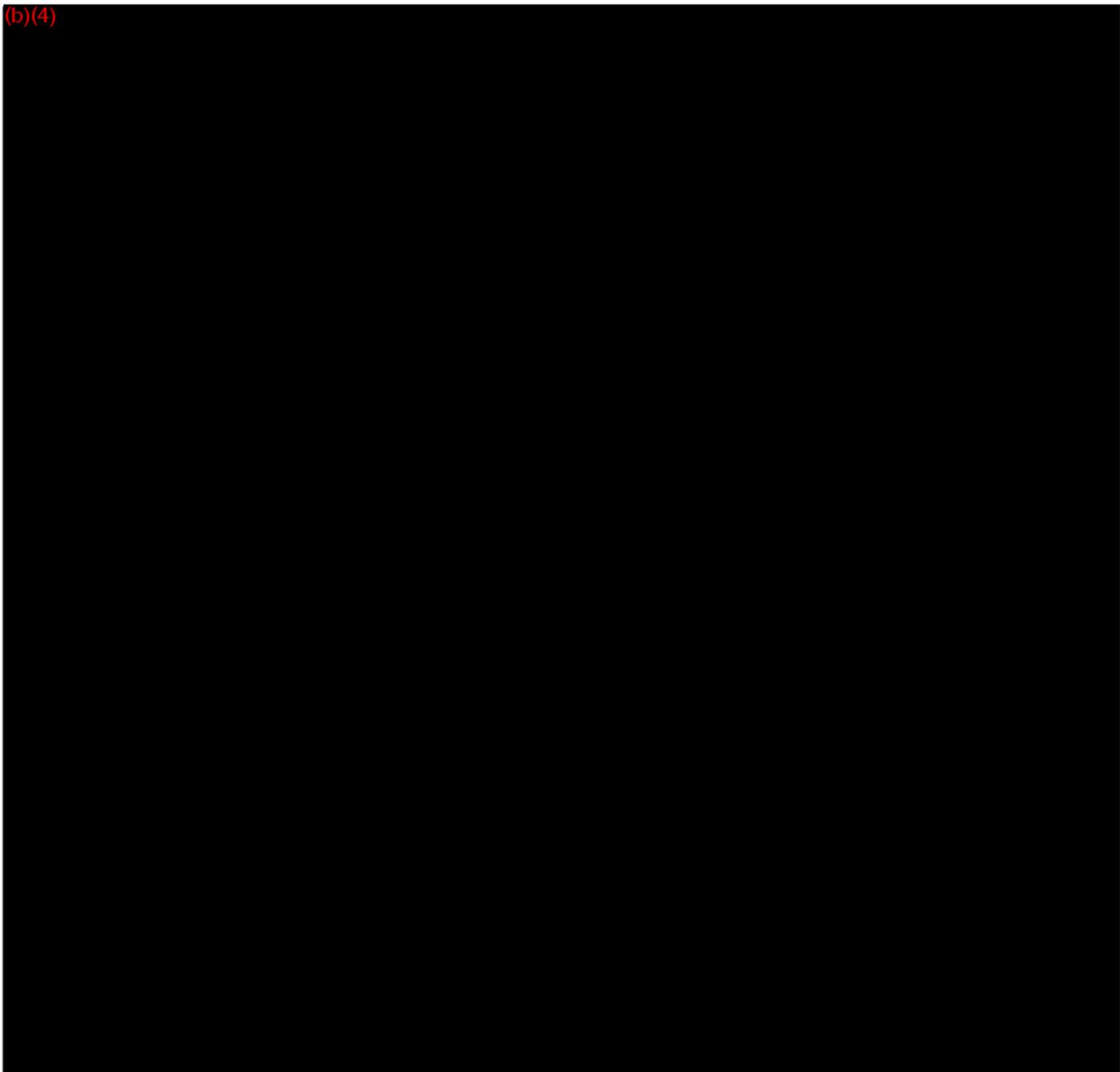
Robert L. Sheridan, Vice President  
Device Evaluation

OK-49

17

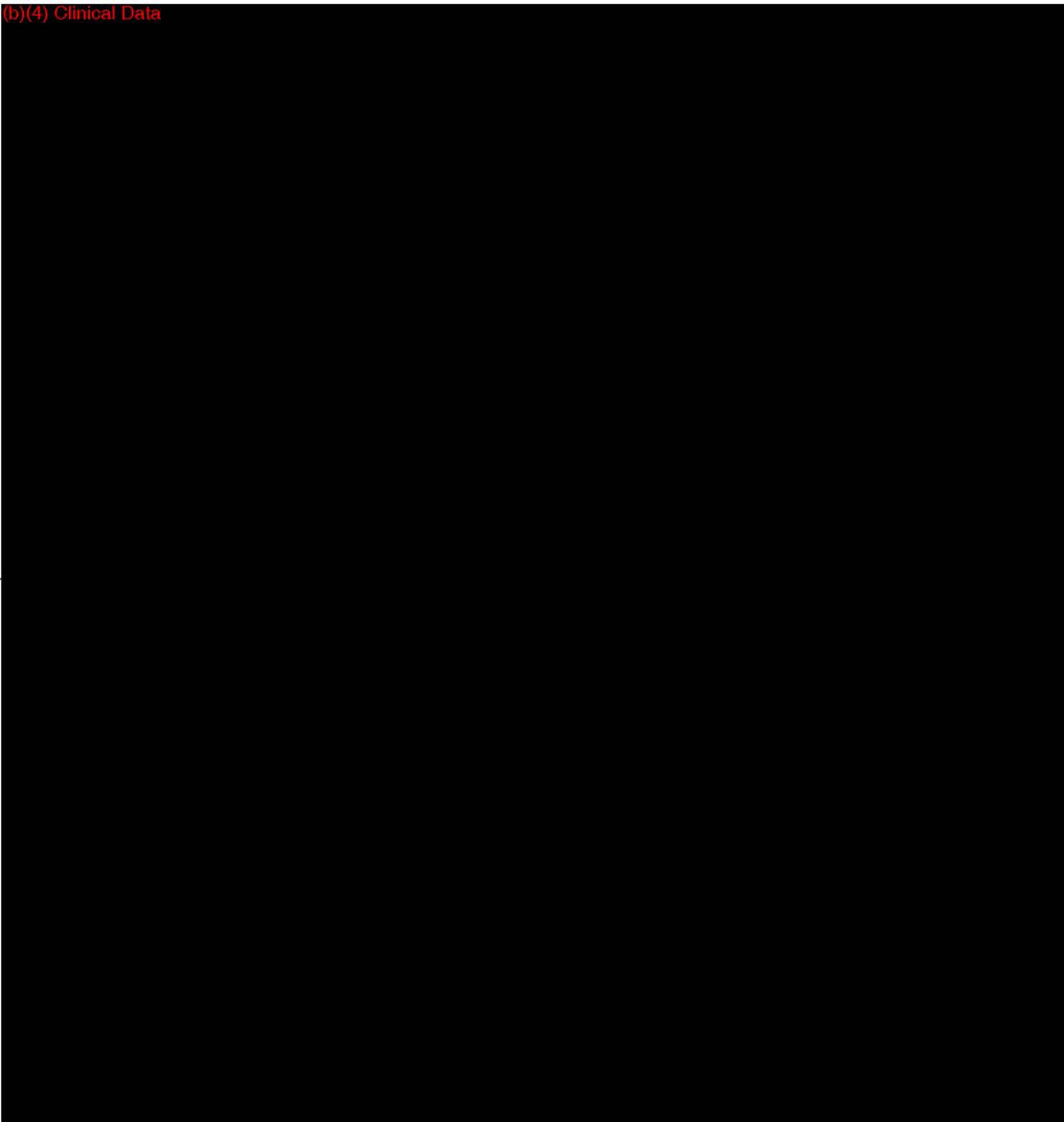
**CONFIDENTIAL**

(b)(4)



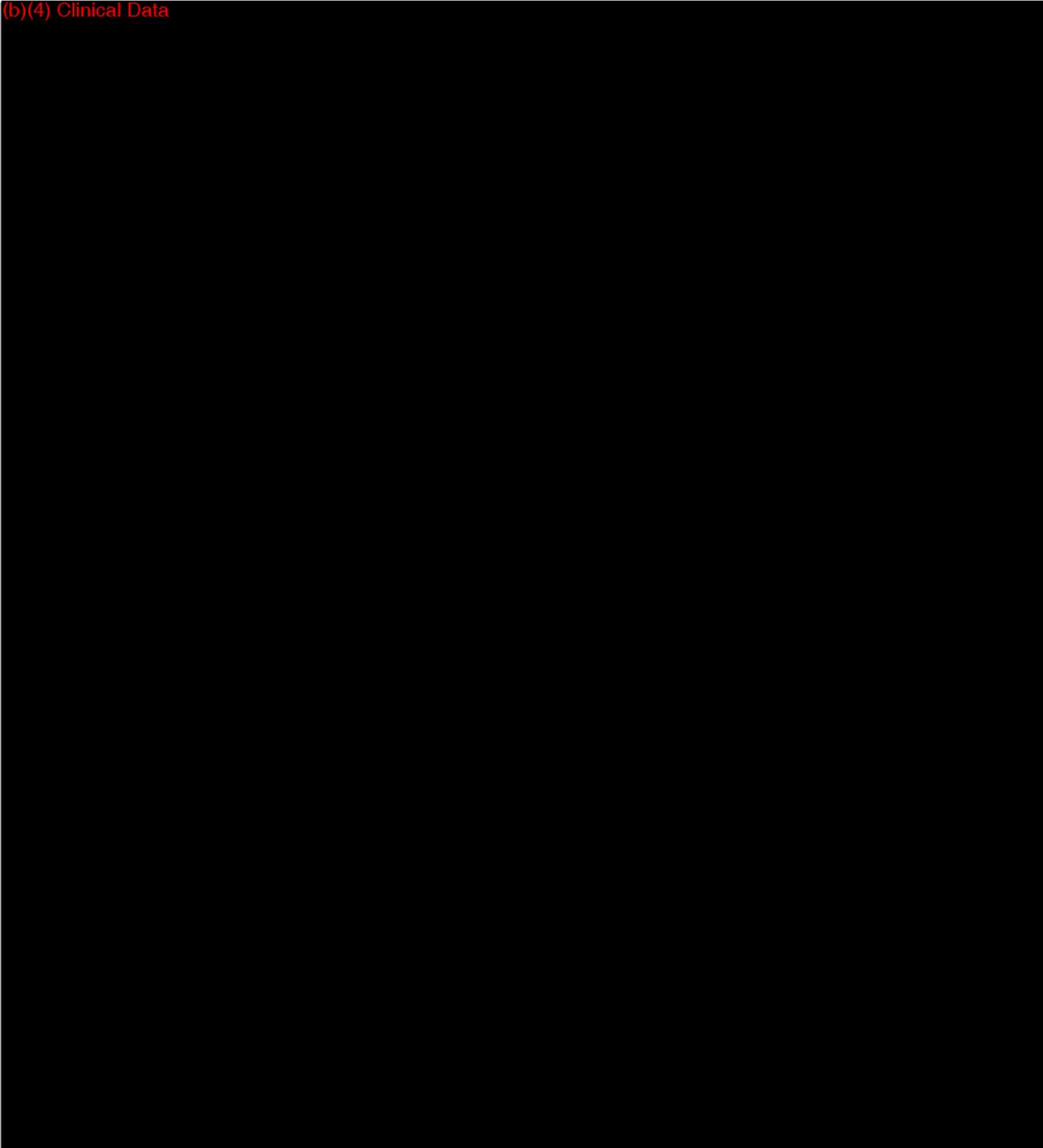
18

(b)(4) Clinical Data



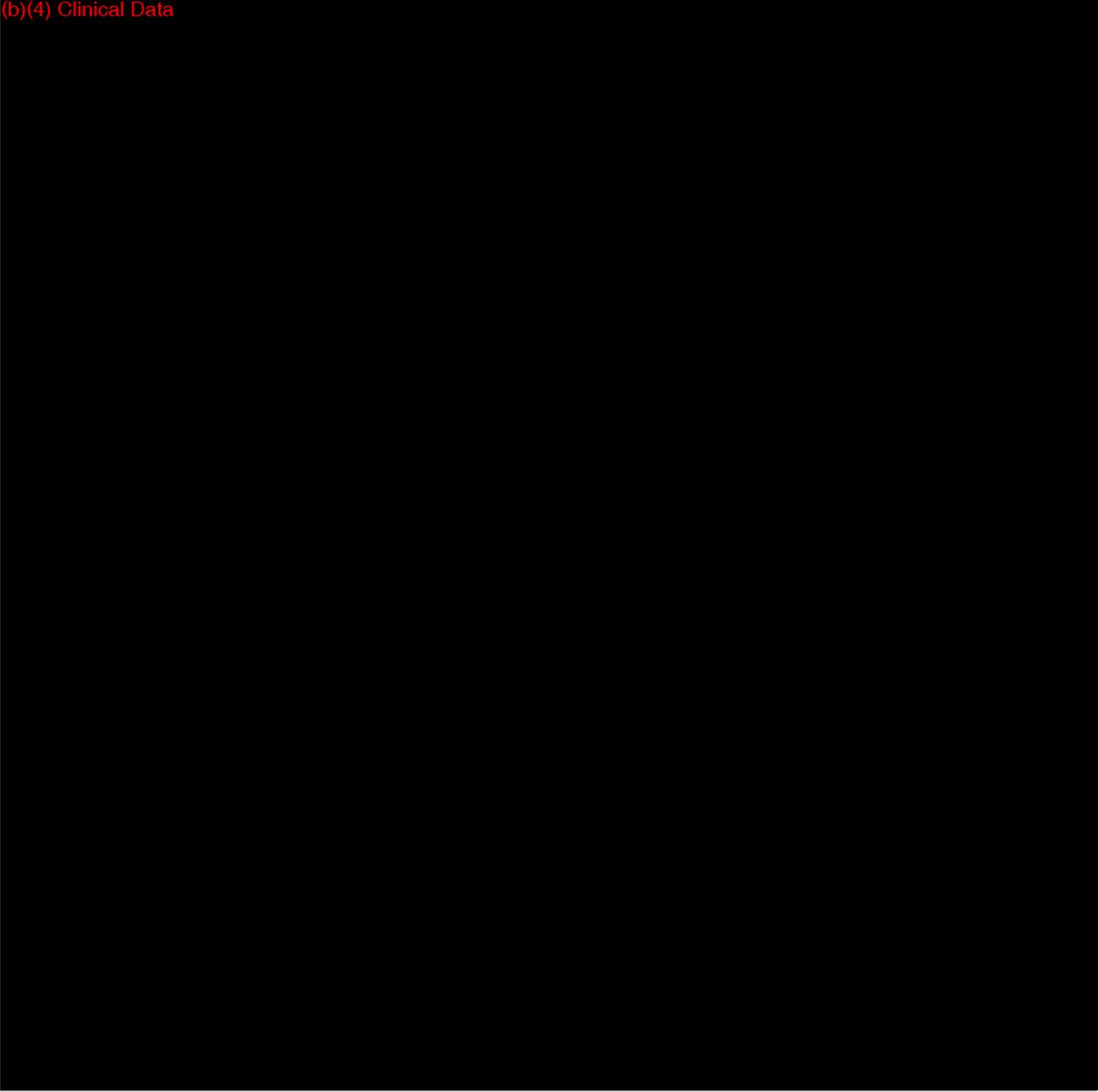
**CONFIDENTIAL**

(b)(4) Clinical Data

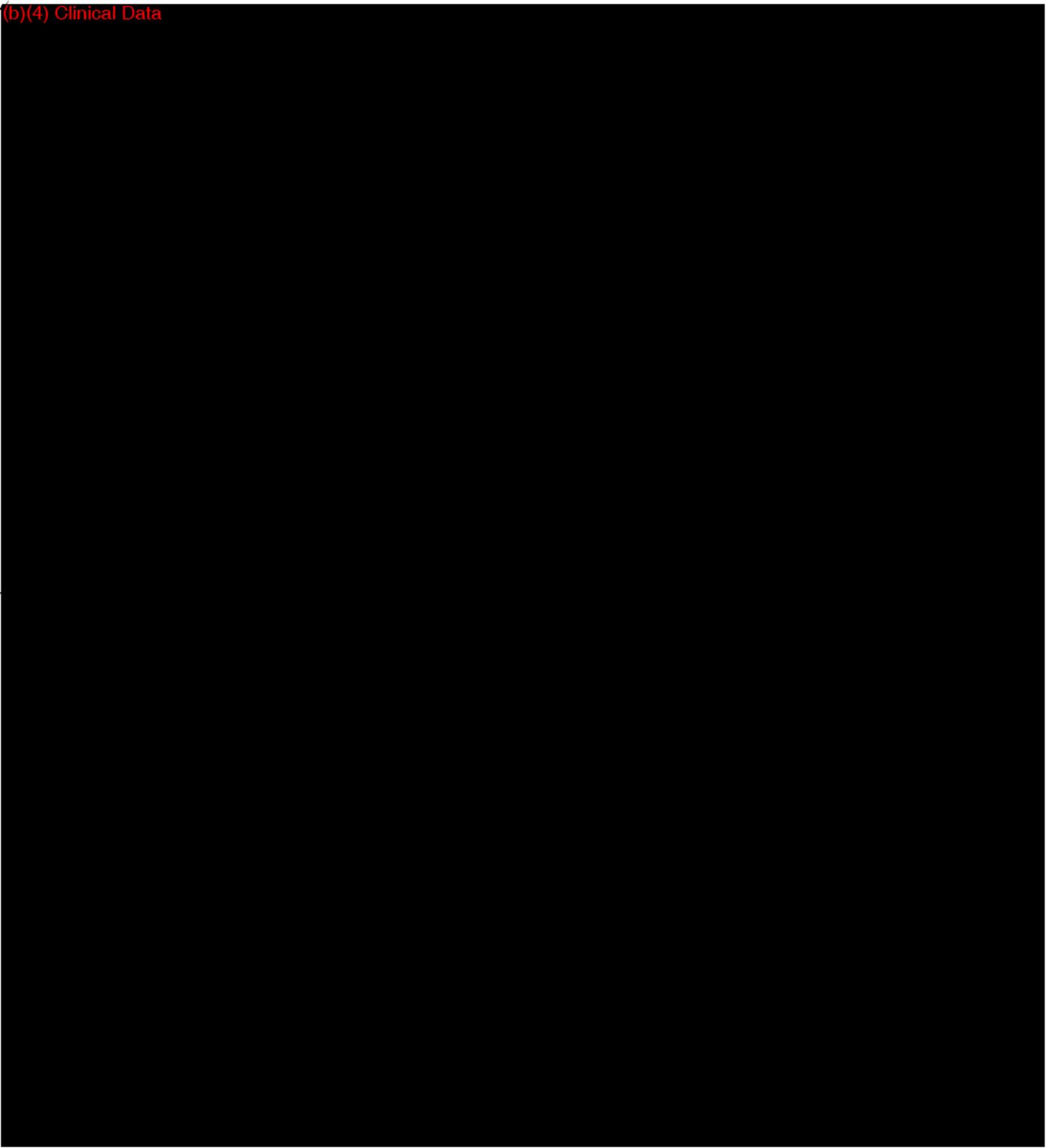


**CONFIDENTIAL**

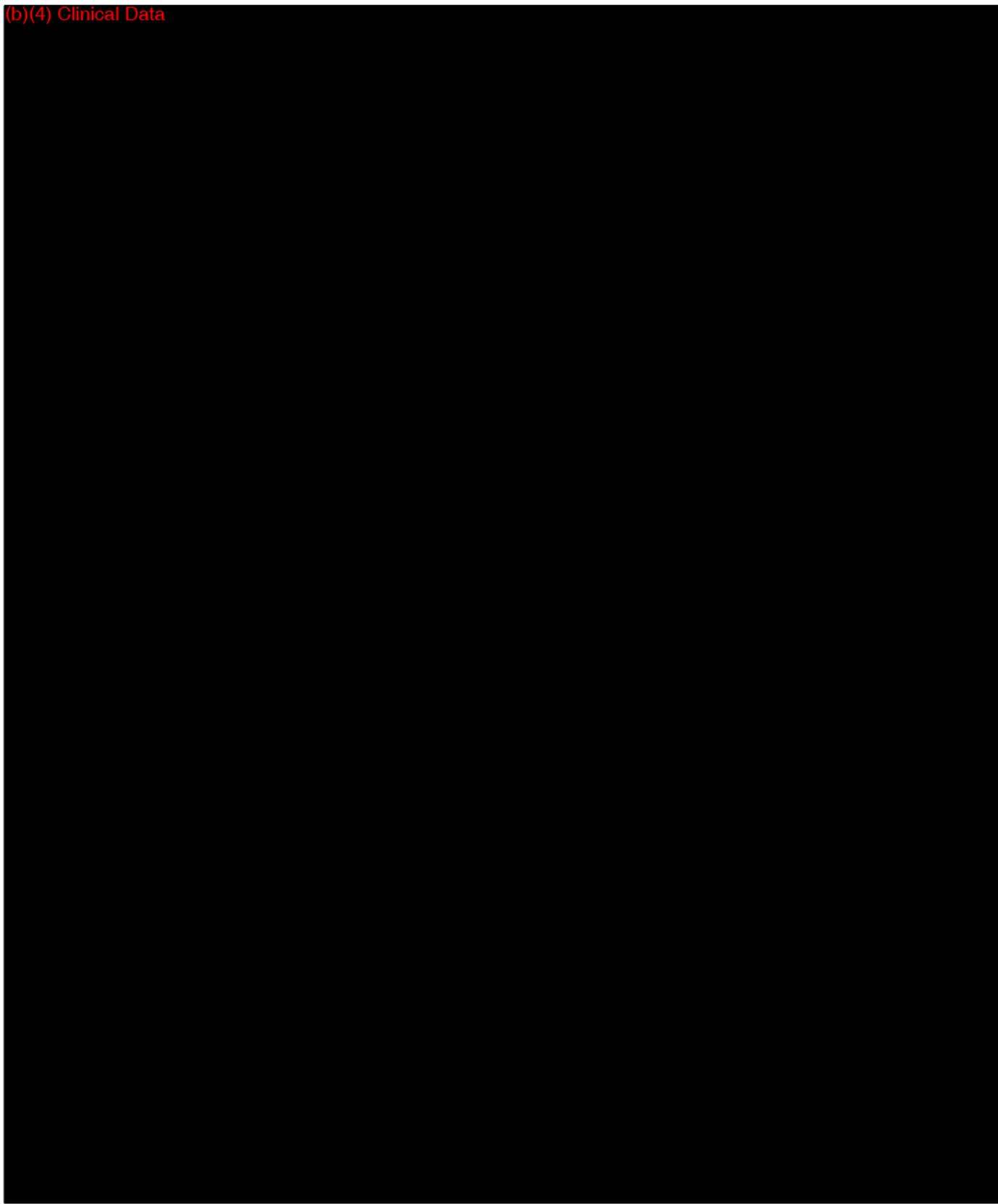
(b)(4) Clinical Data



(b)(4) Clinical Data

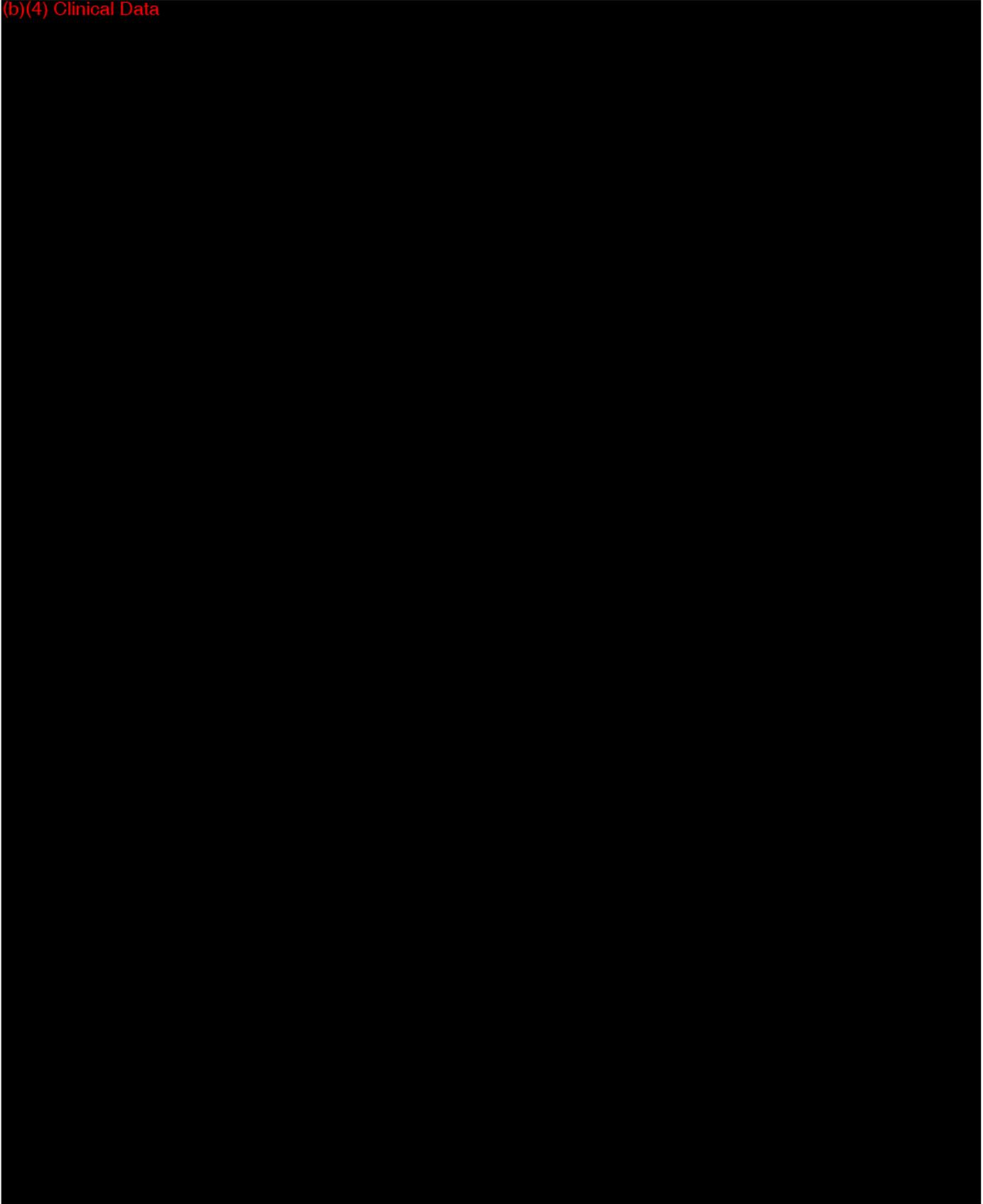


(b)(4) Clinical Data



**CONFIDENTIAL**

(b)(4) Clinical Data



Ch

Premarket Notification  
Orthofix - External Fixation Pin Modification

(b) (4)



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**510(k) SUMMARY<sup>1</sup>**  
**Orthofix® External Fixation Screw**  
**March 3, 1998**

This summary is provided in accordance with the Safe Medical Devices Act of 1990 (SMDA). The information provided in the 510(k), premarket notification was in accordance with 21 CFR 807.87 and the SMDA.

**1. Submitter of 510(k)**

Robert L. Sheridan (Consultant)  
Vice President, Device Evaluation  
C.L. McIntosh & Associates, Inc.  
12300 Twinbrook Parkway, Suite 625  
Rockville, MD 20852

Telephone: (301) 770-9590

Facsimile: (301) 770-9584

**2. Name of Device**

**2.1 Trade/Proprietary Name**

Orthofix® External Fixation Screw (Pin) With Hydroxyapatite Coating

**2.2 Common/Usual Name**

External fixation pin

**2.3 Classification Name**

Smooth or threaded metallic bone fixation fastener (21 CFR 888.3040).

**3. Applicant/Manufacturer**

ORTHOFIX Srl.  
Via delle Nazioni 9  
37012 Bussolengo (VR), Italy  
Attention: Rolando Stanghellini, Director of Quality Assurance

Telephone: 011-39-45-6767030

Facsimile: 011-39-45-6767135

**4. Reason for Submitting the 510(k)**

Orthofix intends to commercially distribute a modified version of its previously 510(k)-cleared external fixation pin. Orthofix wishes to distribute its pins with a very thin plasma sprayed coating of hydroxyapatite (HA).



**5. Device Description**

The Orthofix Hydroxyapatite Coated Screws are manufactured from surgical grade stainless steel AISI 316L. The pins are available in a variety of diameters and lengths. The threaded end is gradually tapered, over approximately the last third of the pin's length. The threaded portion of the pin is coated with a very thin plasma sprayed coating of HA. The HA powder used in the plasma spray coating process conforms to ASTM F 1185. The mechanical properties of the coating conform to ASTM F 1501.

**6. Indications For Use**

The Orthofix external fixation screw (pin) with hydroxyapatite coating is indicated for use in the external fixation of bone.

**7. Substantial Equivalence**

The decision that the Orthofix HA coated pin is substantially equivalent to a legally marketed predicate device is reached through consideration of the requirements for substantial equivalence determinations. These requirements are set forth in the document entitled "Guidance on the Center for Devices and Radiological Health's Premarket Notification Review Program", which was published on June 30, 1986 by the Center for Devices and Radiological Health (CDRH),

FDA guidance documents relevant to this application were used in its preparation. In particular, the guidance document, "510(k) Information Needed for Hydroxyapatite Coated Orthopedic Implants" (revised February 20, 1997), was followed in the preparation of this 510(k). The physical, mechanical and chemical tests prescribed by FDA in its guidance document to characterize the HA coating and HA/substrate interface were conducted.

The substantial equivalence of the Orthofix HA coated pins is supported by the extensive laboratory, animal and clinical testing data presented herein. The preclinical and clinical data presented herein demonstrate that the use of the proprietary HA-coating enhances fixation at the pin/bone interface. The Orthofix HA-coated pins demonstrate statistically significantly better stability or fixation at the time of removal or extraction than do the uncoated pins.

Orthofix pins with the proprietary HA-coating were found in randomized controlled clinical and animal studies to have significantly enhanced fixation and a reduced incidence of clinical loosening. The clinical results demonstrate:

- No significant difference in the insertion torques for standard uncoated and HA-coated Orthofix pins in both metaphyseal and diaphyseal bone.
- The extraction torque is significantly greater for HA-coated Orthofix pins than for uncoated pins in both metaphyseal and diaphyseal bone.

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- For the HA-coated Orthofix pins, the extraction torque is significantly greater than the insertion torque in both metaphyseal and diaphyseal bone; whereas, for the uncoated pins, the extraction torque is significantly lower than the insertion torque in both metaphyseal and diaphyseal bone.

The animal study that was conducted compared uncoated and HA-coated Orthofix pins. Radiographic, histologic, SEM and histomorphometric analyses demonstrate that osseointegration with direct contact between the bone and the screw threads of the Orthofix HA-coated pins.

As reported in the literature, complications of external fixation include pin tract infection and loosening. The enhanced fixation and improved stability at the bone-pin interface seen with the Orthofix Ha-coated pins significantly reduces the incidence of pin loosening. It is generally accepted that a loose pin provides an increased risk of infection.

In summary, the information and data provided in this submission are consistent with FDA's guidance documents for HA coated orthopedic implants and demonstrate that the Orthofix HA coated pin is substantially equivalent to legally marketed predicate devices.

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<sup>1</sup> Any statement made in conjunction with this submission regarding a determination of substantial equivalence to any other product is intended only to refer to whether the product can be lawfully marketed without pre-market approval or reclassification and is not intended to be interpreted as an admission or any other type of evidence in patent infringement litigation. (Establishment Registration and Premarket Notification Procedures, Final Regulation, Preamble, August 23, 1977, FR 42520 (Docket No. 76N-0355))

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February 03, 1998

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

ORTHOFIX SRL  
C/O C.L. MCINTOSH & ASSOCIATES, INC  
12300 TWINBROOK PARKWAY,  
SUITE 625  
ROCKVILLE, MD 20852  
ATTN: ROBERT L. SHERIDAN

510(k) Number: K974186  
Product: ORTHOFIX  
EXTERNAL  
FIXATION SCREW  
(PIN) WITH

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 (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations, we cannot accept telefax material as part of your official premarket notification submission unless specifically requested of you by an FDA official.

If after 30 days the requested information, 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. 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 or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

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

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Handwritten initials/signature

Memorandum

From: Reviewer(s) - Name(s) Peter Allen

Subject: 510(k) Number 1404186

To: The Record - It is my recommendation that the subject 510(k) Notification:

- Refused to accept.
Requires additional information (other than refuse to accept). A.I. (phone hold)
Accepted for review
Is substantially equivalent to marketed devices.
NOT substantially equivalent to marketed devices.
Other (e.g., exempt by regulation, not a device, duplicate, etc.)

- Is this device subject to Postmarket Surveillance? YES NO
Is this device subject to the Tracking Regulation? YES NO
Was clinical data necessary to support the review of this 510(k)? YES NO
Is this a prescription device? YES NO
Was this 510(k) reviewed by a Third Party? YES NO

- This 510(k) contains:
Truthful and Accurate Statement Requested Enclosed
A 510(k) summary OR A 510(k) statement
The required certification and summary for class III devices
The indication for use form (required for originals received 1-1-96 and after)

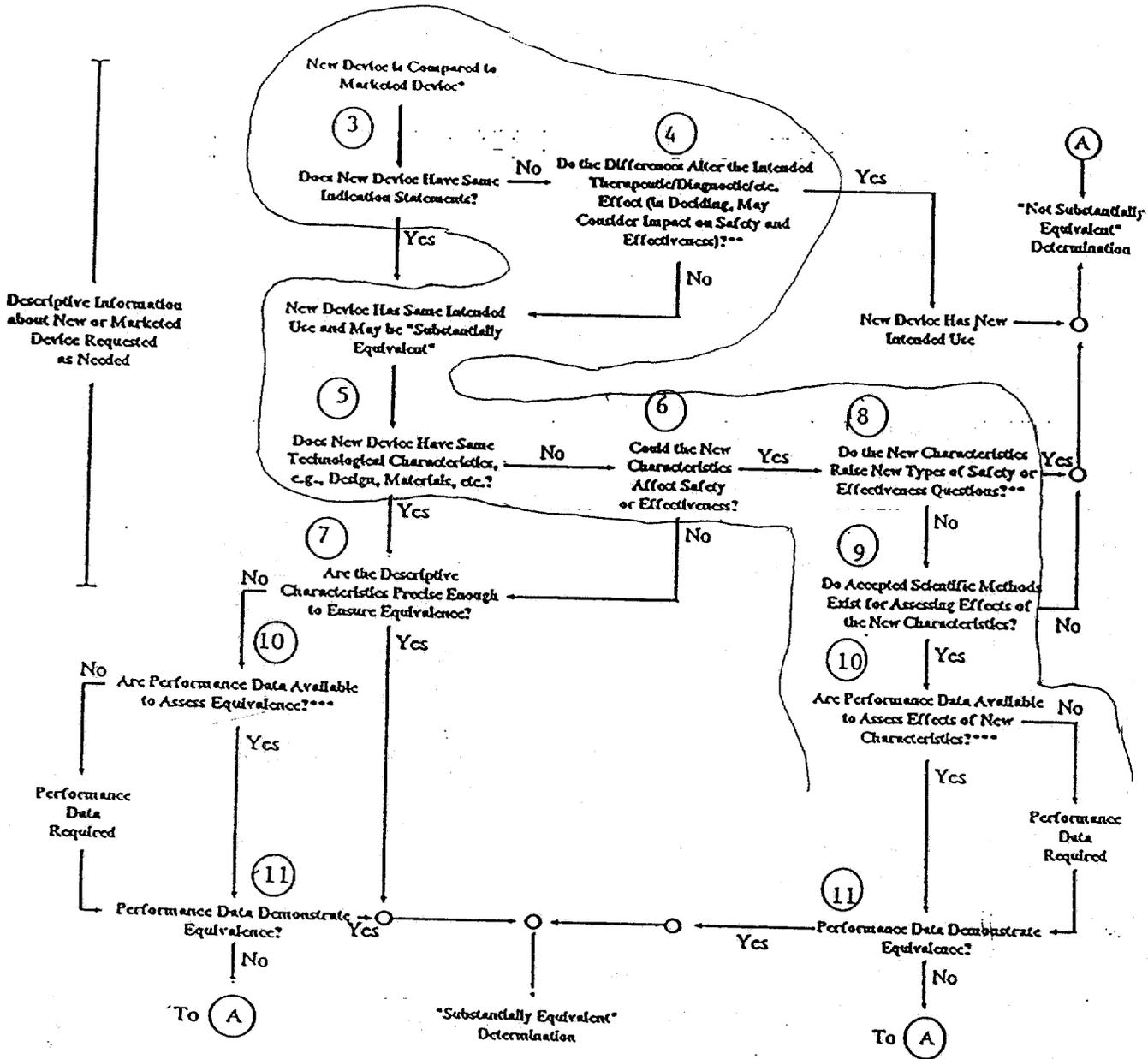
The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):
No Confidentiality Confidentiality for 90 days Continued Confidentiality exceeding 90 days

Predicate Product Code with class and tier: JDW, 87, II Additional Product Code(s) with panel (optional):

Review: (Branch Chief) (Branch Code) (Date)
Final Review: (Division Director) (Date)

Handwritten number 30

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



\* 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.

JD  
2/2/98

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510(k) MEMORANDUM

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**TO:** K974186  
**FROM:** Peter G. Allen, Biomedical Engineer, M.S.  
FDA/CDRH/ODE/DGRD/Orthopedic Devices Branch  
**DATE:** January 30, 1998  
**SUBJ:** Orthofix External Fixation Screw (Pin) with Hydroxyapatite Coating  
Product Code: JDW(87), CFR 888.3040; Class II  
**Company:** Orthofix, Srl (Italy)  
Contact: Robert L. Sheridan, Vice President Device Evaluation, C.L. McIntosh & Associates  
Phone: (301) 770-9590 Fax: (301) 770-9584

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**Recommendation:**

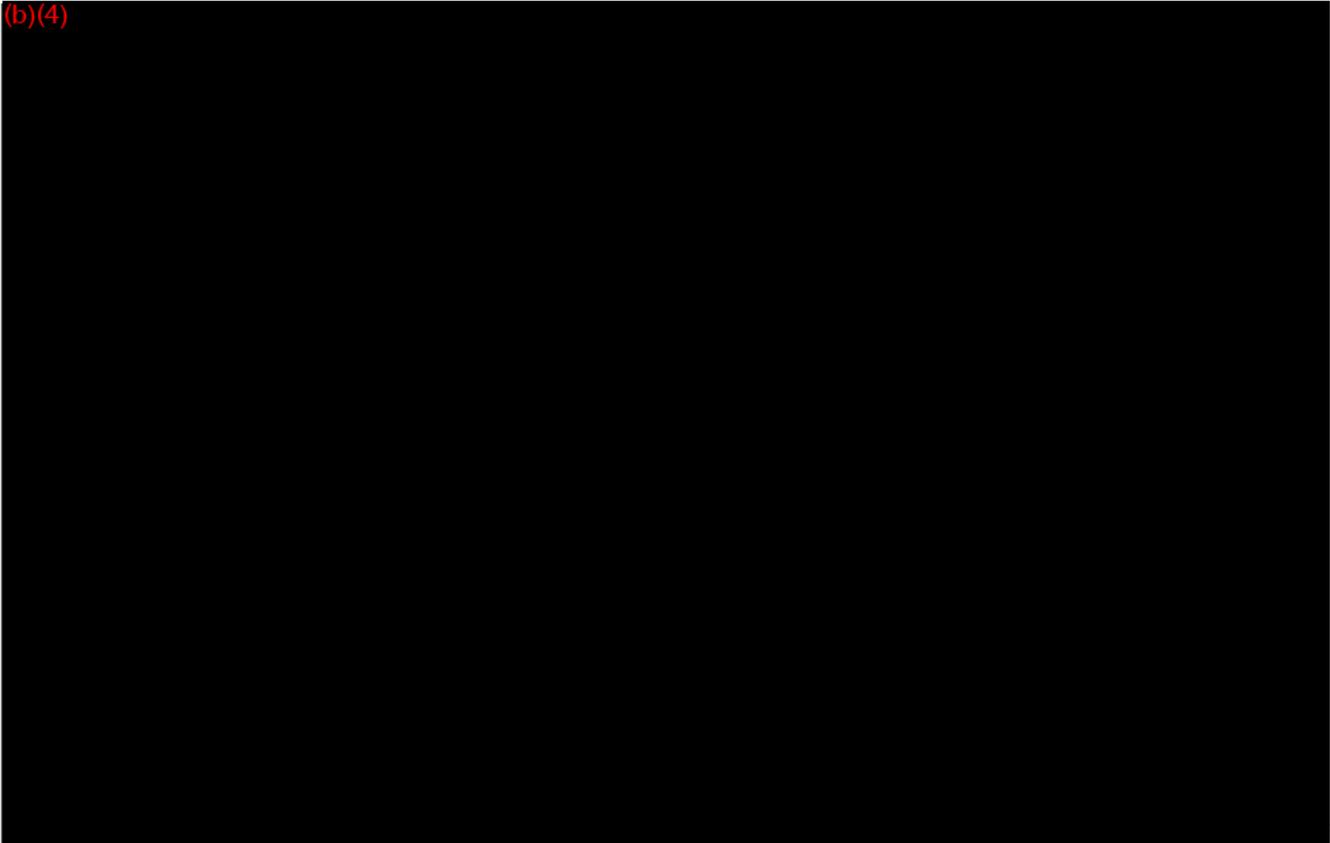
I recommend that the subject device be placed on phone hold (AI) until receipt of additional information requested from the sponsor. The sponsor's contact, Bob Sheridan, was notified of the request and the phone hold status in a teleconference with myself and Mark Melkerson, ORDB Branch Chief, on Thursday, January 29, 1998.

**Review:**

**1. Administrative Requirements:**

This submission included a 510(k) Summary, Indications for Use page, and a Truthful and Accuracy statement. The Summary and Indications for Use page will need to be revised to reflect any claims the sponsor can support based on the additional information provided to FDA.

(b)(4)



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(b)(4)

**2. Device Description:**

The Orthofix External Fixation Pin (without HA) is a component of the Orthofix Dynamic Axial Fixation System, which received FDA clearance under K831576 and K955848. These pins are a cortical, self-tapping, tapered design, manufactured from surgical grade stainless steel. The current submission seeks to add an additional pin option to this system. The 'new' pin is identical to the previous pin, with the exception that the distal threads have a very thin (b)(4) plasma sprayed coating of hydroxyapatite (HA).

The stainless steel, AISI 316L, conforms to ISO 5832-1 and ASTM F 138. The HA powder conforms to ASTM F 1185. The mechanical properties of the powder conform to ASTM F 1501.

The Orthofix HA coated pins are available in a variety of lengths and diameters. The shank or shaft diameter is either 4 or 6 mm. Lengths range from 50 to 250 mm. The threaded end (inserted into the bone) is gradually tapered, over approximately the last third of the pin's length. The threaded end is coated with HA. The exact length of the taper and coating surface are dependent on the pin's length and are given on the engineering drawing of Appendix 2 as A (mm) and L (mm), respectively.

The pins are coated for Orthofix (b)(4)



No special tools are needed to insert or remove the HA coated pins. They use the same surgical instrumentation as the predicate uncoated pins and are to be used with the same external fixator system.

**3. Intended Use:**

The Orthofix External Fixation Screw (Pin) with Hydroxyapatite Coating is indicated for use in the external fixation of bone. This will need to be revised based on the claims the sponsor can make with regards to the additional data they supply to FDA.

**4. Sterilization:**

The device is provided sterile.

Method: 2.5 Mrads (25 kGy) of gamma radiation

Sterility Validation Method: Guideline for Gamma Radiation Sterilization, ANSI/AAMI/ISO 11137.

Sterility Assurance Level: 10<sup>-6</sup>

Description of packaging: polyethylene terephthalate glycol (PETG) modified thermoform inner tray, heat sealed with a Tyvek lid. The inner tray will be enclosed in an outer PETG tray also heat sealed with a Tyvek lid.

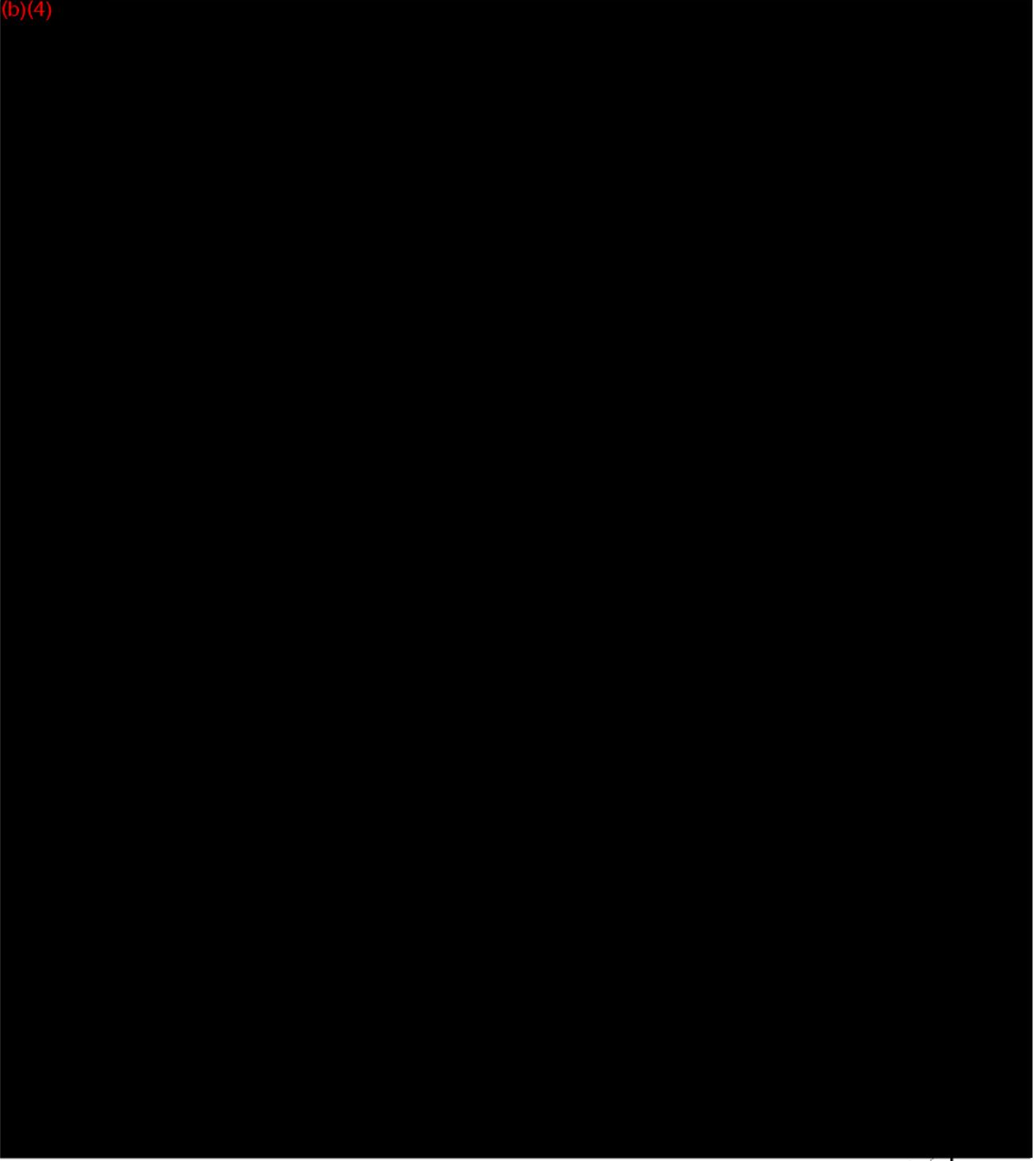
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Is device labeled "pyrogen free"?: No  
Recommended re-sterilization method: none recommended

5. **Labeling:**  
Labeling in the form of draft package labels were provided. However, no package insert was provided. A package insert will need to include any new claims made by the sponsor for the HA coated pins.

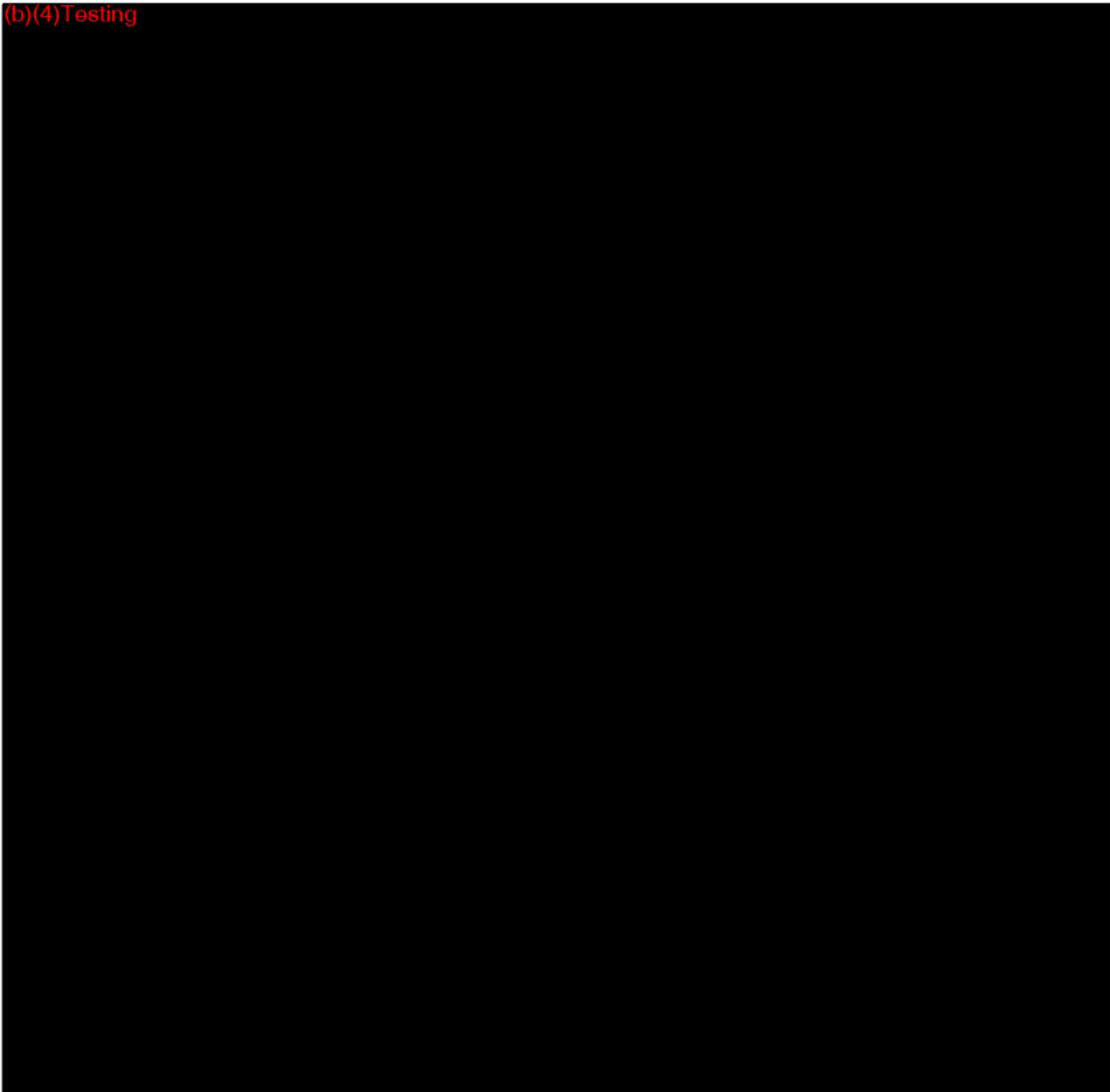
6. **Testing:**

(b)(4)



3h

(b)(4)Testing



7. **Sponsor's Information in Support of SE:**  
K955848, K831576, Orthofix Srl., Orthofix Dynamic Axial Fixation System  
K896047, Osteonics Corp., Omnifit EPF Hip Joint Femoral Stem  
K912369, Biomet, HAP Bio-Groove Total Hip Prosthesis  
K910156, DePuy, Hydroxyapatite Coated Profile Hip Stem  
K961433, Electro-Biology, Inc., EBI X Fix Dynafix System - SC Bone Screws
8. **Review of other 510(k)s for SE:**  
See number 7, above.
9. **Summary of Sponsor's Information in Support of SE:**

(b)(4)



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(b)(4)



**10. Contact History/Requests for More Information:**

(b)(4)



Peter G. Allen, Biomedical Engineer/Reviewer  
DGRD/ORDB  
January 30, 1998

Peter G Allen

PREMARKET NOTIFICATION (510(K)) CHECKLIST FOR ACCEPTANCE DECISION

974186

Device Name Ex. Fix. Screw w/ HA

Division/Branch DGRD/OR

Administrative Reviewer Signature Michael Courtney Date 11/14/97

Supervisory Signature \_\_\_\_\_ Date \_\_\_\_\_

Did the firm request expedited review? Yes  No

Did we grant expedited review? Yes  No

Truthful and accurate statement enclosed?  Yes  No  
(If Not Enclosed, Must Be A Refuse To Accept Letter)  
Required For Originals Received 3/14/95 And After

Is the Indication for Use Form enclosed?  YES  No  
(Required for Original 510(k)s received 1/1/96 and after --  
must be submitted on a separate sheet of paper)

Without reviewing this 510(k), do you believe this device type may be a preamendments class III device? Yes  No  (IF YES, NOTIFY POS IMMEDIATELY IF THE OUTSIDE OF THE 510(k) HAS NOT BEEN STAMPED CLASS III SO THAT THE GMP INSPECTION CAN BE SCHEDULED AS SOON AS POSSIBLE). Class III devices can not receive a determination of substantial equivalence until the GMP inspection process has been completed.

Is this a file that was determined to be substantially equivalent by ODE, but placed on hold due to GMP violations and deleted after 12 months on hold? If so, a new ODE review is not required, please forward to POS.

Yes  No

Accepted

Refuse To Accept

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I. CRITICAL ELEMENTS:	YES PRESENT OMISSION JUSTIFIED	NO INADEQUATE OMITTED
A. Is The Product A Device?	<input type="checkbox"/>	<input type="checkbox"/>
B. Is The Device Exempt From 510(k) By Regulation Or Policy?	<input type="checkbox"/>	<input type="checkbox"/>
C. Is Device Subject To Review By CDRH?	<input type="checkbox"/>	<input type="checkbox"/>
D. (i) Are You Aware That This Device Has Been The Subject Of A Previous NSE Decision?  (ii) If Yes, Does This New 510(k) Address The NSE Issue(s) (E.G., Performance Data)?	<input type="checkbox"/>  <input type="checkbox"/>	<input type="checkbox"/>  <input type="checkbox"/>
E. (i) Are You Aware Of The Submitter Being The Subject Of An Integrity Investigation?  If Yes, Consult The ODE Integrity Officer.  (ii) Has The ODE Integrity Officer Given Permission To Proceed With The Review? (Blue Book Memo #I91-2 And Federal Register 90N-0332, September 10, 1991.)	<input type="checkbox"/>  <input type="checkbox"/>	<input type="checkbox"/>  <input type="checkbox"/>
F. Does The Submission Contain The Information Required Under Sections 510(k), 513(f), And 513(i) Of The Federal Food, Drug, and Cosmetic Act (Act) And Subpart E Of Part 807 In Title 21 Of The Code Of Federal Regulations?:	<input type="checkbox"/>	<input type="checkbox"/>
1. Device Trade Or Proprietary Name	<input type="checkbox"/>	<input type="checkbox"/>
2. Device Common Or Usual Name Or Classification Name	<input type="checkbox"/>	<input type="checkbox"/>
3. Establishment Registration Number (Only Applies If Establishment Is Registered)	<input type="checkbox"/>	<input type="checkbox"/>
4. Class Into Which The Device Is Classified Under (21 CFR Parts 862 to 892)	<input type="checkbox"/>	<input type="checkbox"/>
5. Classification Panel	<input type="checkbox"/>	<input type="checkbox"/>
6. Action Taken To Comply With Section 514 Of The Act	<input type="checkbox"/>	<input type="checkbox"/>
7. Proposed Labels, Labeling And Advertisements (If Available) That Describe The Device, Its Intended Use, And Directions For Use (Blue Book Memo #G91-1)	<input type="checkbox"/>	<input type="checkbox"/>

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8. A 510(k) Summary Of Safety And Effectiveness Or A 510(k) Statement That Safety And Effectiveness Information Will Be Made Available To Any Person Upon Request	<input type="checkbox"/>	<input type="checkbox"/>
9. For Class III Devices Only, A Class III Certification And A Class III Summary	<input type="checkbox"/>	<input type="checkbox"/>
10. Photographs Of The Device	<input type="checkbox"/>	<input type="checkbox"/>
11. Engineering Drawings For The Device With Dimensions And Tolerances	<input type="checkbox"/>	<input type="checkbox"/>
12. The Marketed Device(s) To Which Equivalence Is Claimed Including Labeling And Description Of The Device	<input type="checkbox"/>	<input type="checkbox"/>
13. Statement Of Similarities And/Or Differences With Marketed Device(s)	<input type="checkbox"/>	<input type="checkbox"/>
14. Data To Show Consequences And Effects Of A Modified Device(s)	<input type="checkbox"/>	<input type="checkbox"/>
15. Truthful And Accurate Statement	<input type="checkbox"/>	<input type="checkbox"/>
II. Additional Information That <u>Is</u> Necessary Under 21 CFR 807.87(h):	<input type="checkbox"/>	<input type="checkbox"/>
A. Submitter's Name And Address	<input type="checkbox"/>	<input type="checkbox"/>
B. Contact Person, Telephone Number And Fax Number	<input type="checkbox"/>	<input type="checkbox"/>
C. Representative/Consultant If Applicable	<input type="checkbox"/>	<input type="checkbox"/>
D. Table Of Contents With Pagination	<input type="checkbox"/>	<input type="checkbox"/>
E. Address Of Manufacturing Facility/Facilities And, If Appropriate, Sterilization Site(s)	<input type="checkbox"/>	<input type="checkbox"/>
III. Additional Information That <u>May Be</u> Necessary Under 21 CFR 807.87(h):	<input type="checkbox"/>	<input type="checkbox"/>
A. Comparison Table Of The New Device To The Marketed Device(s)	<input type="checkbox"/>	<input type="checkbox"/>
B. Action Taken To Comply With Voluntary Standards	<input type="checkbox"/>	<input type="checkbox"/>
C. Performance Data	<input type="checkbox"/>	<input type="checkbox"/>
MARKETED DEVICE:	<input type="checkbox"/>	<input type="checkbox"/>
Bench Testing	<input type="checkbox"/>	<input type="checkbox"/>
Animal Testing	<input type="checkbox"/>	<input type="checkbox"/>
Clinical Data	<input type="checkbox"/>	<input type="checkbox"/>
NEW DEVICE:	<input type="checkbox"/>	<input type="checkbox"/>
Bench Testing	<input type="checkbox"/>	<input type="checkbox"/>
Animal Testing	<input type="checkbox"/>	<input type="checkbox"/>

Clinical Data	<input type="checkbox"/>	<input type="checkbox"/>
D. Sterilization Information	<input type="checkbox"/>	<input type="checkbox"/>
E. Software Information	<input type="checkbox"/>	<input type="checkbox"/>
F. Hardware Information	<input type="checkbox"/>	<input type="checkbox"/>
G. If This 510(k) Is For A Kit, Has The Kit Certification Statement Been Provided?	<input type="checkbox"/>	<input type="checkbox"/>
H. Is This Device Subject To Issues That Have Been Addressed In Specific Guidance Document(s)?	<input type="checkbox"/>	<input type="checkbox"/>
If Yes, Continue Review With Checklist From Any Appropriate Guidance Documents.	<input type="checkbox"/>	<input type="checkbox"/>
If No, Is 510(k) Sufficiently Complete To Allow Substantive Review?	<input type="checkbox"/>	<input type="checkbox"/>
I. Other (Specify)	<input type="checkbox"/>	<input type="checkbox"/>

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November 10, 1997

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

ORTHOFIX SRL  
C/O C.L. MCINTOSH & ASSOCIATES, INC  
12300 TWINBROOK PARKWAY,  
SUITE 625  
ROCKVILLE, MD 20852  
ATTN: ROBERT L. SHERIDAN

510(k) Number: K974186  
Received: 07-NOV-97  
Product: ORTHOFIX EXTERNAL  
FIXATION SCREW (PIN)  
WITH HYDROXYAPATITE  
COATING

The Center for Devices and Radiological Health (CDRH), Office of Device Evaluation (ODE), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification 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.

On January 1, 1996, FDA began requiring that all 510(k) submitters provide on a separate page and clearly marked "Indication For Use" the indication for use of their device. If you have not included this information on a separate page in your submission, please complete the attached and amend your 510(k) as soon as possible. Also if you have not included your 510(k) Summary or 510(k) Statement, or your Truthful and Accurate Statement, please do so as soon as possible. There may be other regulations or requirements affecting your device such as Postmarket Surveillance (Section 522(a)(1) of the Act) and the Device Tracking regulation (21 CFR Part 821). Please contact the Division of Small Manufacturers Assistance (DSMA) at the telephone or web site below for more information.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the Document Mail Center will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations, we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official. Any telefaxed material must be followed by a hard copy to the Document Mail Center (HFZ-401).

You should be familiar with the manual entitled, "Premarket Notification 510(k) Regulatory Requirements for Medical Devices" available from DSMA. If you have other procedural or policy questions, or want information on how to check on the status of your submission (after 90 days from the receipt date), please contact DSMA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address <http://www.fda.gov/cdrh/dsmamain.html> or me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman  
Consumer Safety Officer  
Premarket Notification Staff

h1

K974186

**CENTER FOR DEVICES AND RADIOLOGICAL HEALTH**  
**Premarket Submission Cover Sheet**

Date of Submission:

FDA Document Number:

**Section A** **Type of Submission**

- |   |   |  |   |
|---|---|--|---|
| <input checked="" type="checkbox"/> 510(k)        | <input type="checkbox"/> IDE            | <input type="checkbox"/> PMA           | <input type="checkbox"/> PMA Supplement - Regular     |
| <input type="checkbox"/> 510(k) Add'l information | <input type="checkbox"/> IDE Amendment  | <input type="checkbox"/> PMA Amendment | <input type="checkbox"/> PMA Supplement - Special     |
|   | <input type="checkbox"/> IDE Supplement | <input type="checkbox"/> PMA Report    | <input type="checkbox"/> PMA Supplement - 30 day      |
|   | <input type="checkbox"/> IDE Report     |  | <input type="checkbox"/> PMA Supplement - Panel Track |

**Section B1** **Reason for Submission - 510(k)s Only**

- |  |   |  |
|--|---|--|
| <input checked="" type="checkbox"/> New device   | <input type="checkbox"/> Additional or expanded indications | <input type="checkbox"/> Change in technology, design, materials, or manufacturing process |
| <input type="checkbox"/> Other reason (specify): |   |  |

**Section B2** **Reason for Submission - PMA's Only**

- |   |   |  |
|---|---|--|
| <input type="checkbox"/> New device                         | <input type="checkbox"/> Change in design, component, or specification: | <input type="checkbox"/> Location change:    |
| <input type="checkbox"/> Withdrawal                         | <input type="checkbox"/> Software                                       | <input type="checkbox"/> Manufacturer        |
| <input type="checkbox"/> Additional or expanded indications | <input type="checkbox"/> Color Additive                                 | <input type="checkbox"/> Sterilizer          |
| <input type="checkbox"/> Licensing agreement                | <input type="checkbox"/> Other (specify below)                          | <input type="checkbox"/> Packager            |
| <input type="checkbox"/> Labeling change:                   | <input type="checkbox"/> Process change:                                | <input type="checkbox"/> Distributor         |
| <input type="checkbox"/> Indications                        | <input type="checkbox"/> Manufacturer                                   | <input type="checkbox"/> Report submission:  |
| <input type="checkbox"/> Instructions                       | <input type="checkbox"/> Sterilizer                                     | <input type="checkbox"/> Annual or periodic  |
| <input type="checkbox"/> Performance Characteristics        | <input type="checkbox"/> Packager                                       | <input type="checkbox"/> Post-approval study |
| <input type="checkbox"/> Shelf life                         |   | <input type="checkbox"/> Adverse reaction    |
| <input type="checkbox"/> Trade name                         |   | <input type="checkbox"/> Device defect       |
| <input type="checkbox"/> Other (specify below)              | <input type="checkbox"/> Response to FDA correspondence (specify below) | <input type="checkbox"/> Amendment           |
| <input type="checkbox"/> Change in ownership                | <input type="checkbox"/> Request for applicant hold                     |  |
| <input type="checkbox"/> Change in correspondent            | <input type="checkbox"/> Request for removal of applicant hold          |  |
|   | <input type="checkbox"/> Request for extension                          |  |
| <input type="checkbox"/> Other reason (specify):            | <input type="checkbox"/> Request to remove or add manufacturing site    |  |

**Section B3** **Reason for Submission - IDEs Only**

- |  |  |  |
|--|--|--|
| <input type="checkbox"/> New device                    | <input type="checkbox"/> Change in:                | <input type="checkbox"/> Response to FDA letter concerning:          |
| <input type="checkbox"/> Addition of institution       | <input type="checkbox"/> Correspondent             | <input type="checkbox"/> Conditional approval                        |
| <input type="checkbox"/> Expansion/extension of study  | <input type="checkbox"/> Design                    | <input type="checkbox"/> Deemed approved                             |
| <input type="checkbox"/> IRB certification             | <input type="checkbox"/> Informed consent          | <input type="checkbox"/> Deficient final report                      |
| <input type="checkbox"/> Request hearing               | <input type="checkbox"/> Manufacturer              | <input type="checkbox"/> Deficient progress report                   |
| <input type="checkbox"/> Request waiver                | <input type="checkbox"/> Protocol - feasibility    | <input type="checkbox"/> Deficient investigator report               |
| <input type="checkbox"/> Termination of study          | <input type="checkbox"/> Protocol - other          | <input type="checkbox"/> Disapproval                                 |
| <input type="checkbox"/> Withdrawal of application     | <input type="checkbox"/> Sponsor                   | <input type="checkbox"/> Request extension of time to respond to FDA |
| <input type="checkbox"/> Emergency use:                | <input type="checkbox"/> Report submission:        | <input type="checkbox"/> Request meeting                             |
| <input type="checkbox"/> Notification of emergency use | <input type="checkbox"/> Current investigator      | <input type="checkbox"/> IOL submissions only:                       |
| <input type="checkbox"/> Additional information        | <input type="checkbox"/> Annual progress           | <input type="checkbox"/> Change in IOL style                         |
|  | <input type="checkbox"/> Site waiver limit reached | <input type="checkbox"/> Request for protocol waiver                 |
| <input type="checkbox"/> Other reason (specify):       | <input type="checkbox"/> Final                     |  |

K2  
CR  
class  
II

FDA Document Number:

**Section G Applicant or Sponsor**

Company / Institution name: Orthofix, Srl.

FDA establishment registration number:  
9680825

Division name (if applicable):

Phone number (include area code):  
39-45-6767030

Street address: Via delle Nazioni 9

FAX number (include area code):  
39-45-6767135

City: Bussolengo, VR

State/Province

Country: Italy

ZIP / Postal Code: 37012

Signature: 510(k) signed by contact/consultant, see below

Name: Rolando Stanghellini,

Title: Director of Quality Assurance

**Section H Submission correspondent (if different from above)**

Company / Institution name: C.L. McIntosh & Associates, Inc.

Division name (if applicable):

Phone number (include area code):  
(301) 770-9590

Street address: 12300 Twinbrook Parkway, Suite 625

FAX number (include area code):  
(301) 770-9584

City: Rockville

State / Province  
MD

Country:

ZIP / Postal Code: 20852

Contact name: Robert L. Sheridan

Contact title: Vice President, Device Evaluation

Your voluntary completion of this Premarket Submission Cover Sheet will not affect any FDA decision concerning your submission, but will help FDA's Center for Devices and Radiological Health process your submission more efficiently. The information you provide should apply *only* to a single accompanying submission. Please do not send cover sheets for any previous submissions. See the instructions for additional information on completing the cover sheet. If you have a question concerning completion of the cover sheet, please contact the Division of Small Manufacturers Assistance at (800) 638-2041 or (301) 443-6597.

h3

FDA Document Number:

**Section C Product Classification**

Product code: JDW      CFR Section: 21 CFR 888.3040

Device class:

Classification panel: Orthopedic and Rehabilitation Devices Panel

Class I  
 Class III       Unclassified

**Section D Information on 510(k) Submissions**

Product codes of devices to which substantial equivalence is claimed:

Summary of, or statement concerning, safety and effectiveness data:

1 JDW	2	3	4
5	6	7	8

510(k) summary attached  
 510(k) statement

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or proprietary or model name	Manufacturer
1 955848	1 Orthofix uncoated external fixation pin	1 Orthofix
2	2	2
3	3	3
4	4	4
5	5	5
6	8	8

**Section E Product Information - Applicable to All Applications**

Common or usual name or classification name: External fixation pin

Trade or proprietary or model name	Model number
1 External Fixation Screw (Pin) With Hydroxyapatite Coating	1
2	2

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

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

Data included in submission:       Laboratory testing       Animal trials       Human trials

Indications (from labeling): The Orthofix external fixation screw (pin) with hydroxyapatite coating is indicated for use in the external fixation of bone.

hh

FDA Document Number:

**Section F Manufacturing / Packaging / Sterilization Sites**

Original  
 Add    Delete

FDA establishment registration  
number: same as above

Manufacturer    Contract sterilizer  
 Contract manufacturer    Repackager / relabeler

Company / Institution name: same

Division name (if applicable):

Phone number (include area code):

Street address:

FAX number (include area code):

City:

State / Province:

Country:

ZIP / Postal Code:

Contact name:

Contact title:

Original  
 Add    Delete

FDA establishment registration  
number:

Manufacturer    Contract sterilizer  
 Contract manufacturer    Repackager / relabeler

Company / Institution name:

Division name (if applicable):

Phone number (include area code):

Street address:

FAX number (include area code):

City:

State / Province:

Country:

ZIP / Postal Code:

Contact name:

Contact title:

Original  
 Add    Delete

FDA establishment registration  
number:

Manufacturer    Contract sterilizer  
 Contract manufacturer    Repackager / relabeler

Company / Institution name:

Division name (if applicable):

Phone number (include area code):

Street address:

FAX Number (include area code):

City:

State / Province:

Country:

ZIP / Postal Code:

Contact name:

Contact title:

HS

**Premarket Notification (510(k)) Checklist for Acceptance Decision**

K 974186 Device Name Orthofix® External Fixation Screw (Pin) With Hydroxyapatite Coating  
 Division/Branch Division of General and Restorative Devices/Orthopedic Devices Branch Date \_\_\_\_\_  
 Administrative Reviewer Signature \_\_\_\_\_ Date \_\_\_\_\_  
 Supervisory Signature \_\_\_\_\_ Date \_\_\_\_\_  
 Did the firm request expedited review? Yes  No   
 Did we grant expedited review? Yes  No   
 Truthful and accurate statement enclosed?  Yes  No

Accepted \_\_\_\_\_ Refuse to Accept \_\_\_\_\_

510(k) ELEMENTS		YES <sup>1</sup>	NO <sup>2</sup>	LOCATION OF ELEMENT IN 510(K)
<b>I. Critical Elements:</b>				
A.	Is the product a device?	X		
B.	Is the device exempt from 510(k) by regulation or policy?		X	
C.	Is device subject to review by CDRH?	X		
D.	(i) Are you aware that this device has been the subject of a previous NSE decision?		X	
	(ii) If yes, does this new 510(k) address the NSE issue(s) (e.g., performance data)?	--	--	
E.	(i) Are you aware of the submitter being the subject of an integrity investigation?		X	
If yes, consult the ODE Integrity Officer.				

510(k) ELEMENTS	YES <sup>1</sup>	NO <sup>2</sup>	LOCATION OF ELEMENT IN 510(K)
(ii) Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and F R90N-0332, September 10, 1991.)	--	--	
F. Does the submission contain the information required under Sections 510(k), 513(f), and 513(i) of the Federal Food, Drug, and Cosmetic Act (Act) and Subpart E of Part 807 in Title 21 of the Code of Federal Regulations?	X		
Device trade name or proprietary name	X		Section 1.2, Name of Device
Device common or usual name or classification name	X		Section 1.2, Name of Device
Establishment registration number (only applies if establishment is registered)	X		Section 1.3, Establishment Registration
Class into which the device is classified under (21CFR Parts 862 to 892)	X		Section 1.4, Classification Information
Classification Panel	X		Section 1.4, Classification Information
Action taken to comply with Section 514 of the Act	X		Section 1.5, Performance Standards
Proposed labels, labeling and advertisements (if available) that describe the device, its intended use, and directions for use (Blue Book Memo #G91-1)	X		Appendices 1
A 510(k) summary of safety and effectiveness or a 510(k) statement that safety and effectiveness information will be made available to any person upon request	X		Appendix 6
For class III devices only, a class III certification and a class III summary	N/A <sup>3</sup>		

510(k) ELEMENTS		YES <sup>1</sup>	NO <sup>2</sup>	LOCATION OF ELEMENT IN 510(K)
Photographs of the device		X		Appendices 2 (engineering drawing) and 3
Engineering drawings for the device with dimensions and tolerances		X		Appendix 2
The marketed device(s) to which equivalence is claimed including labeling and description of the device		X		Section 3. Rationale for Substantial Equivalence
Statement of similarities and/or differences with marketed device(s)		X		Section 3. Rationale for Substantial Equivalence
Data to show consequences and effects of a modified device		X		Section 4. Performance Data
II. Additional Information that is necessary under 21 CFR 807.87(h):				
A. Submitter's name and address		X		Section 1.3. Establishment Registration
B. Contact person, telephone number and fax number		X		Section 1.3. Establishment Registration
C. Representative/Consultant if applicable		X		Section 1.3. Establishment Registration
D. Table of Contents with pagination		X		Table of Contents
E. Address of manufacturing facility/facilities and, if appropriate, sterilization site(s)		X		Section 1.3. Establishment Registration

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510(k) ELEMENTS	YES <sup>1</sup>	NO <sup>2</sup>	LOCATION OF ELEMENT IN 510(K)
III. Additional Information that may be necessary under 21 CFR 807.87(h):			
A. Comparison table of the new device to the marketed device(s)	X		Section 3. Rationale for Substantial Equivalence
B. Action taken to comply with voluntary standards	X		Section 1.5. Performance Standards
C. Performance data			Section 4. Performance Data & Append. 3 & 4
marketed device	X		
bench testing	X		
animal testing	X		
clinical data	X		
new device	X		
bench testing	X		
animal testing	X		
clinical data	X		
D. Sterilization information	X		Section 2. Device Description

h9

Premarket Notification  
Orthofix Femoral Nailing System

510(k) ELEMENTS	YES <sup>1</sup>	NO <sup>2</sup>	LOCATION OF ELEMENT IN 510(K)
E. Software information	N/A		
F. Hardware information	N/A		
G. Is this device subject to issues that have been addressed in specific guidance documents(s)?	**		** Only in part. The coating is subject to the guidance "510(k) Information Needed for Hydroxyapatite Coated Orthopedic Implants"
If yes, continue review with checklist from any appropriate guidance documents.	--	--	
If no, is 510(k) sufficiently complete to allow substantive review?	X		
H. Other (specify)	--	--	

1. Critical element present or omission justified.
2. Critical element not present, inadequate or omitted.
3. N/A - Not Applicable

SO

# C.L. McIntosh

& ASSOCIATES, INC.

Medical and Regulatory Affairs Services

12300 Twinbrook Parkway, Suite 625  
Rockville, Maryland 20852

Tel: (301) 770-9590  
Fax: (301) 770-9584

November 6, 1997

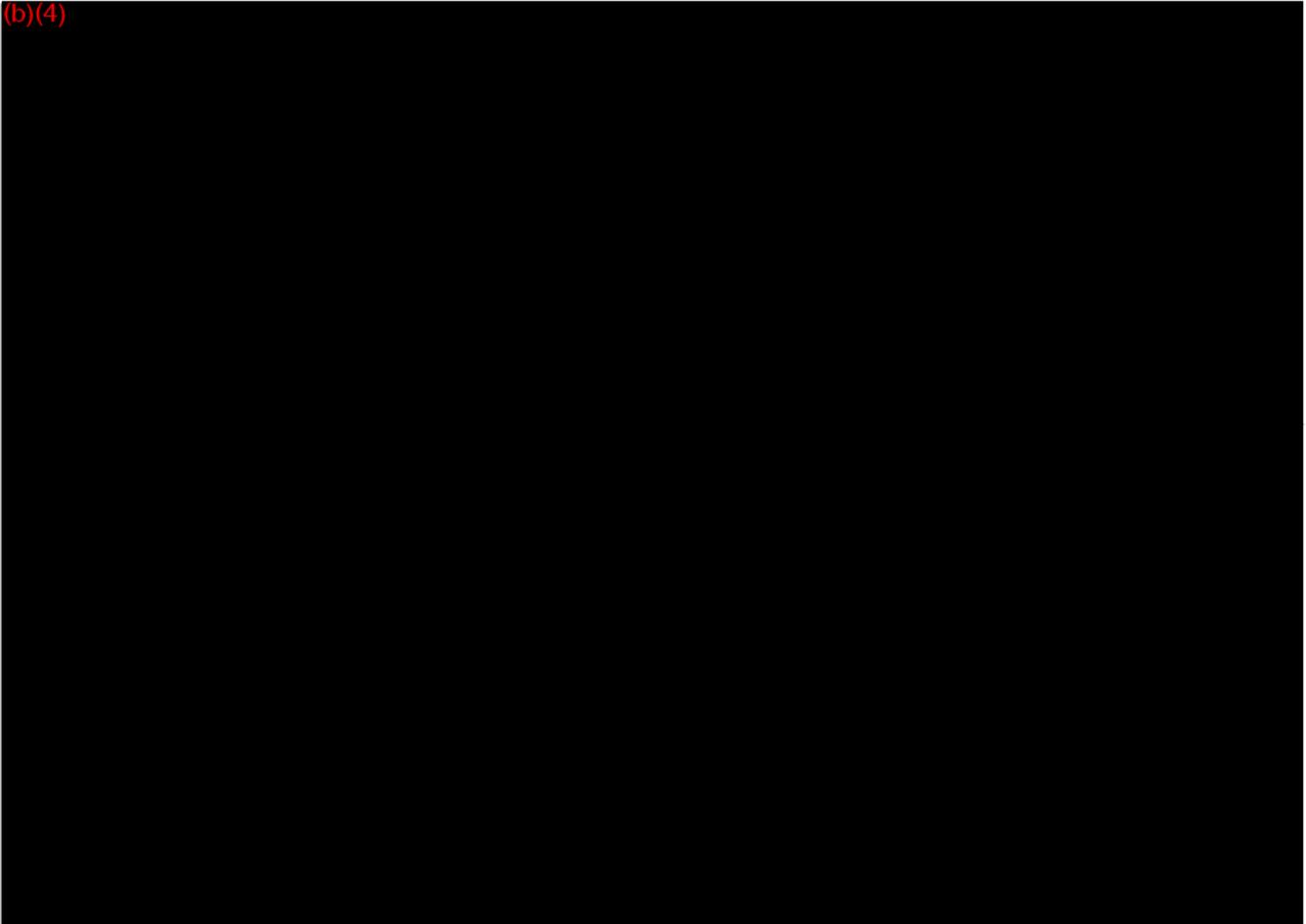
Document Mail Center (HFZ-401)  
Center for Devices and Radiological Health  
Food and Drug Administration  
9200 Corporate Boulevard  
Rockville, MD 20850

Attn: Orthopedic Devices Branch  
Division of General and Restorative Devices, HFZ-410

Re: 510(k) Premarket Notification  
Orthofix® External Fixation Pin  
Modification

Dear Sir or Madam:

(b)(4)



FDA/CDRH/ODE/DHG

NOV 7 2 52 PM '97

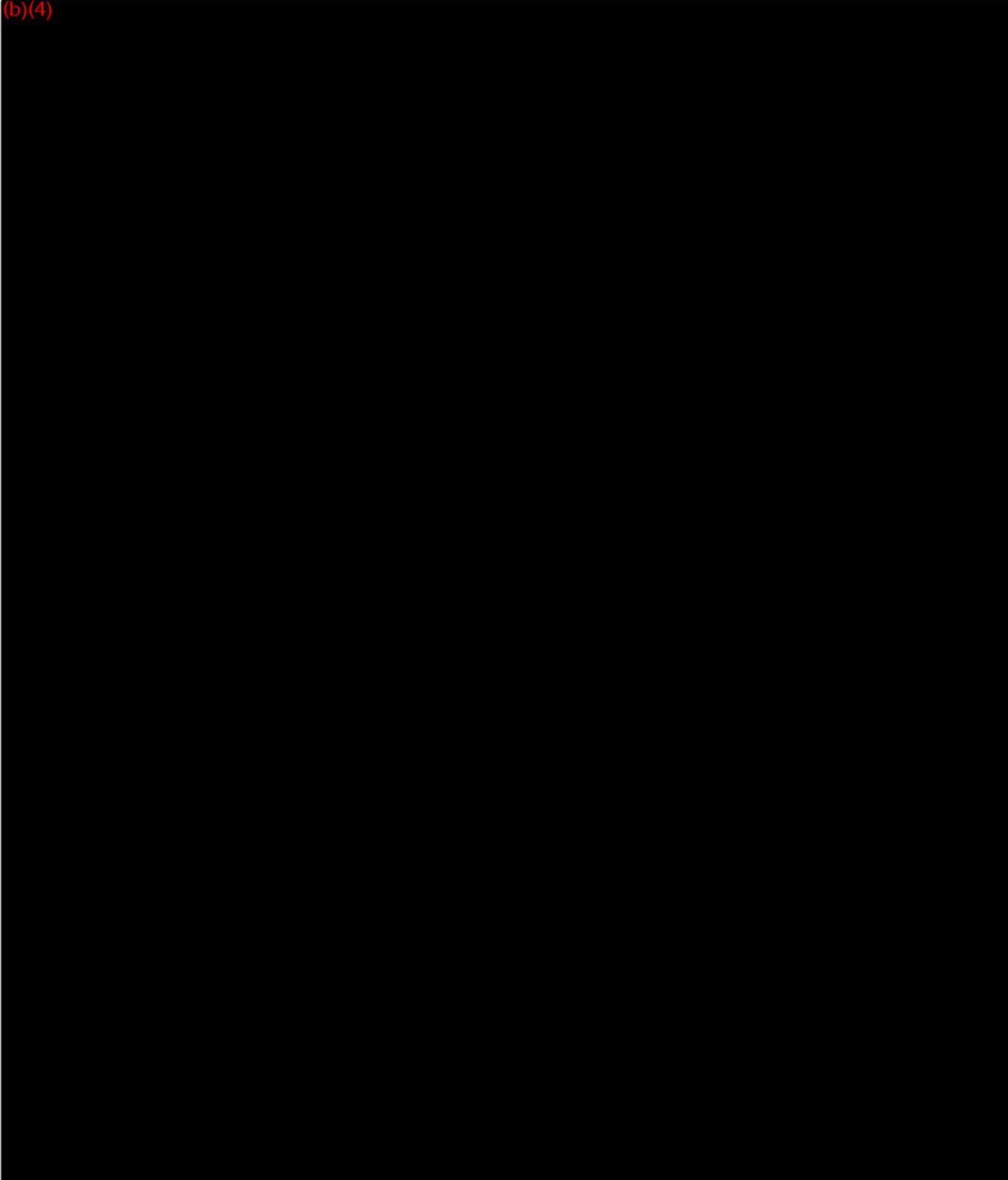
RECEIVED

SK-42

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Premarket Notification  
Orthofix - External Fixation Pin Modification

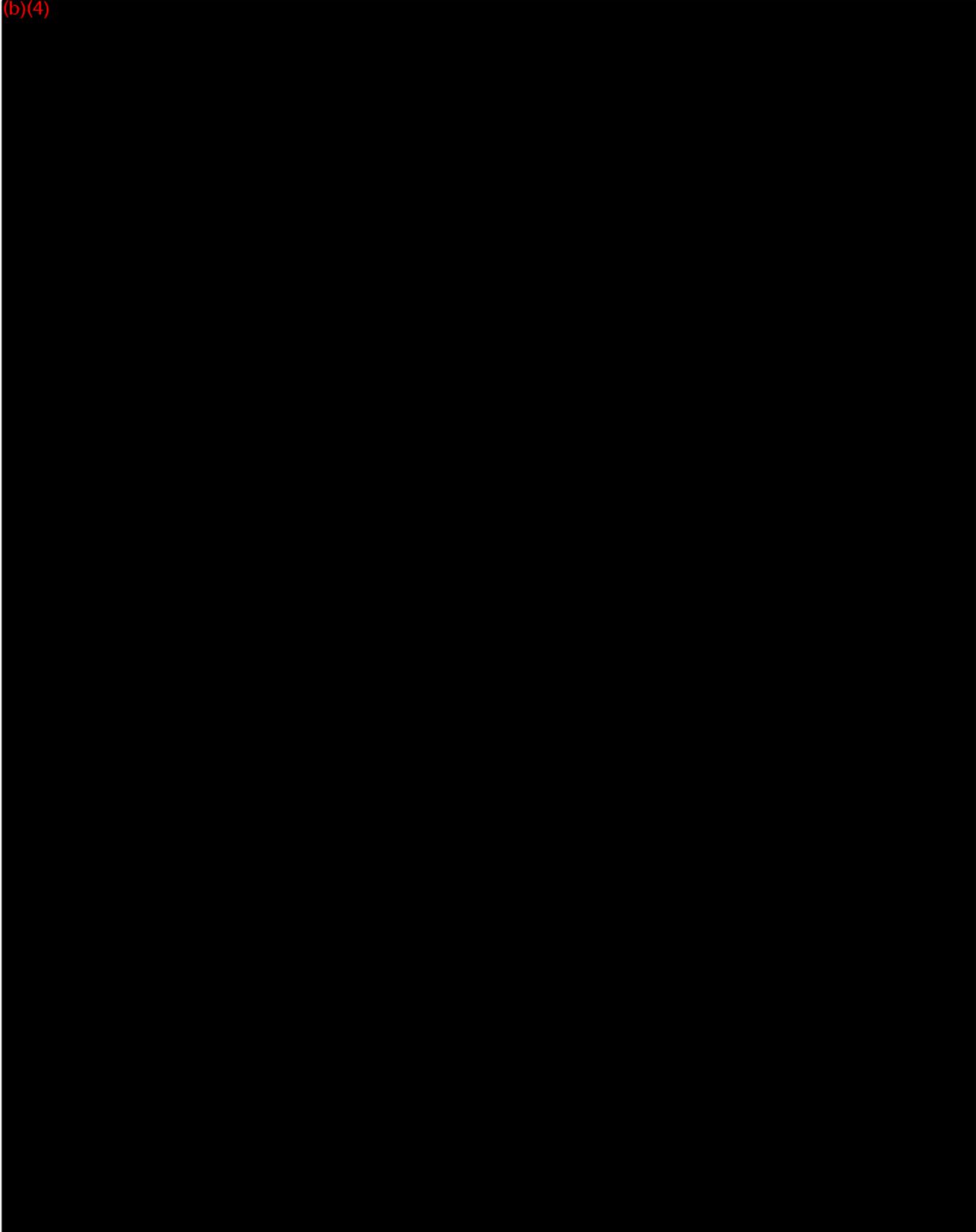
(b)(4)



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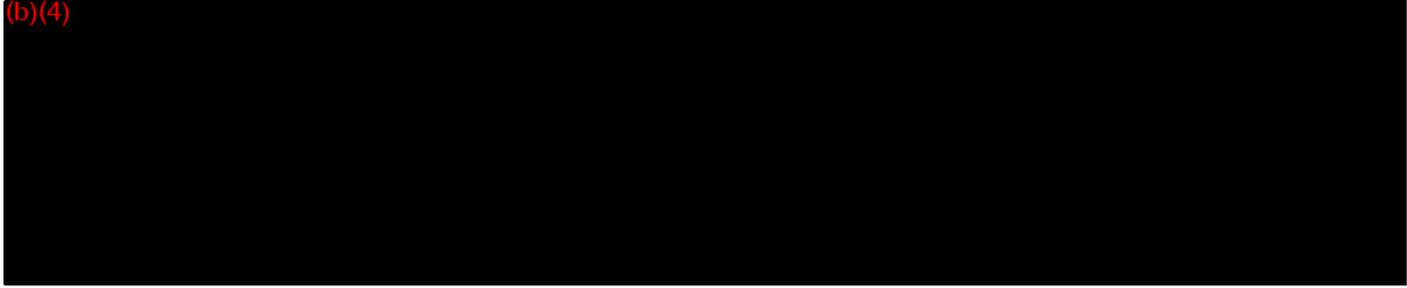
Premarket Notification  
Orthofix - External Fixation Pin Modification

(b)(4)



S3

(b)(4)



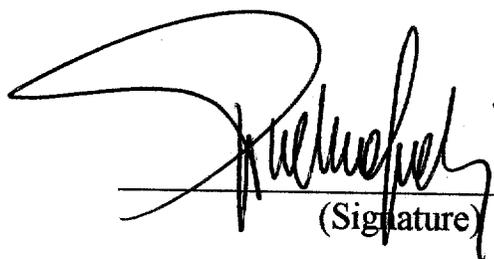
Sincerely,



Robert L. Sheridan  
Vice President  
Device Evaluation

**Premarket Notification Truthful and**  
**Accurate Statement**

I certify that, in my capacity as General Director, I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

  
\_\_\_\_\_  
(Signature)

Vittorio Pietropoli  
General Director  
Orthofix S.r.l.

11-6-97  
\_\_\_\_\_  
(Date)

\_\_\_\_\_  
(Premarket Notification Number \*)

\* For a new submission, do not fill in the 510(k) number

### Indications For Use

**Device Name:** Orthofix External Fixation Screw (Pin) With Hydroxyapatite Coating

**Indications For Use:** The Orthofix external fixation screw (pin) with hydroxyapatite coating is indicated for use in the external fixation of bone.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: \_\_\_\_\_  
(Per 21 CFR 801.109)

OR

Over-The-Counter: \_\_\_\_\_

(Optional Format 1-2-96)

\_\_\_\_\_  
Division Sign-Off  
Division of General Restorative Devices  
11/5/9711:11 510(k) Number \_\_\_\_\_

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## Table of Contents

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## SECTION 1.0 GENERAL INFORMATION

General information pertaining to the device, manufacturer and substantial equivalence are provided below in accordance with 21 CFR 807.87 and Center for Devices and Radiological Health (CDRH) guidance documents. The information presented in this document conforms to the requirements outlined in the Center for Devices and Radiological Health's (CDRH) "Premarket Notification (510(k)) Refuse to Accept Policy". Preceding the cover letter of this 510(k) is a copy of the "Premarket Notification (510(k)) Checklist for Acceptance Decision". The appropriate critical elements have been checked and reference has been made to the location in the document that addresses each of these critical elements.

### 1.1 REASON FOR 510(K)

We are hereby notifying FDA of Orthofix's intention to commercially distribute a modified version of its previously 510(k)-cleared external fixation pin.

The Orthofix external fixation pin, a component of the Orthofix Dynamic Axial Fixation System, received FDA clearance under premarket notifications K831576 and K955848. These external fixation pins are manufactured from surgical grade stainless steel, AISI 316L. External fixation pins are used in conjunction with a rigid frame for the fixation of bone fractures.

Orthofix also wishes to distribute its pins with a very thin [avg.  $45 \pm 15$  micron ( $\mu\text{m}$ )] plasma sprayed coating of hydroxyapatite (HA). There are two facts that support this modification and its substantial equivalence to legally marketed predicate devices. First, HA provides excellent biocompatibility at the implant/bone interface. HA coatings have been added to other orthopedic implants including femoral and acetabular prostheses. The transition from the uncoated implant to the HA coated version has been cleared via the 510(k) process numerous times (e.g., K896047, K912369, K910156). Second, a coated external fixation pin has been cleared via the 510(k) process. Fixation pins coated with silver were found substantially equivalent on June 28, 1996 to uncoated pins under 510(k) K961433.

The substantial equivalence of the Orthofix HA coated pins is supported by the extensive laboratory, animal and clinical testing data presented herein, as well as by the clearance of the other coated implants and external fixation pins. The preclinical and clinical data presented herein demonstrate that the use of the HA coating enhances fixation at the pin/bone interface. The coated pins demonstrate statistically significantly better stability or fixation at the time of removal or extraction than the uncoated pins. Laboratory studies including physical, mechanical and chemical testing provide a full characterization of the HA coating. The laboratory and *in vivo* studies conducted are summarized in Section 4 - Performance Data and complete study reports are provided in the Appendices.

FDA guidance documents relevant to this application have been used in its preparation. In particular, the guidance document "510(k) Information Needed for Hydroxyapatite Coated

Orthopedic Implants" (revised February 20,1997), was followed in the preparation of this 510(k). The physical, mechanical and chemical tests prescribed by FDA in its guidance document to characterize the HA coating and HA/substrate interface were conducted. As previously stated, in addition to the tests prescribed, Orthofix has conducted animal and human clinical studies of the coated pins.

In addition, the materials used in the manufacture of this pin conform to various international standards where appropriate. The external fixation pins are manufactured from surgical grade stainless steel, AISI 316L, which conforms to ISO 5832-1 and ASTM F 138. The HA powder used in the plasma spray coating process conforms to ASTM F-1185. The HA coating conforms to ASTM F 1501.

In summary, the information and data provided in this submission are consistent with FDA's guidance documents for HA coated orthopedic implants and demonstrate that the Orthofix HA coated pin is substantially equivalent to its legally marketed uncoated version.

## **1.2 NAME OF DEVICE**

### **1.2.1 Trade/Proprietary Name**

Orthofix® External Fixation Screw (Pin) With Hydroxyapatite Coating

### **1.2.2 Common/Usual Name**

External fixation pin

### **1.2.3 Classification Name**

Smooth or threaded metallic bone fixation fastener (21 CFR 888.3040).

The name and class provided are in accordance with FDA's manual, "Classification Names for Medical Devices and *In Vitro* Diagnostic Products" and listings of prior 510(k) clearances of similar products.

## **1.3 ESTABLISHMENT REGISTRATION**

### **1.3.1 Applicant and Owner of 510(k)**

Name/Address: ORTHOFIX Srl  
Via delle Nazioni 9  
37012 Bussolengo (VR), Italy

Attention: Rolando Stanghellini, Director of Quality Assurance

Telephone: 011-39-45-6767030

Facsimile: 011-39-45-6767135

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**1.3.2 Contact Person For all Questions Regarding 510(k)**

Consultant [Submitter of 510(k)]

Robert L. Sheridan  
Vice President, Device Evaluation  
C.L. McIntosh & Associates, Inc.  
12300 Twinbrook Parkway, Suite 625  
Rockville, MD 20852

Telephone: (301) 770-9590

Facsimile: (301) 770-9584

**1.3.3 Manufacturing Facility**

Registration Number: 9680825

Name/Address: ORTHOFIX Srl  
Via delle Nazioni 9  
37012 Bussolengo (VR), Italy

**1.3.4 Distributor**

Registration Number: 2183449

Name/Address: Orthofix, Inc.  
250 East Arapaho Road  
Richardson, Texas 75081  
Attention: Lynn Stimpson, Manager Of Quality Assurance

**1.4 CLASSIFICATION INFORMATION**

**1.4.1 Name/Class**

21 CFR 888.3040 "Smooth or Threaded Metallic Bone Fixation Fastener", Class II.

The name and class provided are in accordance with FDA's manual, "Classification Names for Medical Devices and *In Vitro* Diagnostic Products" and listings of prior 510(k) clearances of similar products.

**1.4.2 Panel**

Orthopedic and Rehabilitation Devices Panel

**1.4.3 Product Code and Name**

87JDW, "Threaded Fixation Pin"

The product code and name provided are in accordance with FDA's manual, "Classification Names for Medical Devices and *In Vitro* Diagnostic Products" and listings of prior 510(k) clearances of similar products.

## 1.5 PERFORMANCE STANDARDS

No performance standard applicable to this device has been promulgated under Section 514 of the Act. The materials used in the Orthofix coated pin are manufactured in accordance with various international and US standard setting organizations. These standards include the following:

- ISO 5832-1 "Implants for Surgery - Metallic Materials - Part 1: Wrought Stainless Steel".
- ASTM Designation: F 138 "Standard Specification for Stainless Steel Bar and Wire for Surgical Implants (Special Quality)".
- ASTM Designation: F 1185 (Reapproved 1993) "Standard Specification for Composition of Ceramic Hydroxylapatite for Surgical Implants.
- ASTM F 1501 (Standard Test Method for Tension Testing of Calcium Phosphate Coating, 1995).

The materials used in the manufacture of this pin conform to various international standards. The pin is manufactured from surgical grade stainless steel, AISI 316L, which conforms to ISO 5832-1 and ASTM F 138. The hydroxyapatite powder used in the plasma spray coating process conforms to ASTM F 1185. The coating conforms to ASTM F 1501.

In addition, FDA guidance documents relevant to this application have been used in its preparation. In particular, the guidance document "510(k) Information Needed for Hydroxyapatite Coated Orthopedic Implants" (revised February 20, 1997), was followed in the preparation of this 510(k). The physical, mechanical and chemical tests prescribed by FDA in its guidance document to characterize the HA coating and HA/substrate interface were conducted.

Further, the testing performed per FDA's guidance was conducted in accordance with international standards where applicable. Applicable standards are cited where appropriate. As previously stated, in addition to the tests prescribed, Orthofix has conducted animal and human clinical studies of the coated pins.

## 1.6 LABELING

Orthofix will continue to distribute their uncoated pin, as well as now offer the coated version. Copies of draft package labeling are provided in Appendix 1. Orthofix has not yet drafted additional labeling or promotional materials specific to the coated pins. If and when such materials are printed in the future, all claims made will be consistent with the statements and findings presented in this 510(k).

## 1.7 ENGINEERING DRAWINGS

Engineering drawings of the Orthofix HA coated pin are provided in Appendix 2. The drawings include physical dimensions, material composition and reference to applicable material standards.

## **1.8 PATIENT CONTACTING MATERIALS**

The threaded end of the pin, the portion that is HA coated, is implanted in the bone. The materials used in the manufacture of this pin conform to various international standards. The pins are manufactured from surgical grade stainless steel, AISI 316L, which conforms to ISO 5832-1 and ASTM F 138. The hydroxyapatite powder used in the plasma spray coating process conforms to ASTM F 1185. The mechanical and chemical characteristics of the coating are detailed in Section 2.0 - Device Description.

## **1.9 PACKAGING/STERILITY**

Copies of draft package labeling are provided in Appendix 1. The packaging bears the prescription labeling in accordance with 21 CFR 801.109, "Prescription Devices". In addition, the device is labeled for single use only.

The coated pins will be provided sterile. The components will be packaged in a polyethylene terephthalate glycol (PETG) modified thermoform inner tray, heat-sealed with a Tyvek® lid. The inner tray will be enclosed in an outer PETG tray also heat-sealed with a Tyvek® lid. The packaged pins will be sterilized by gamma radiation, 25 kGy. The sterilization process will be validated in accordance with ANSI/AAMI/ISO 11137 "Guideline for Gamma Radiation Sterilization" so as to ensure a Sterility Assurance Level (SAL) of  $10^{-6}$ . The device will not be labeled nonpyrogenic.

## **1.10 SOFTWARE**

This device contains no software.

## **1.11 KIT CERTIFICATION**

Not Applicable

## **1.12 CLASS III CERTIFICATION AND SUMMARY**

Not Applicable

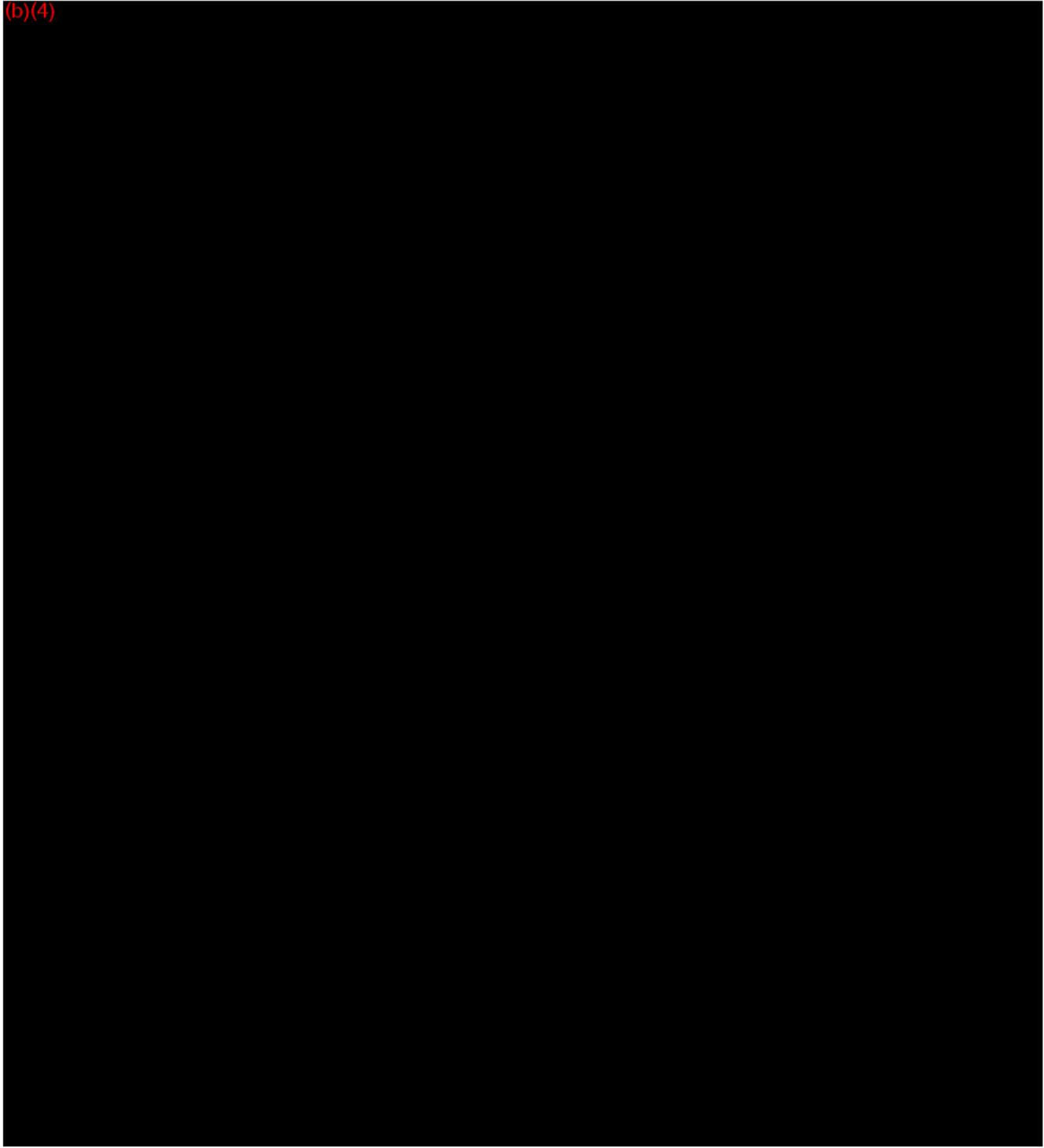
## **1.13 510(K) SUMMARY**

In accordance with the Safe Medical Devices Act of 1990 (SMDA), a "510(K) Summary" of the safety and effectiveness information upon which this substantial equivalence determination is based is provided in Appendix 6.

## SECTION 2.0 DEVICE DESCRIPTION

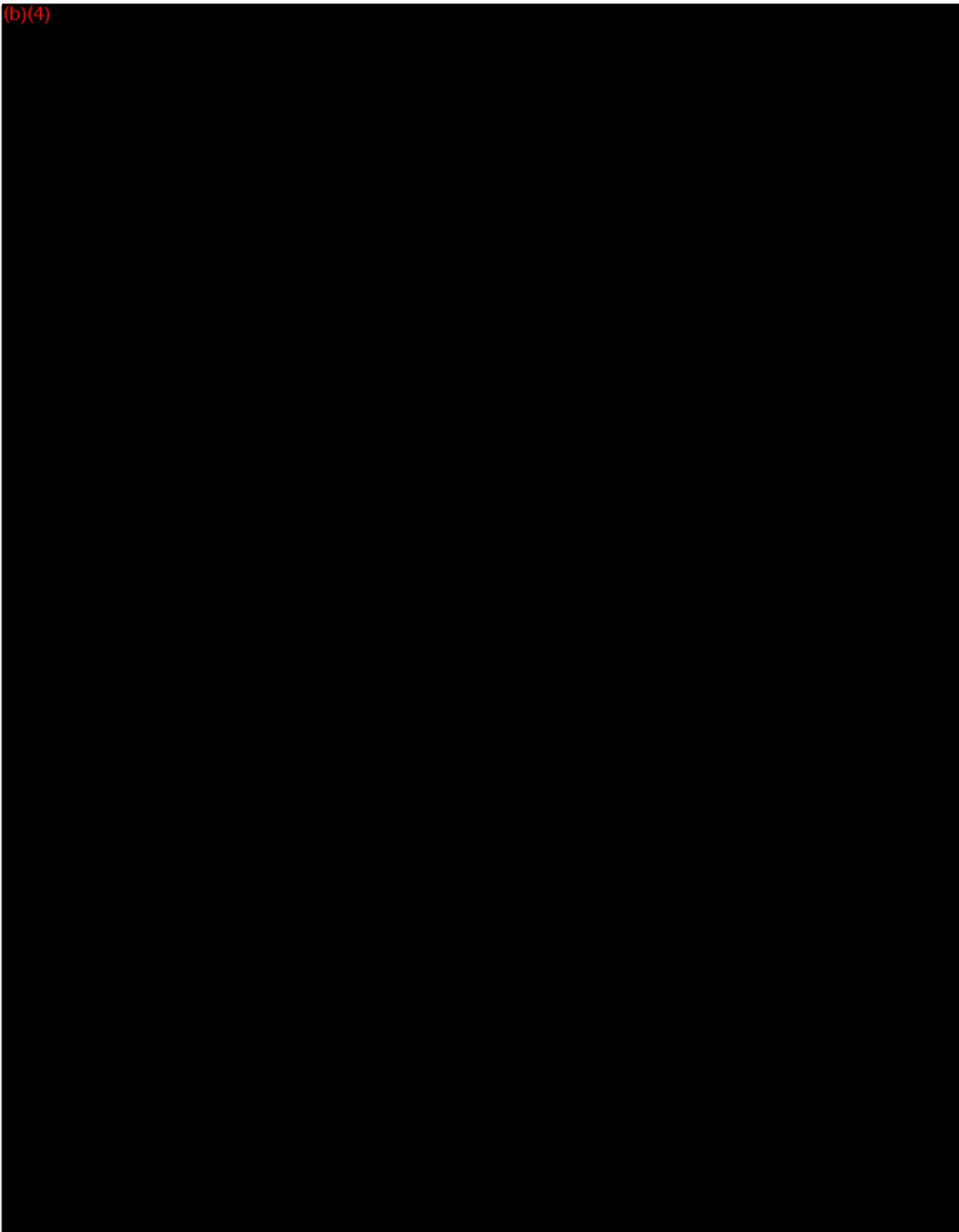
### 2.1 DESIGN RATIONALE

(b)(4)



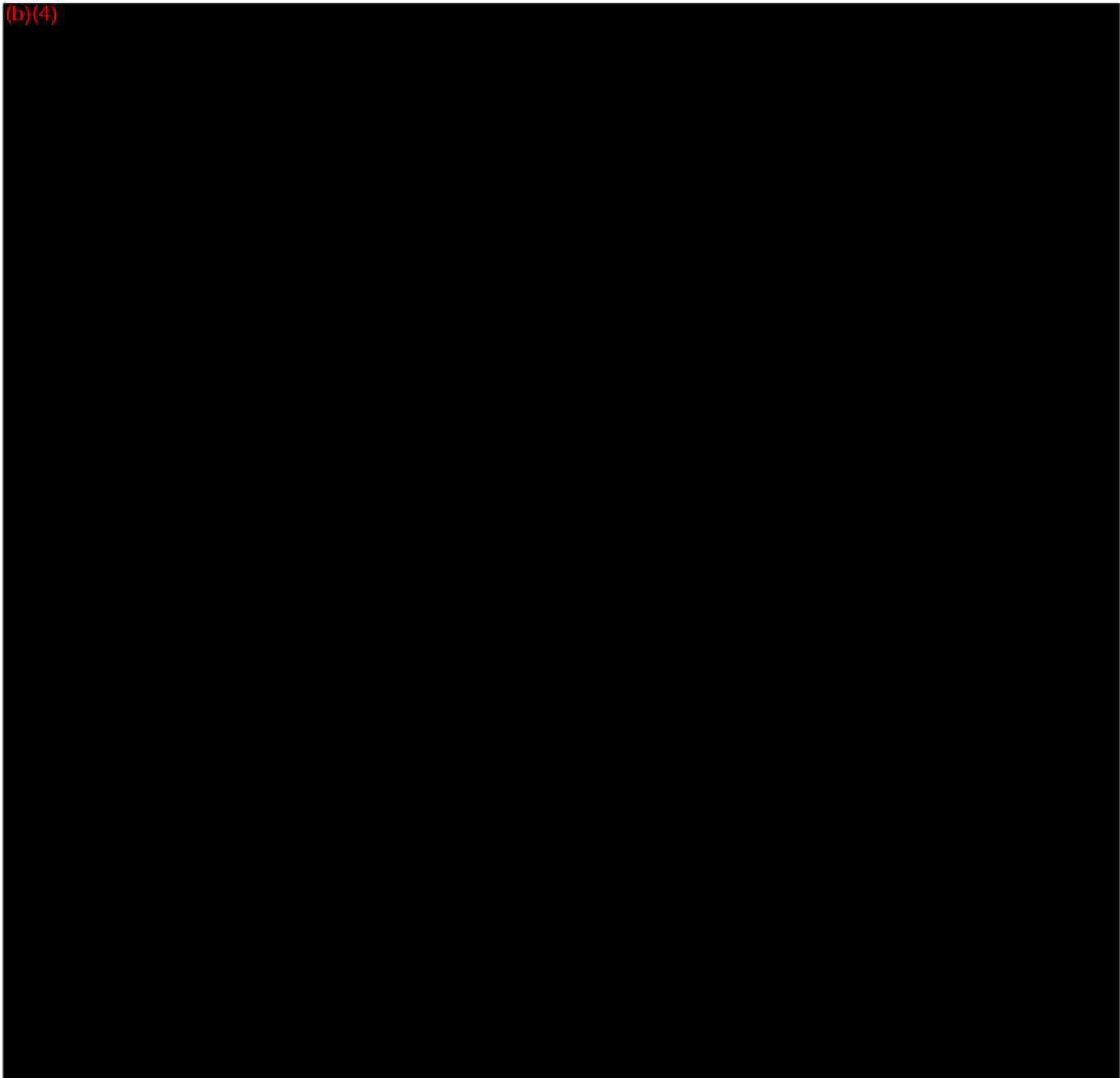
Premarket Notification  
Orthofix - External Fixation Pin Modification

(b)(4)



6h

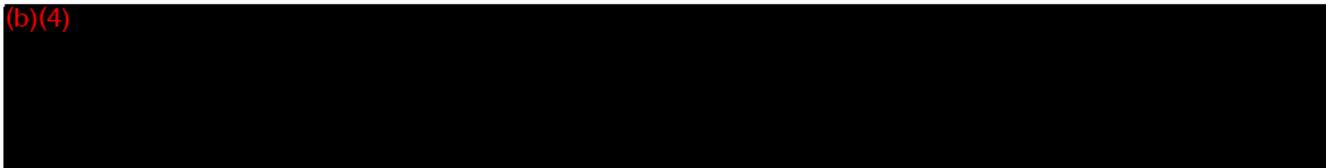
(b)(4)



## 2.2 PHYSICAL DESCRIPTION

Engineering drawings of the Orthofix HA coated pin are provided in Appendix 2. The drawings include physical dimensions, material composition and reference to applicable material standards.

(b)(4)



Provided in the table below are the physical specifications for the Orthofix pin. (The terminology used in these descriptions are consistent with ASTM F 1541.)

**Table 2 - 1**  
**Physical Specifications**

(b)(4)

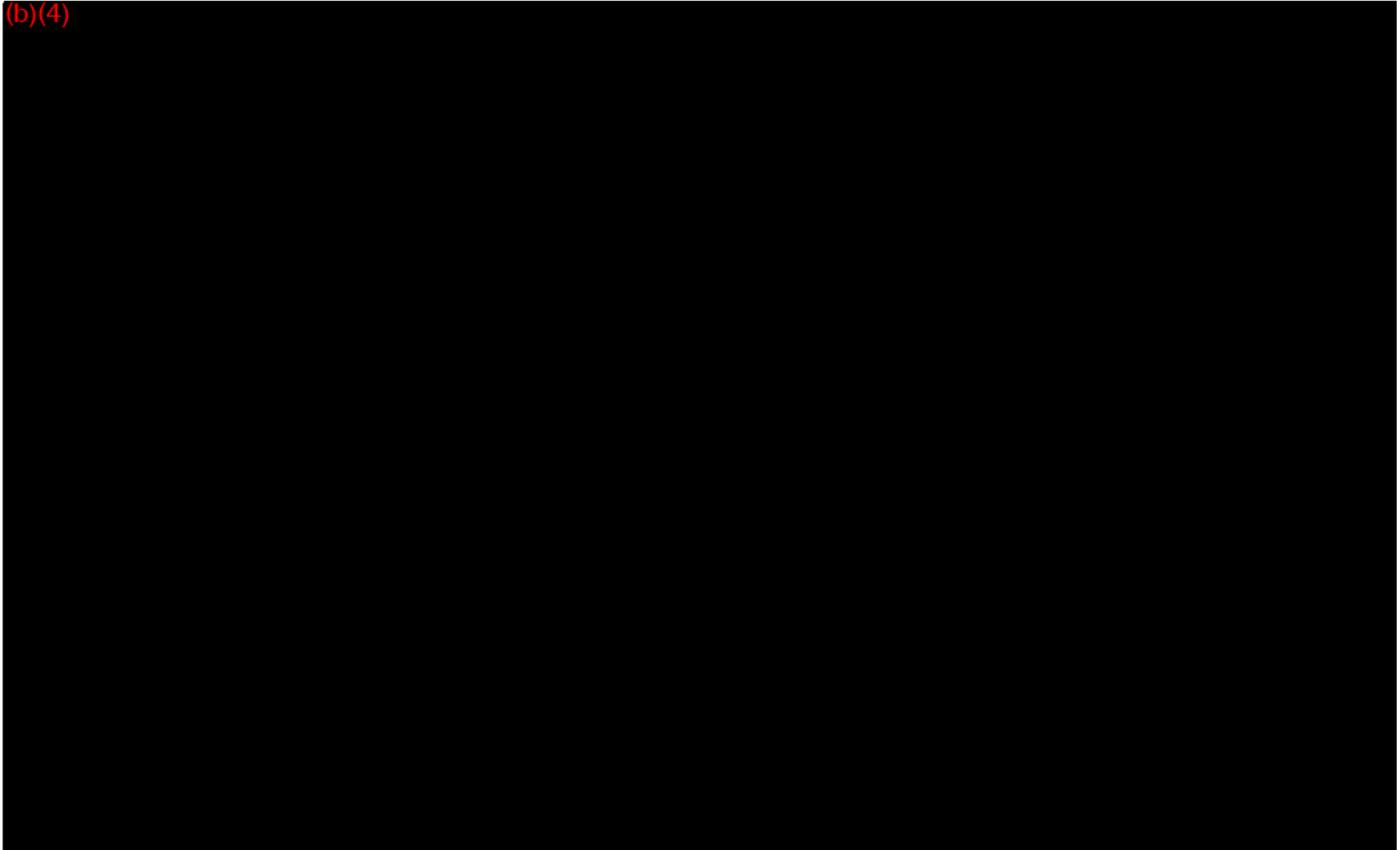
A detailed summary of the manufacturing/coating process, is provided below.

**2.3 HA COATING PROCESS**

(b)(4)

66

(b)(4)



**2.4 PACKAGING AND STERILITY**

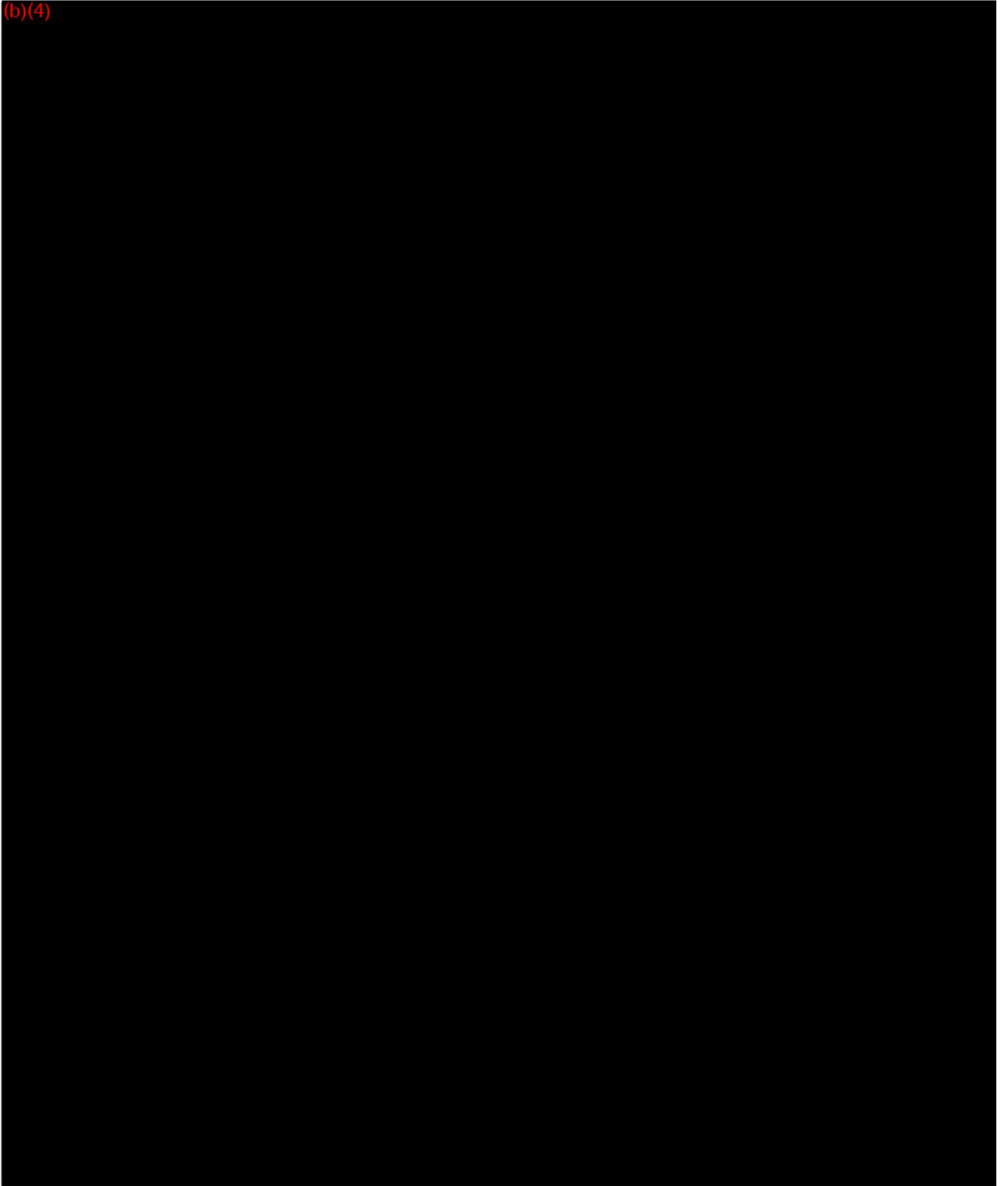
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Premarket Notification  
Orthofix - External Fixation Pin Modification

(b)(4)



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Premarket Notification  
Orthofix - External Fixation Pin Modification

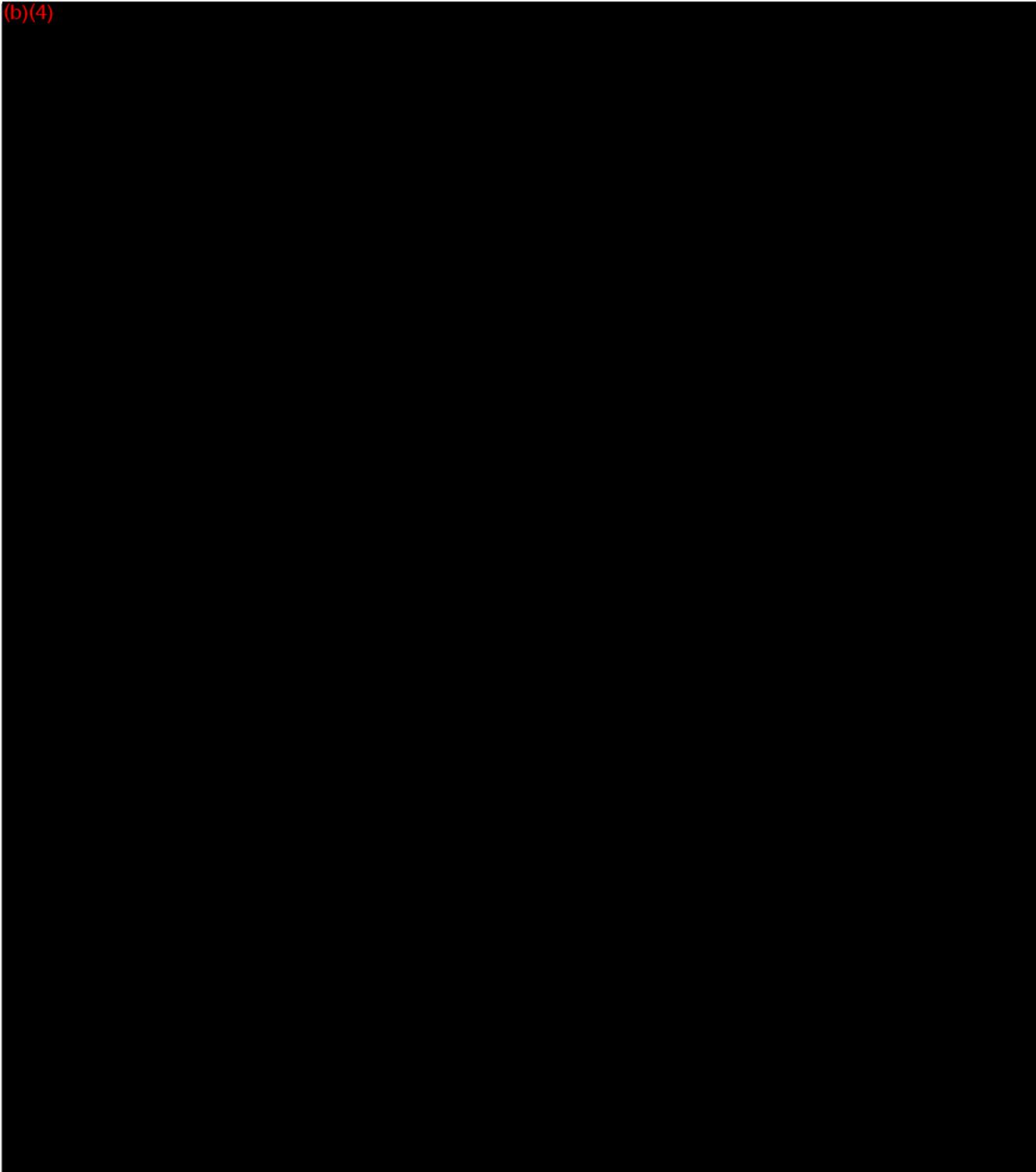
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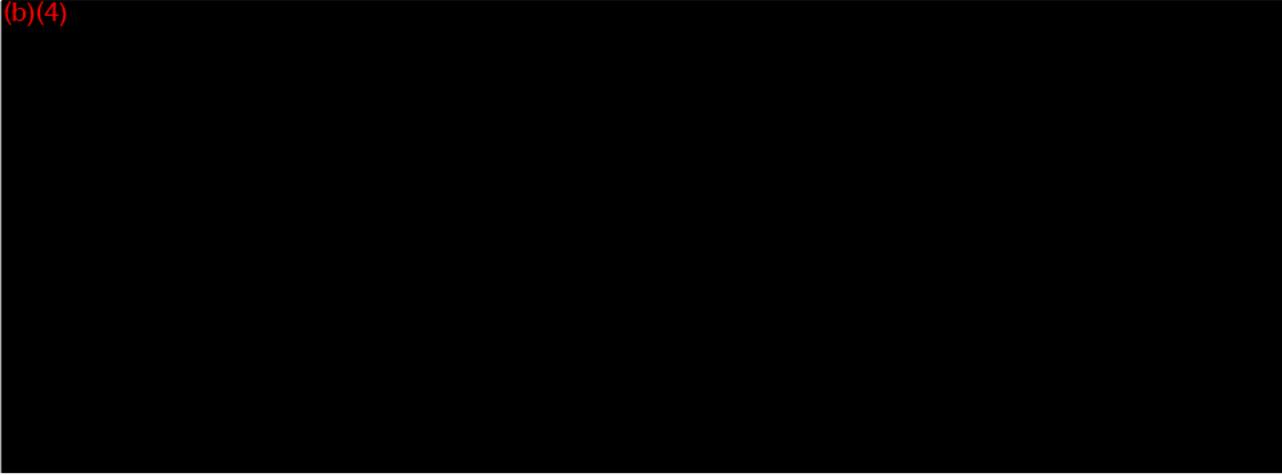
69

**SECTION 3.0**  
**RATIONALE FOR SUBSTANTIAL EQUIVALENCE**

(b)(4)

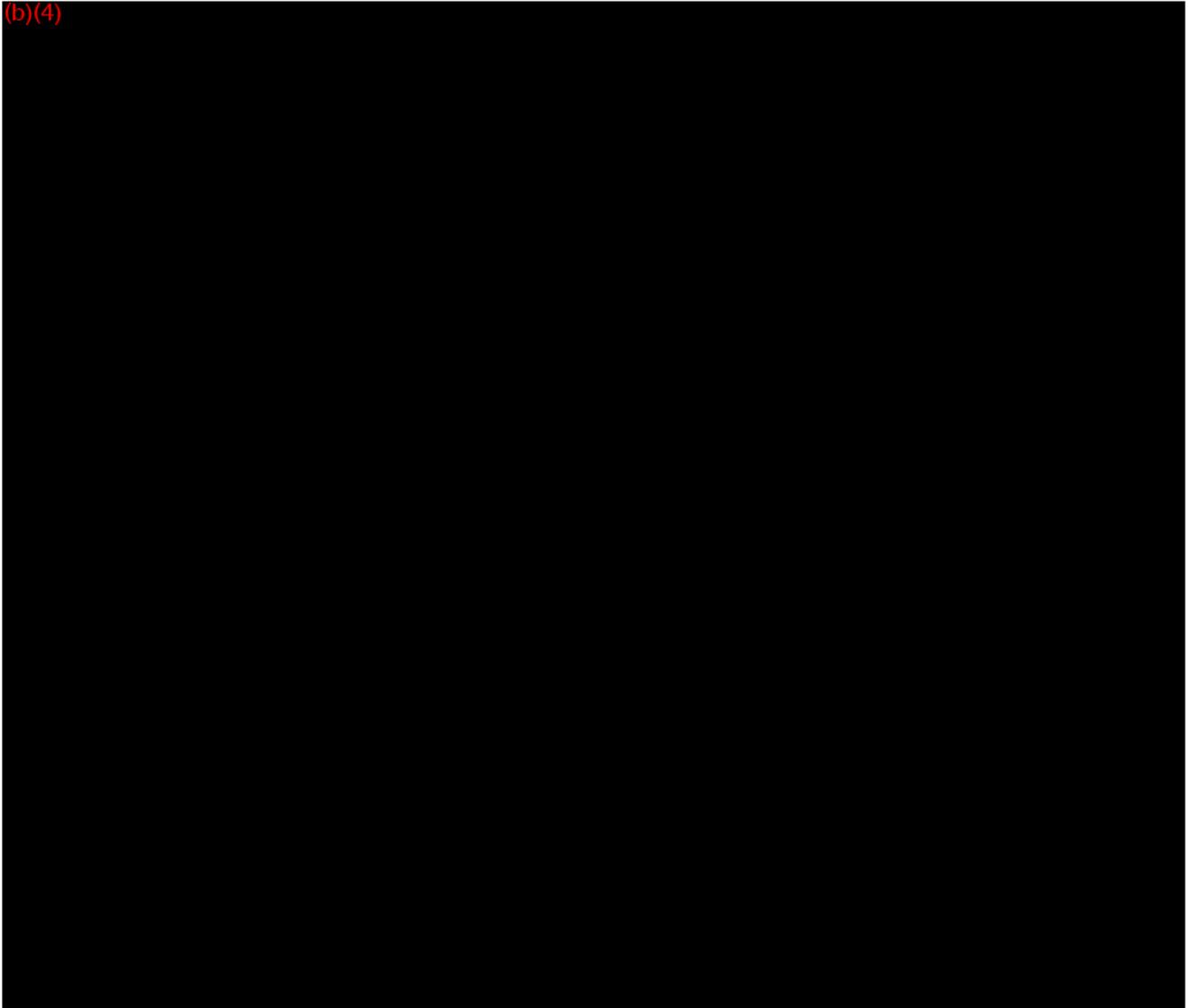


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**3.2 RATIONALE**

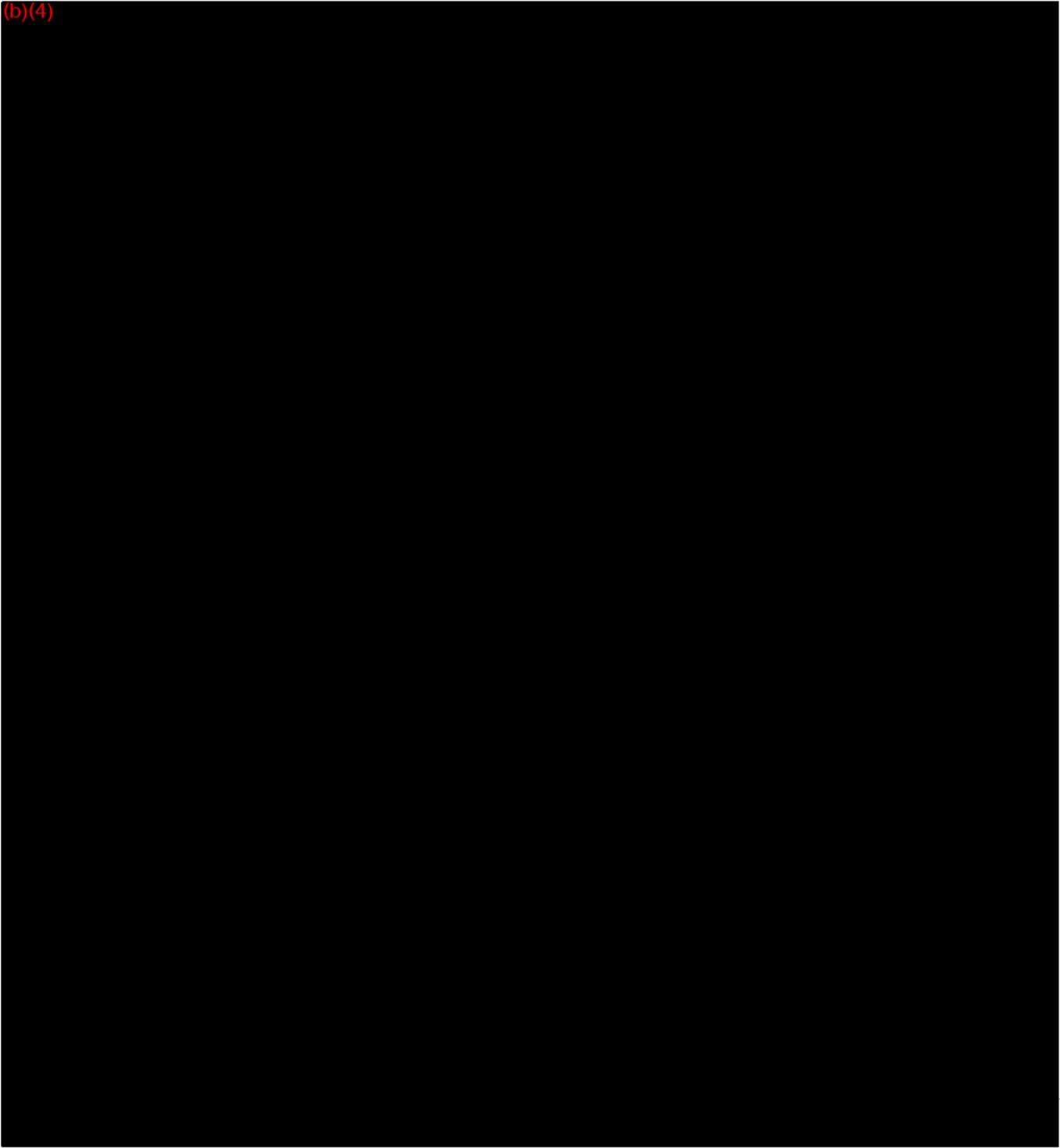
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Premarket Notification  
Orthofix - External Fixation Pin Modification

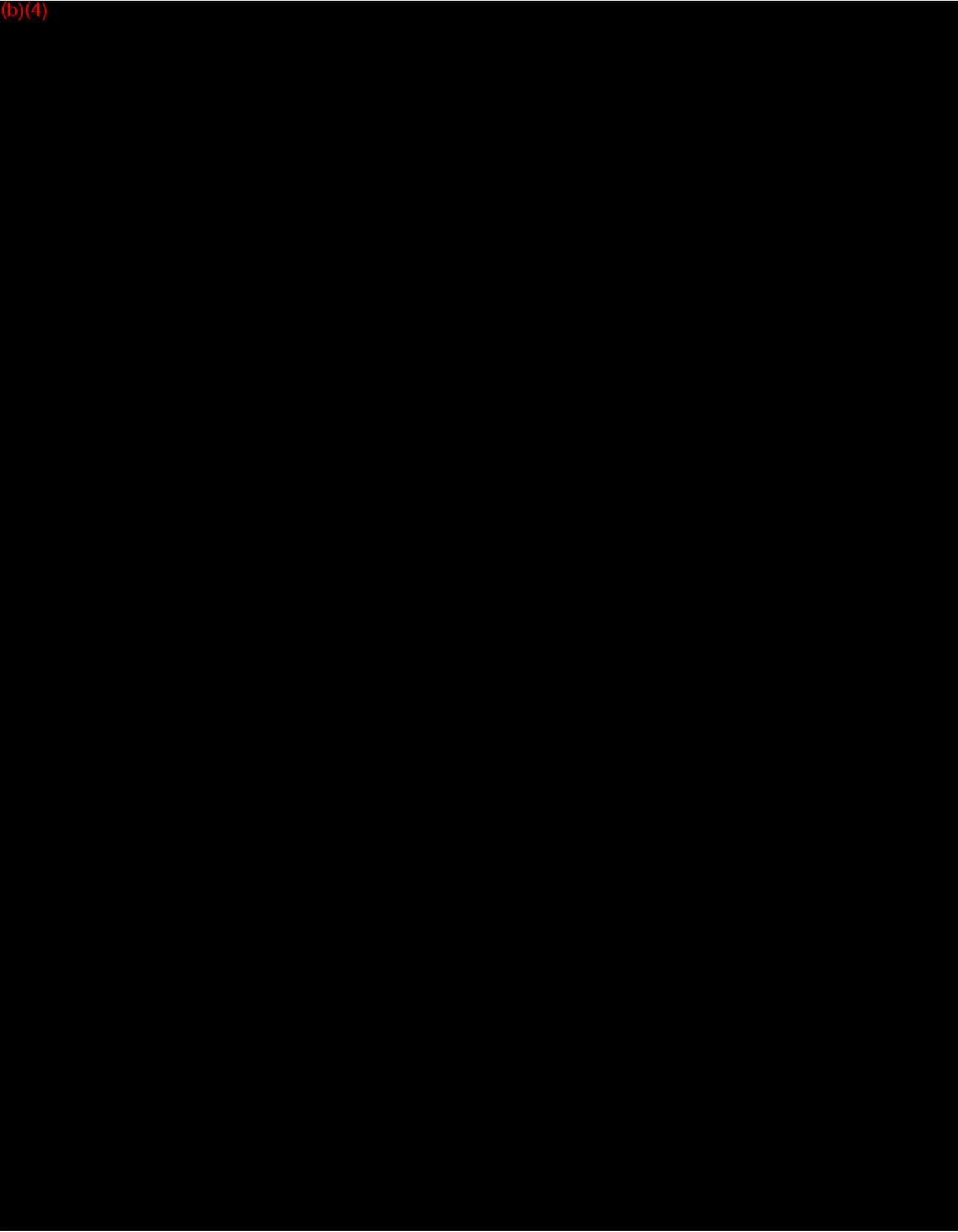
(b)(4)



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Premarket Notification  
Orthofix - External Fixation Pin Modification

(b)(4)



Premarket Notification  
Orthofix - External Fixation Pin Modification

(b)(4)

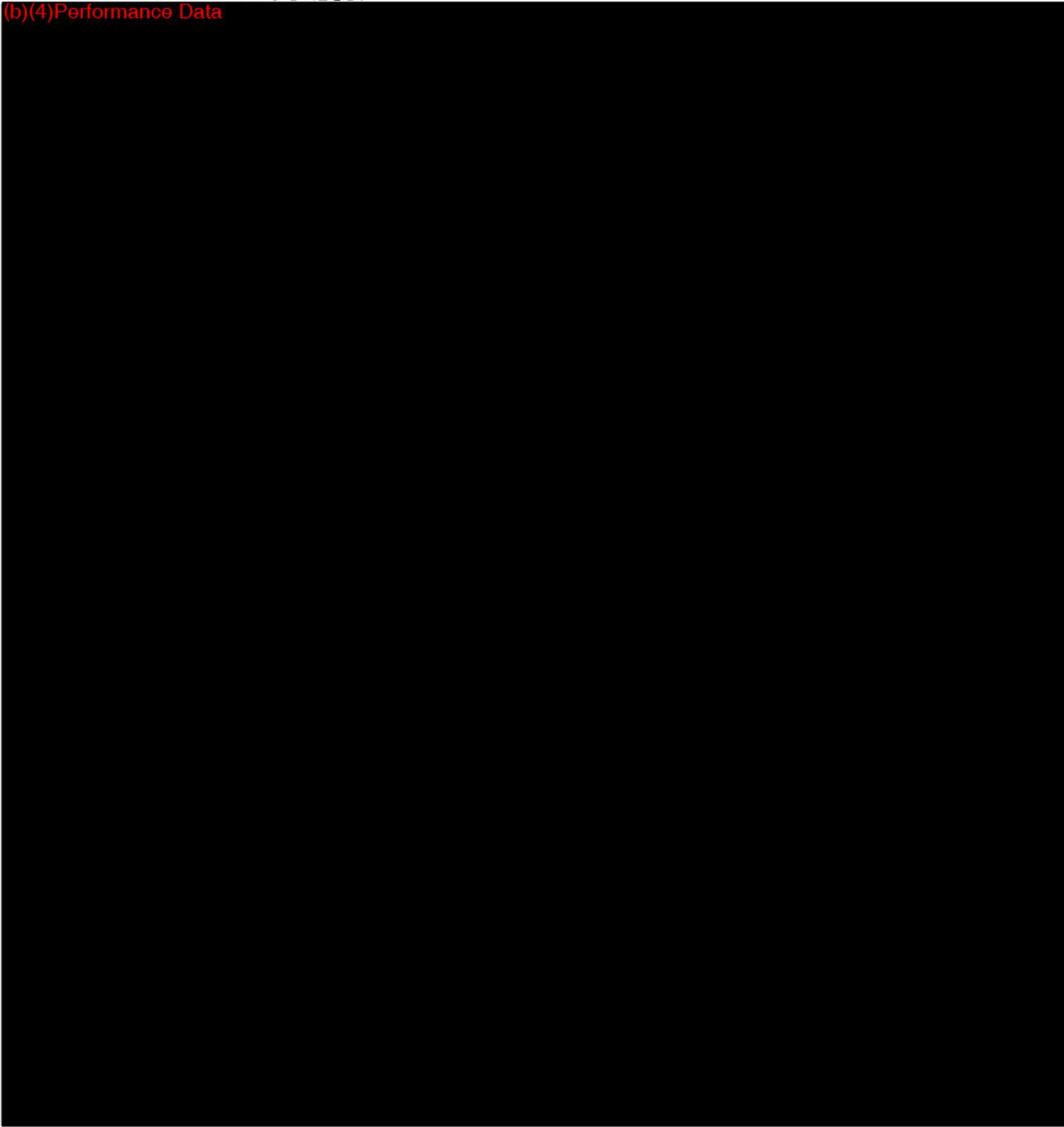


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***CONFIDENTIAL INFORMATION***  
**SECTION 4.0**  
**PERFORMANCE DATA**

**4.1 INTRODUCTION**

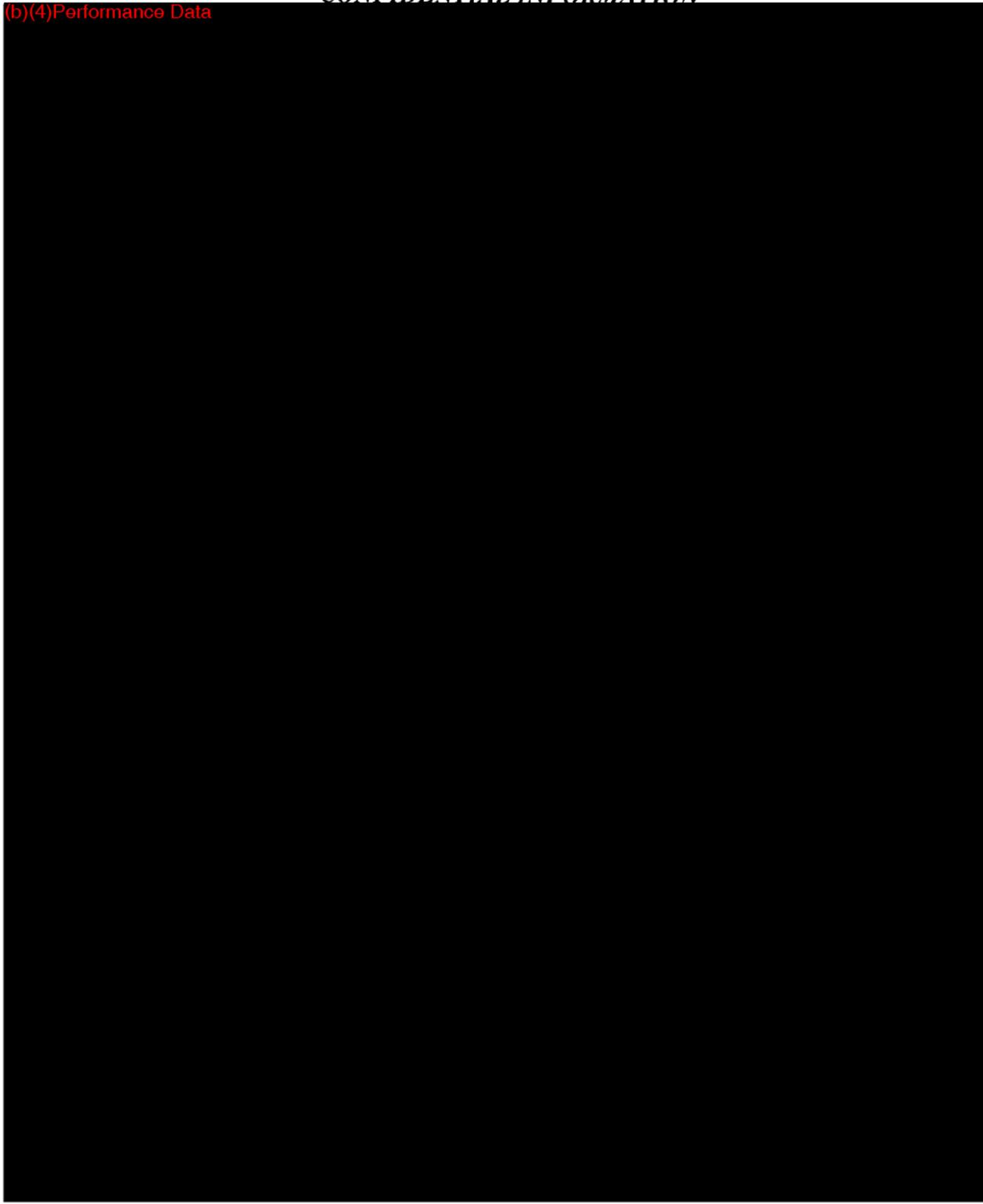
(b)(4) Performance Data



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***CONFIDENTIAL INFORMATION***

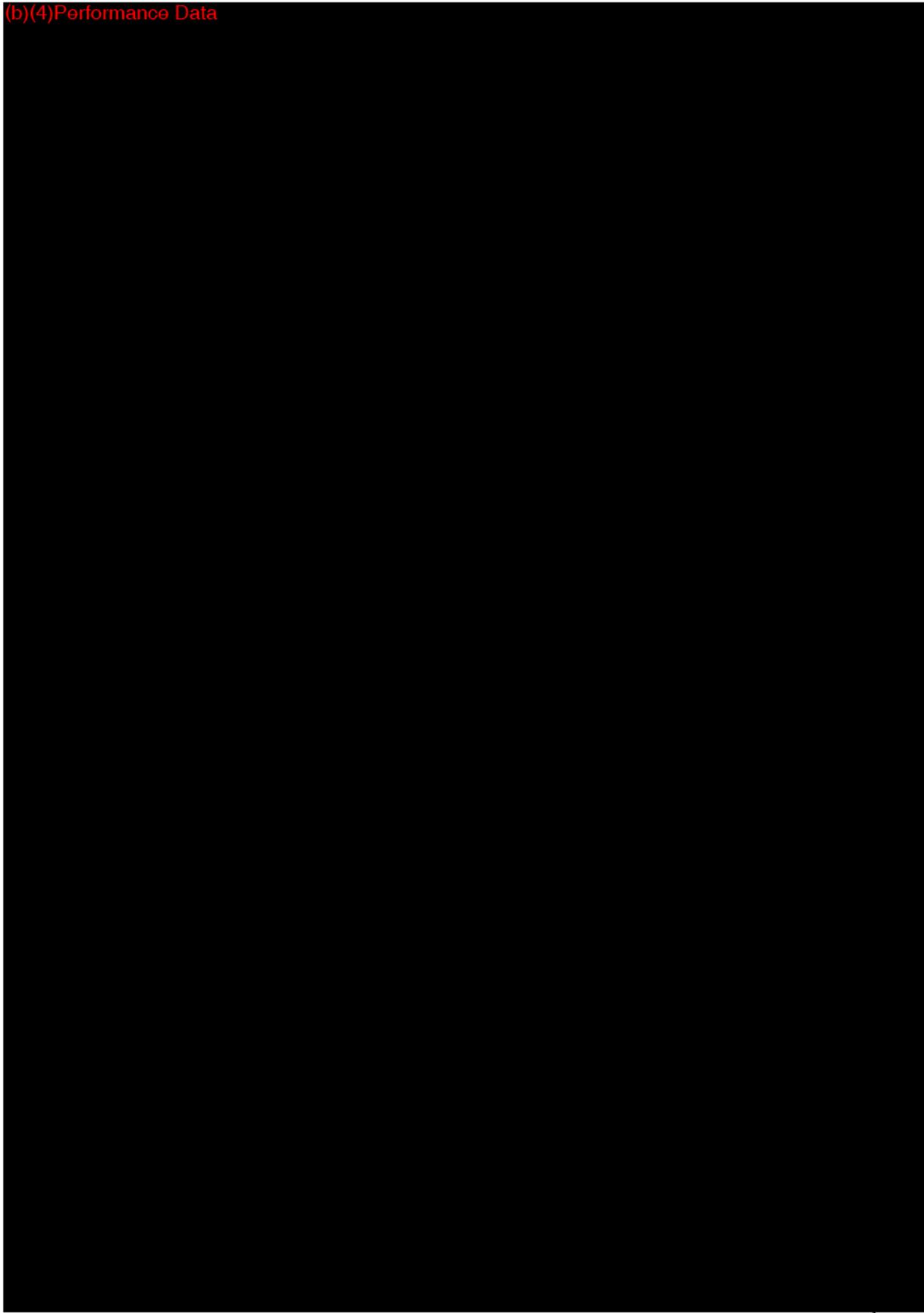
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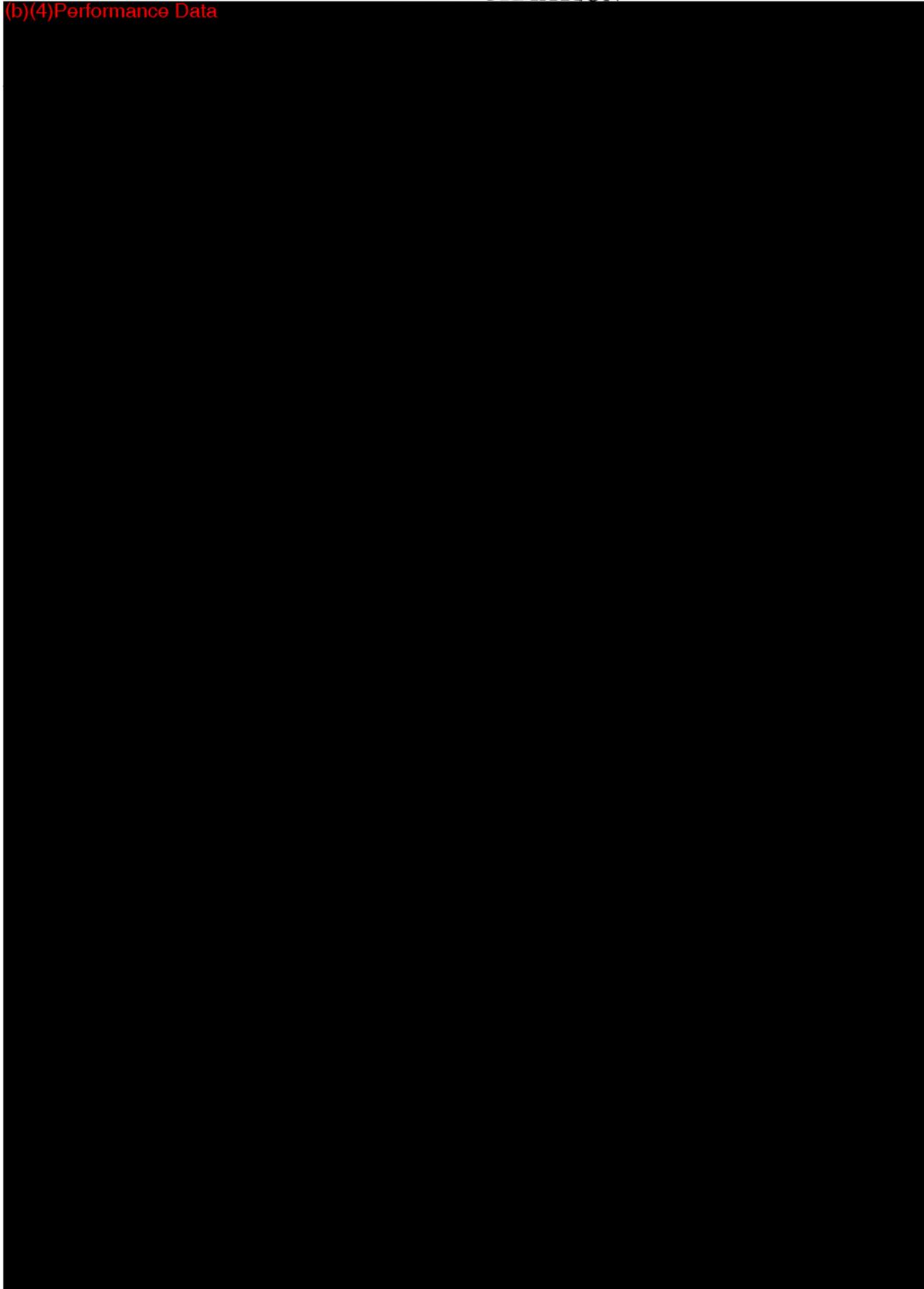
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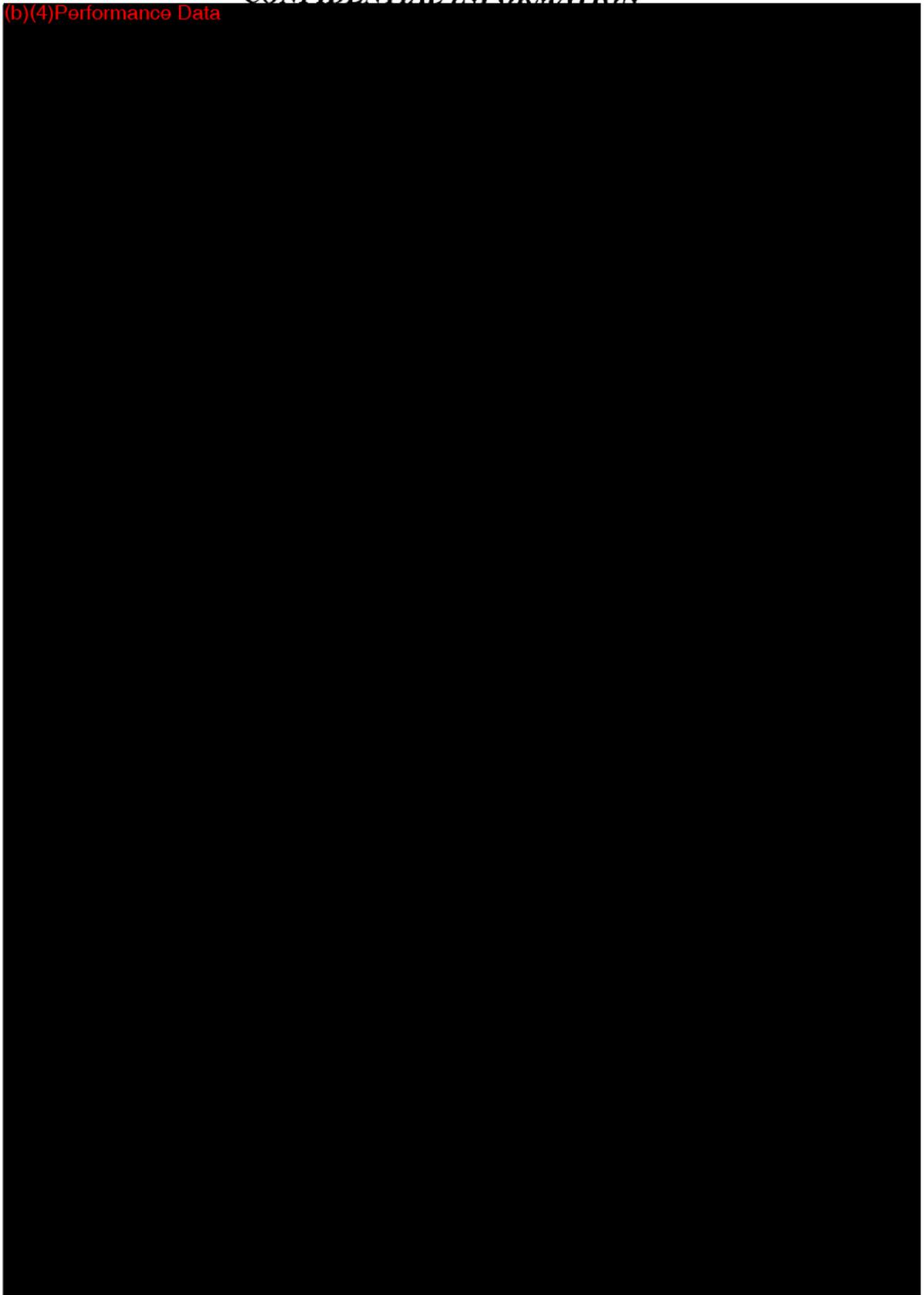
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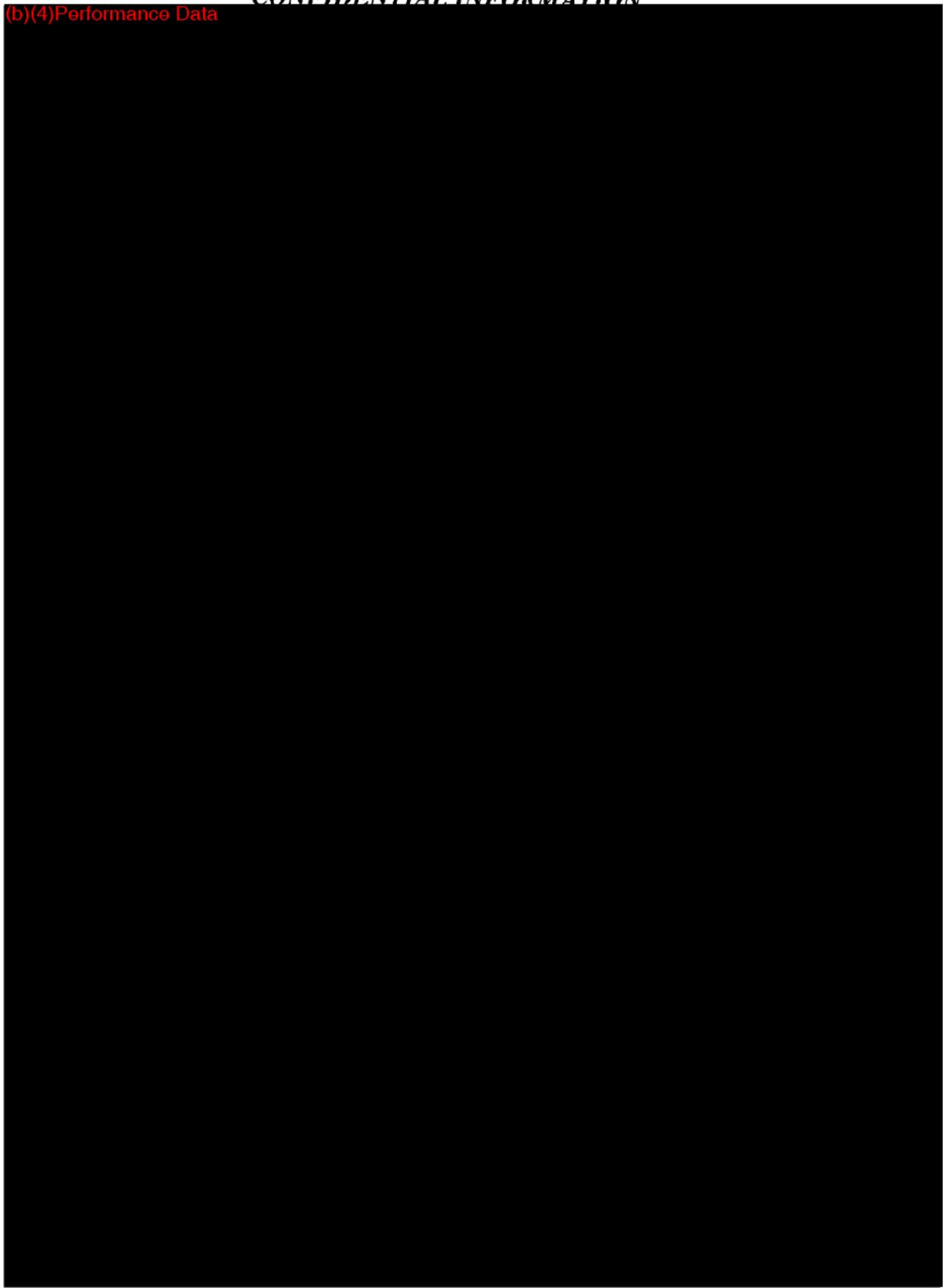
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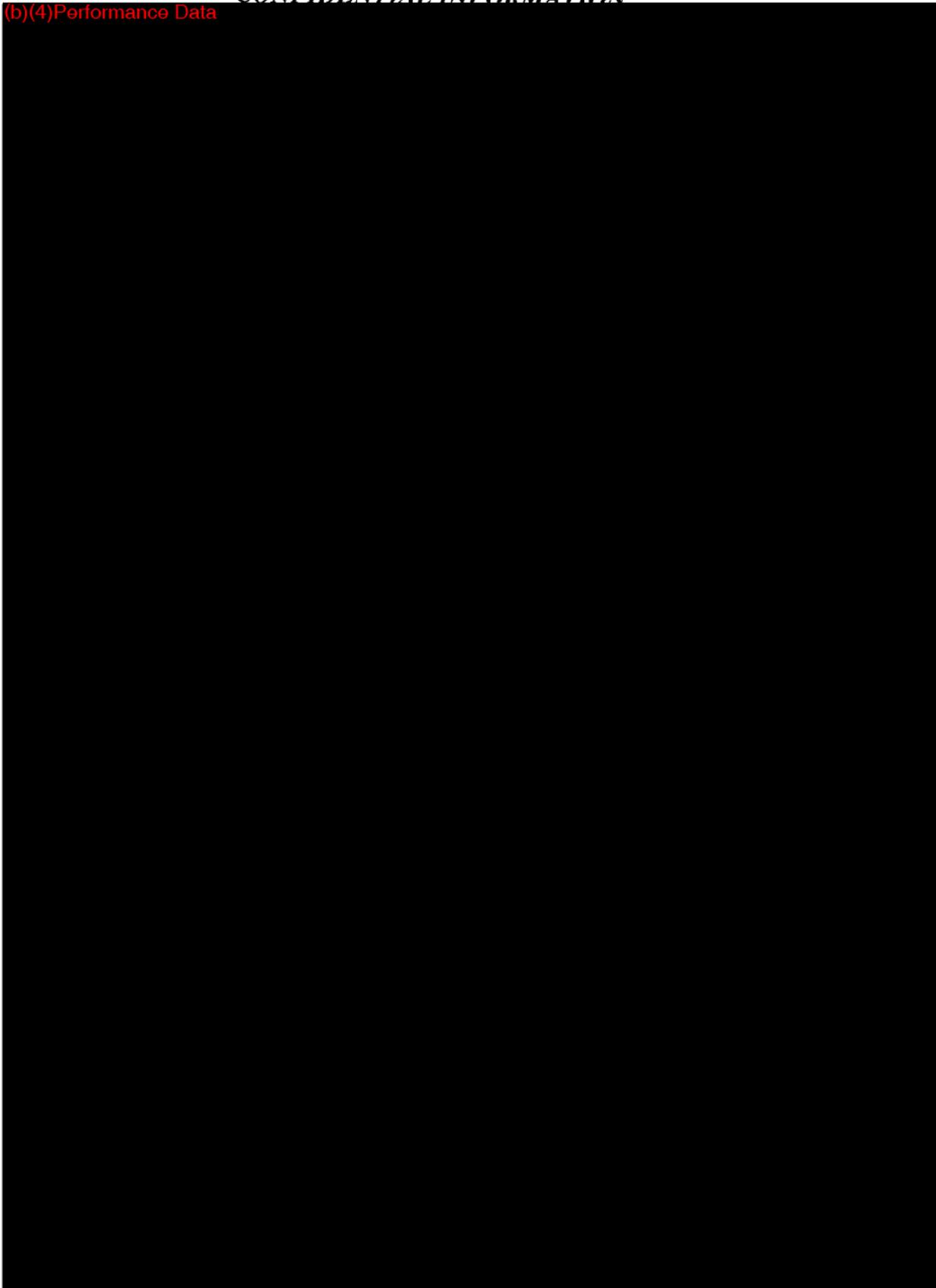
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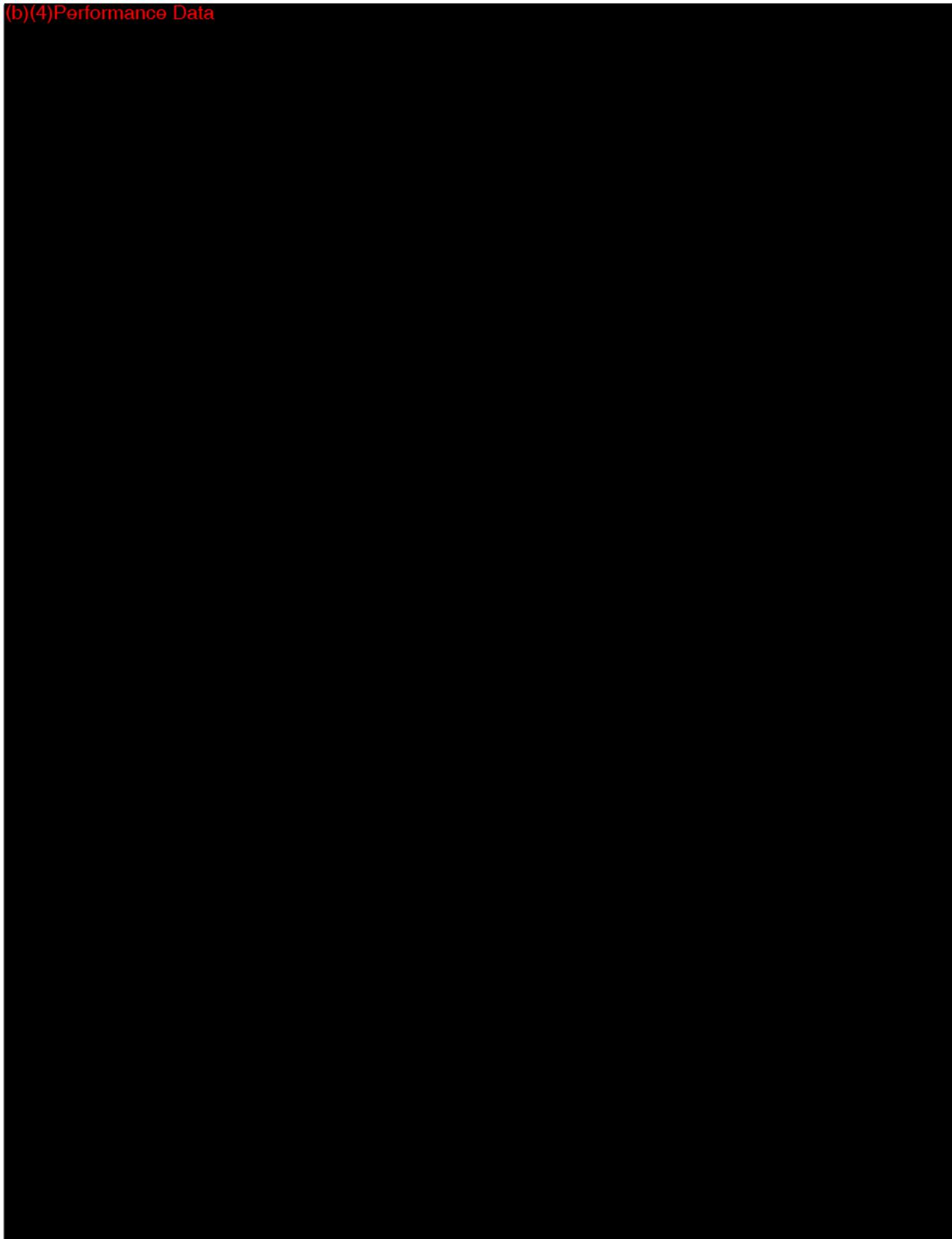
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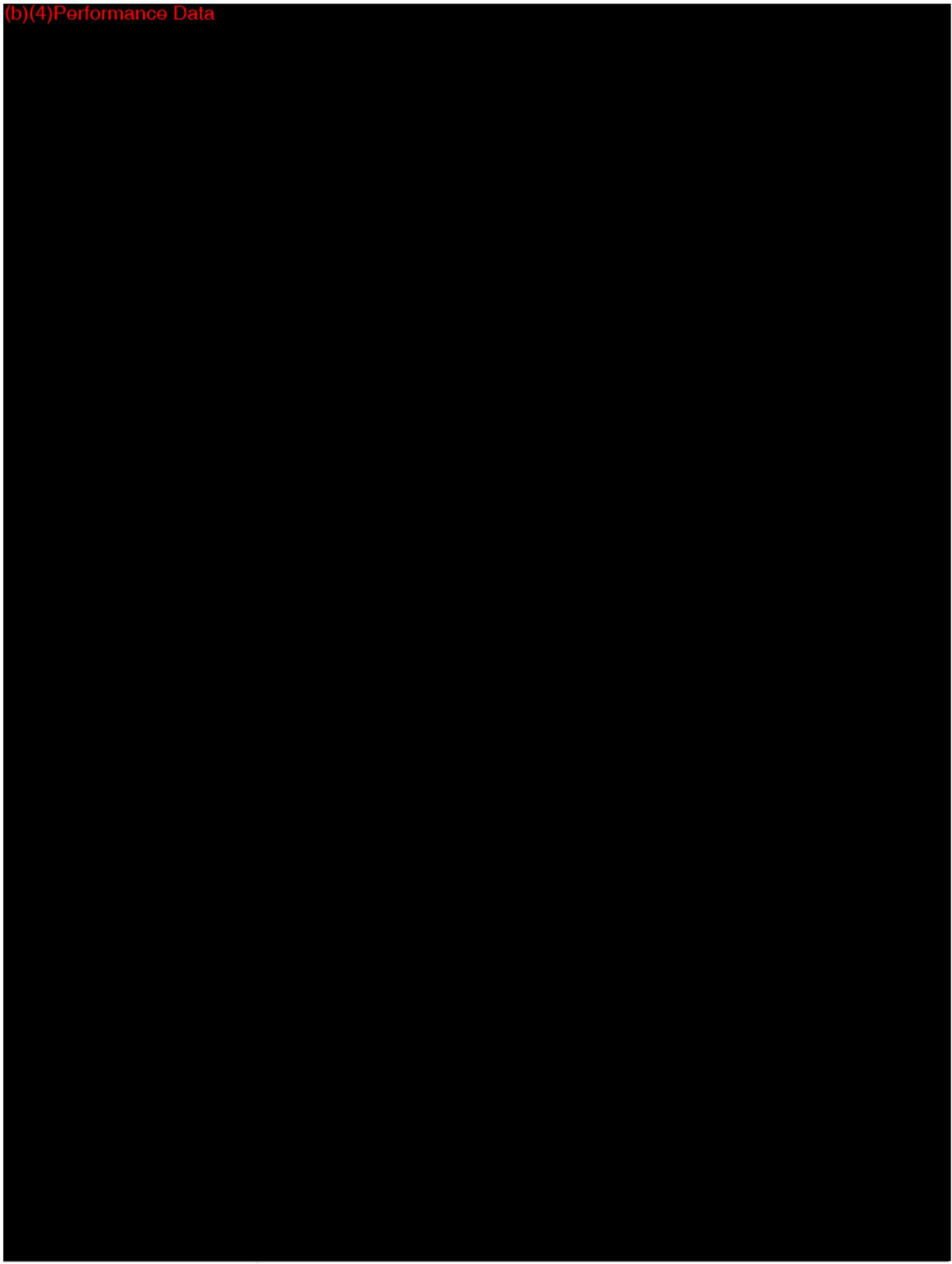
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***CONFIDENTIAL INFORMATION***

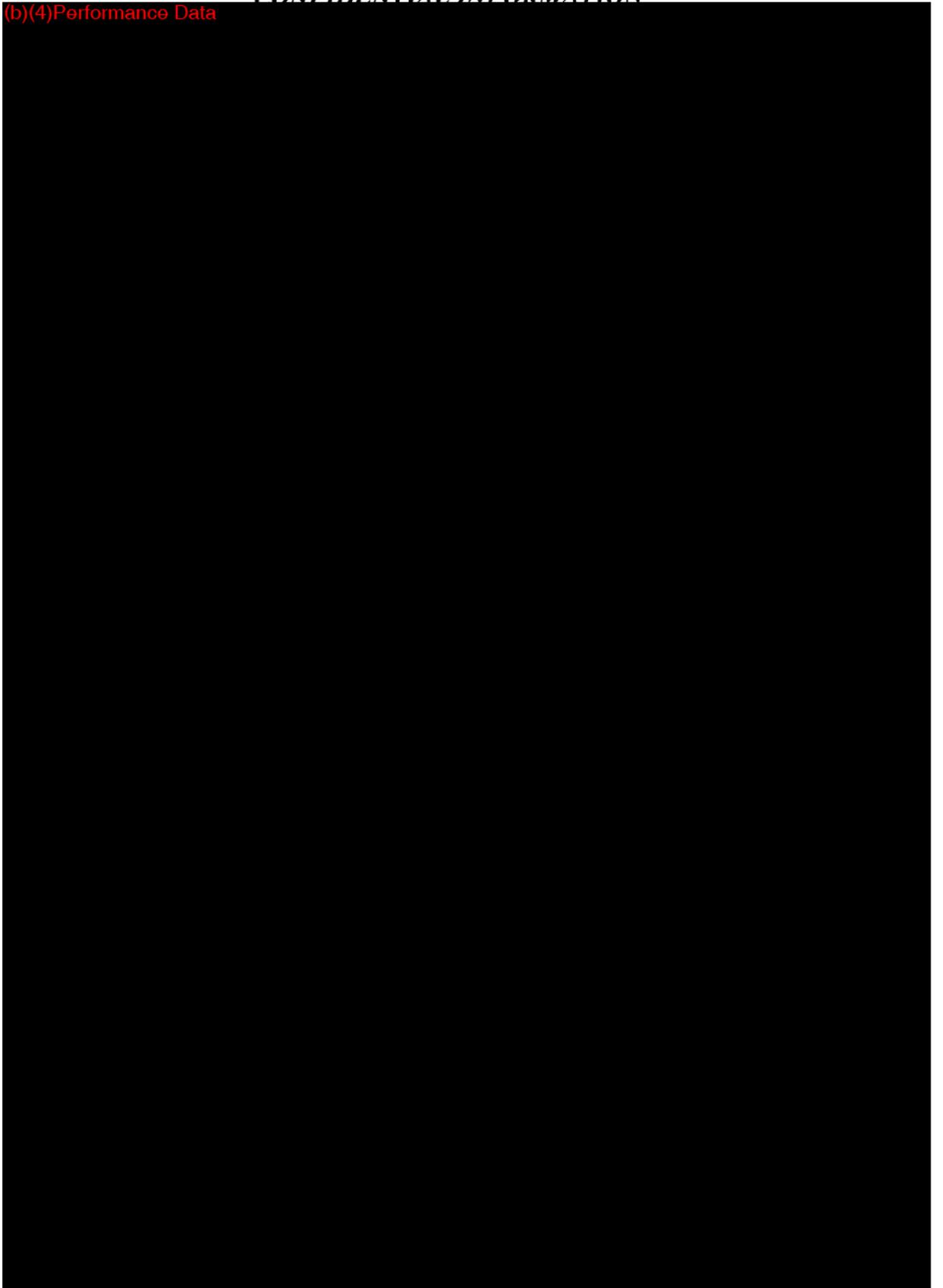
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**CONFIDENTIAL INFORMATION**

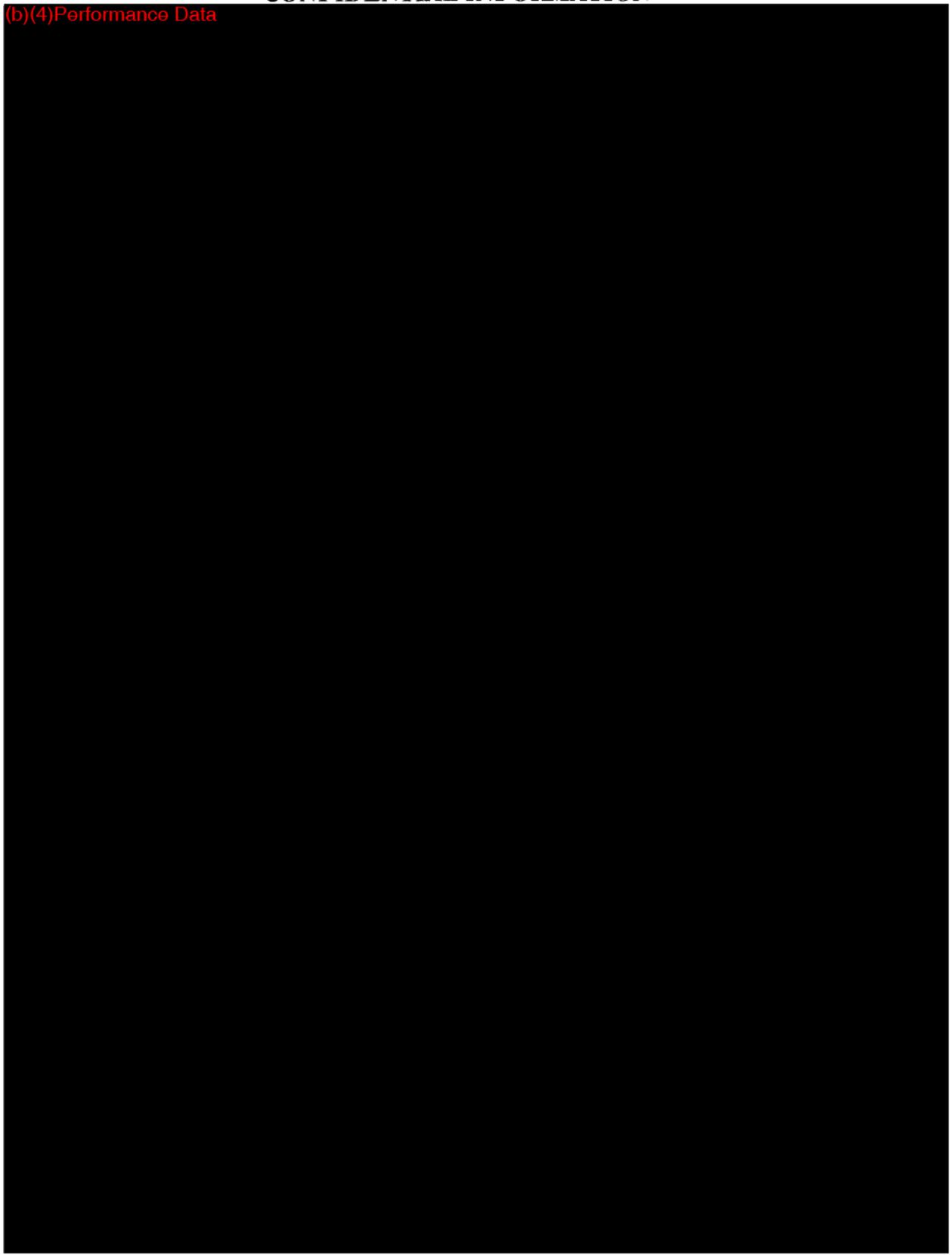
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***CONFIDENTIAL INFORMATION***

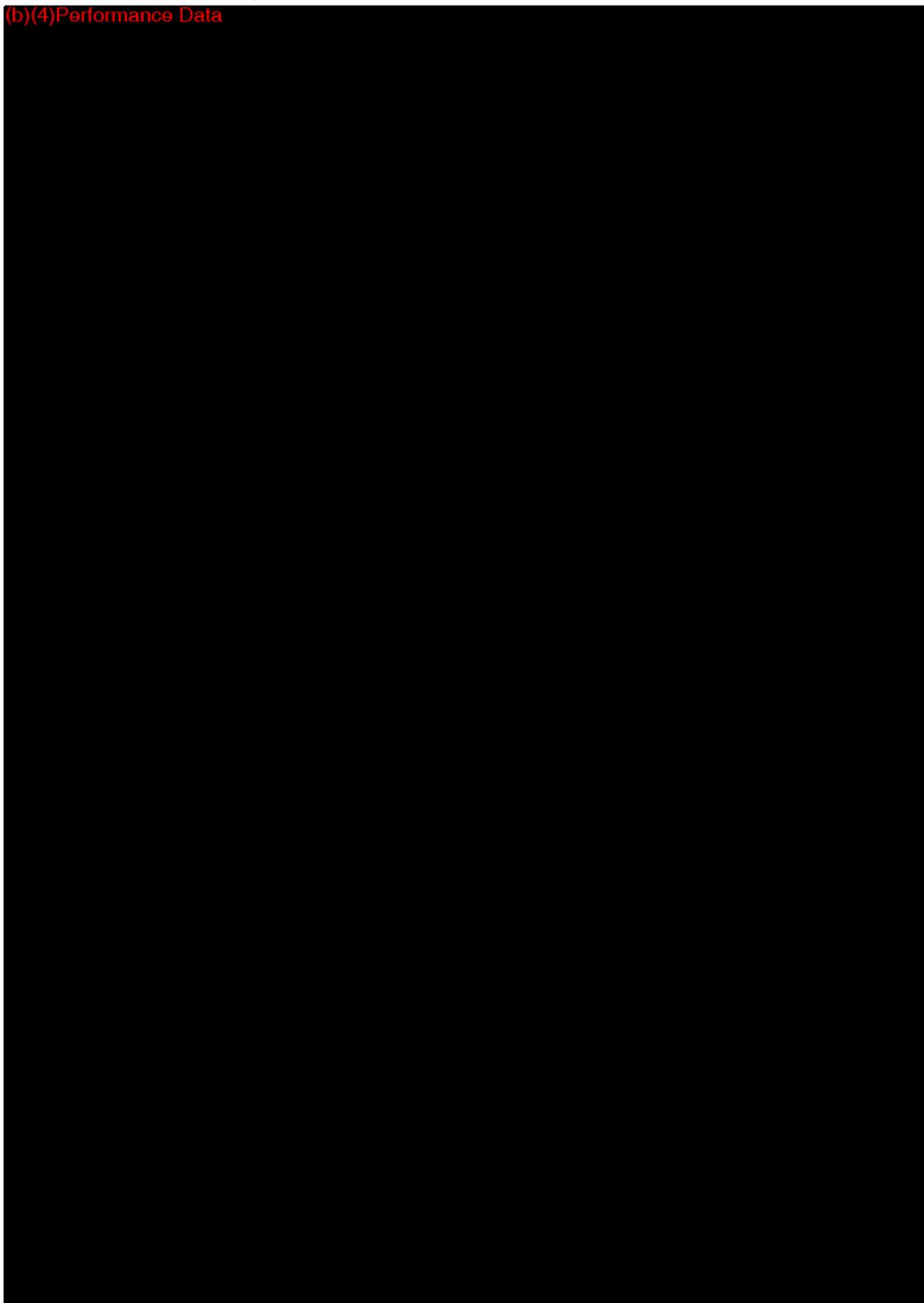
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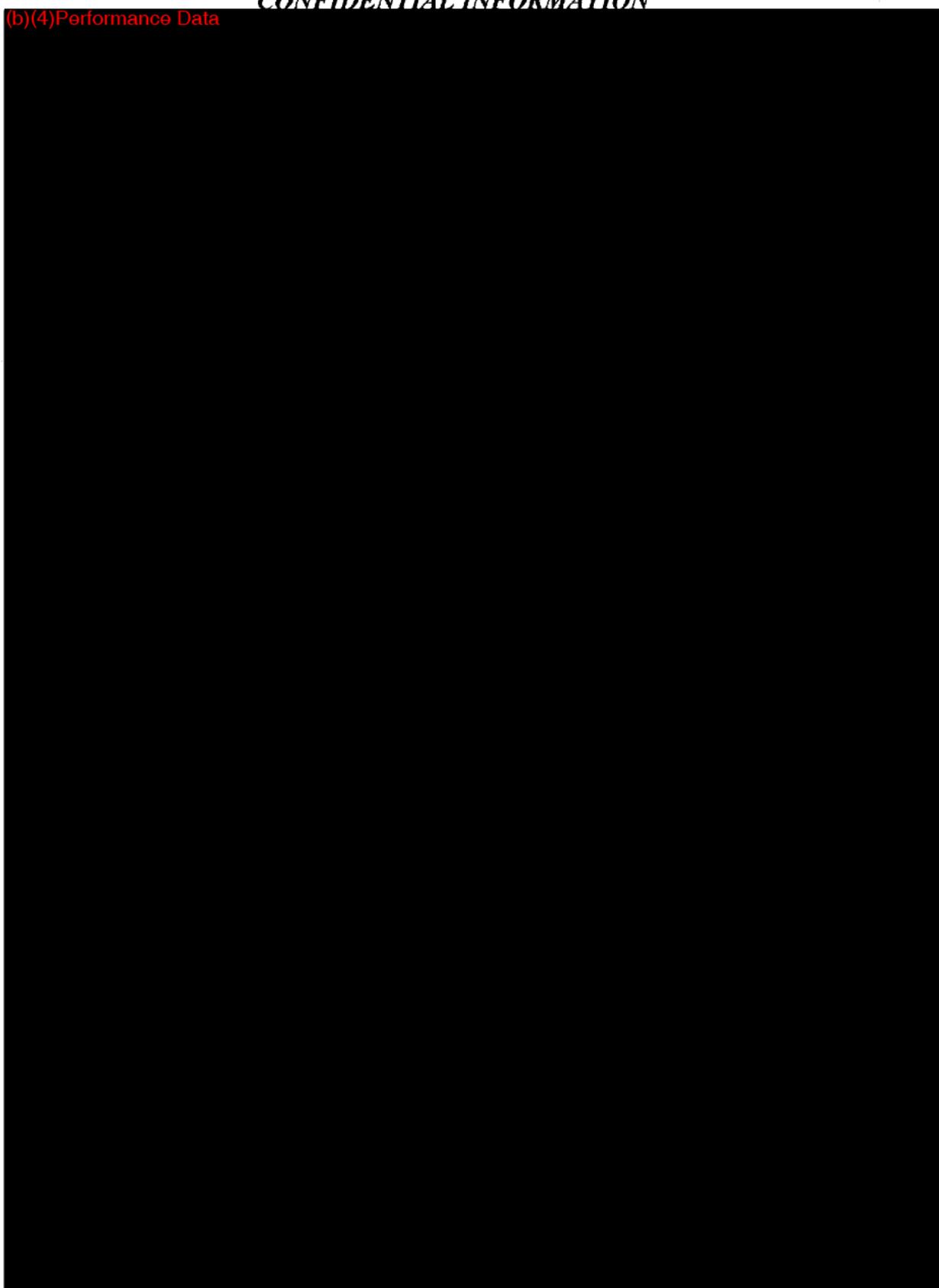
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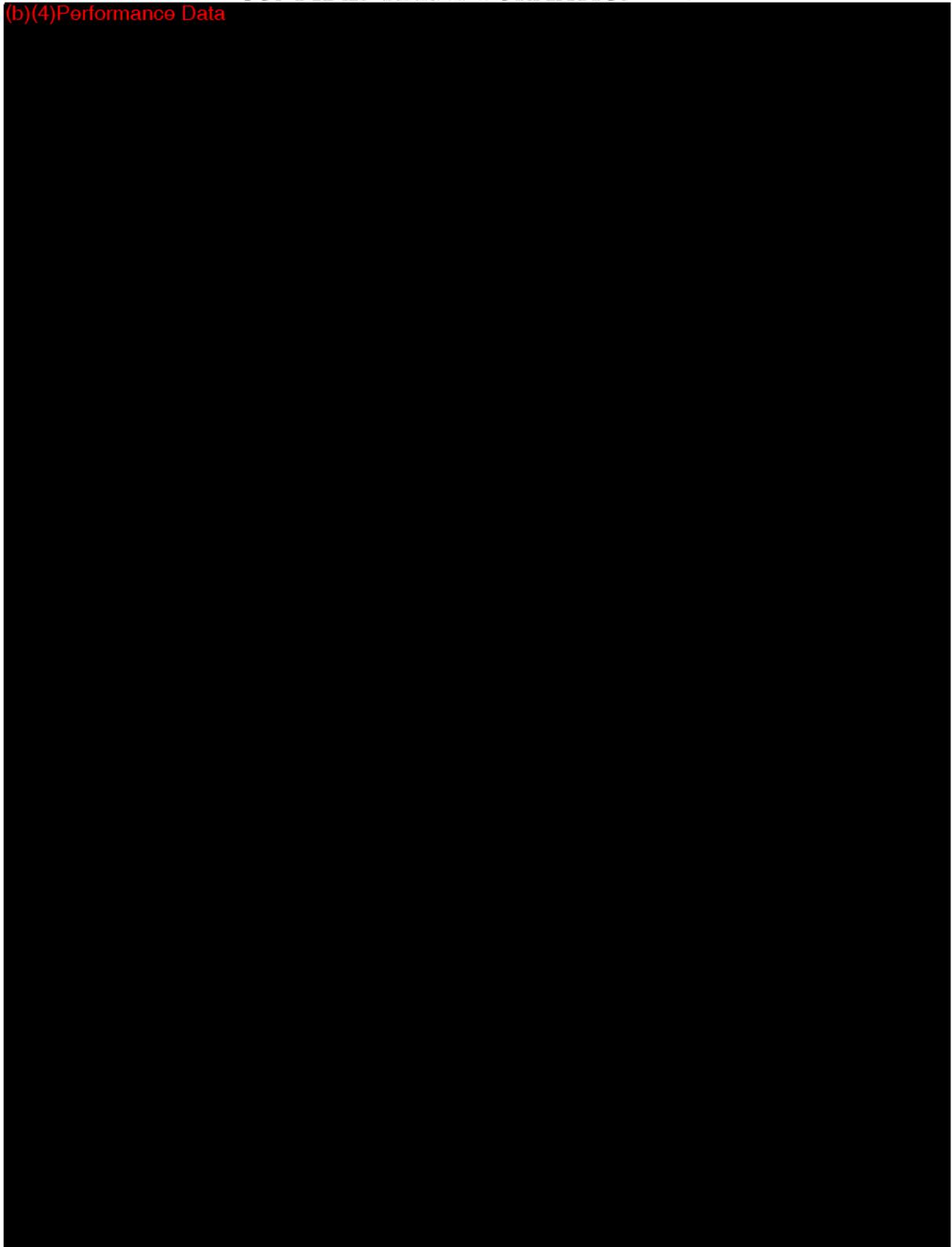
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***CONFIDENTIAL INFORMATION***

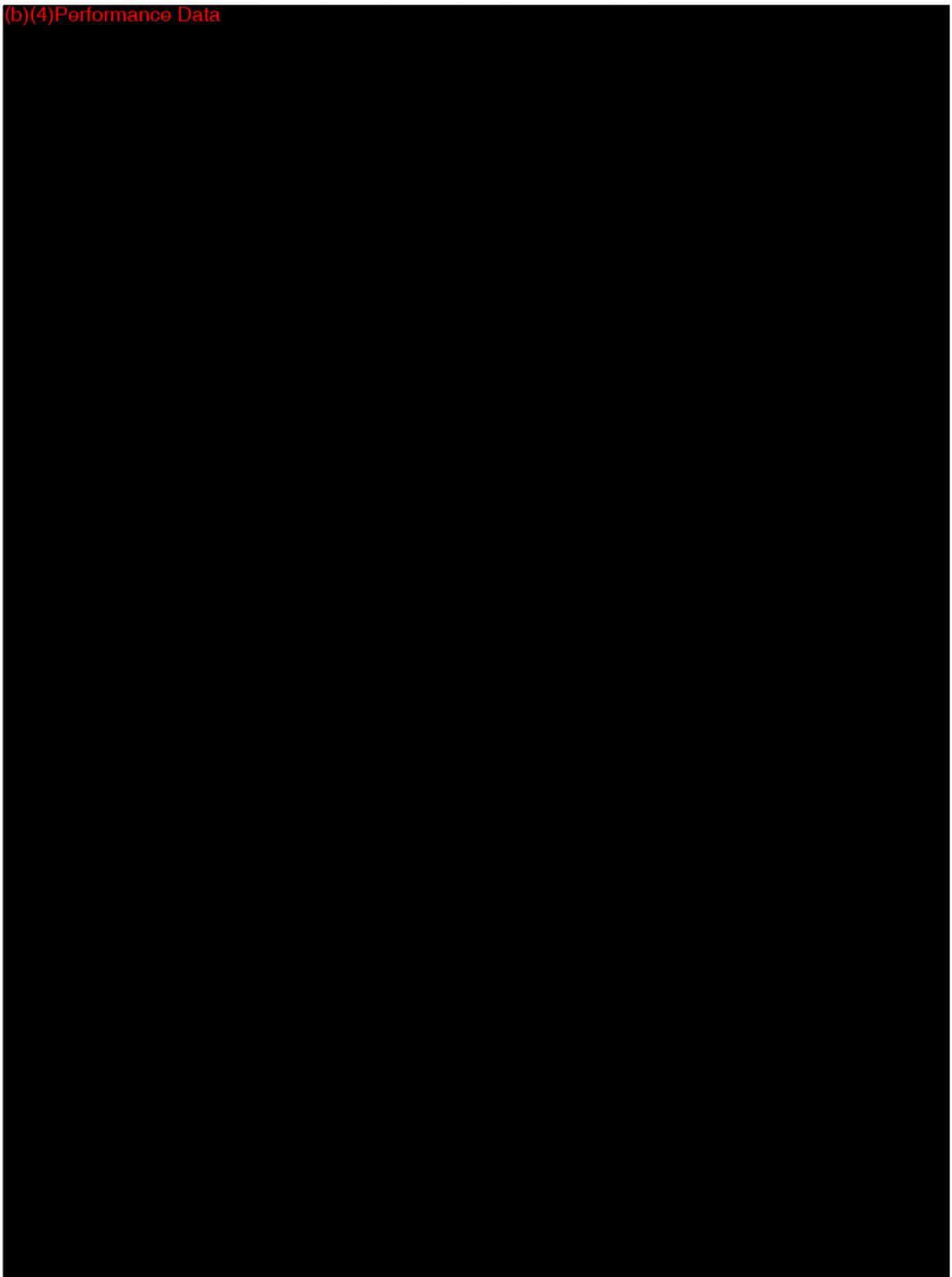
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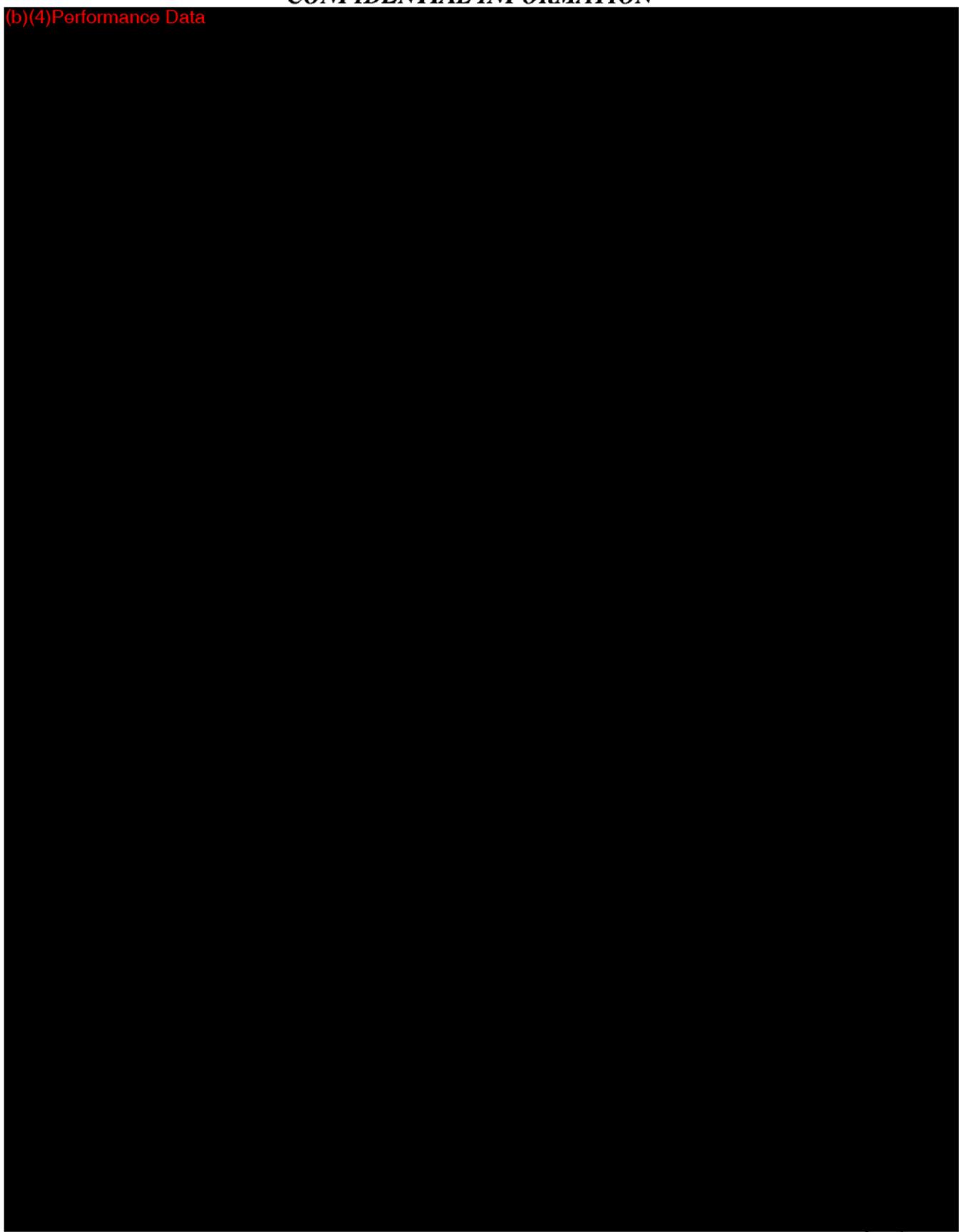
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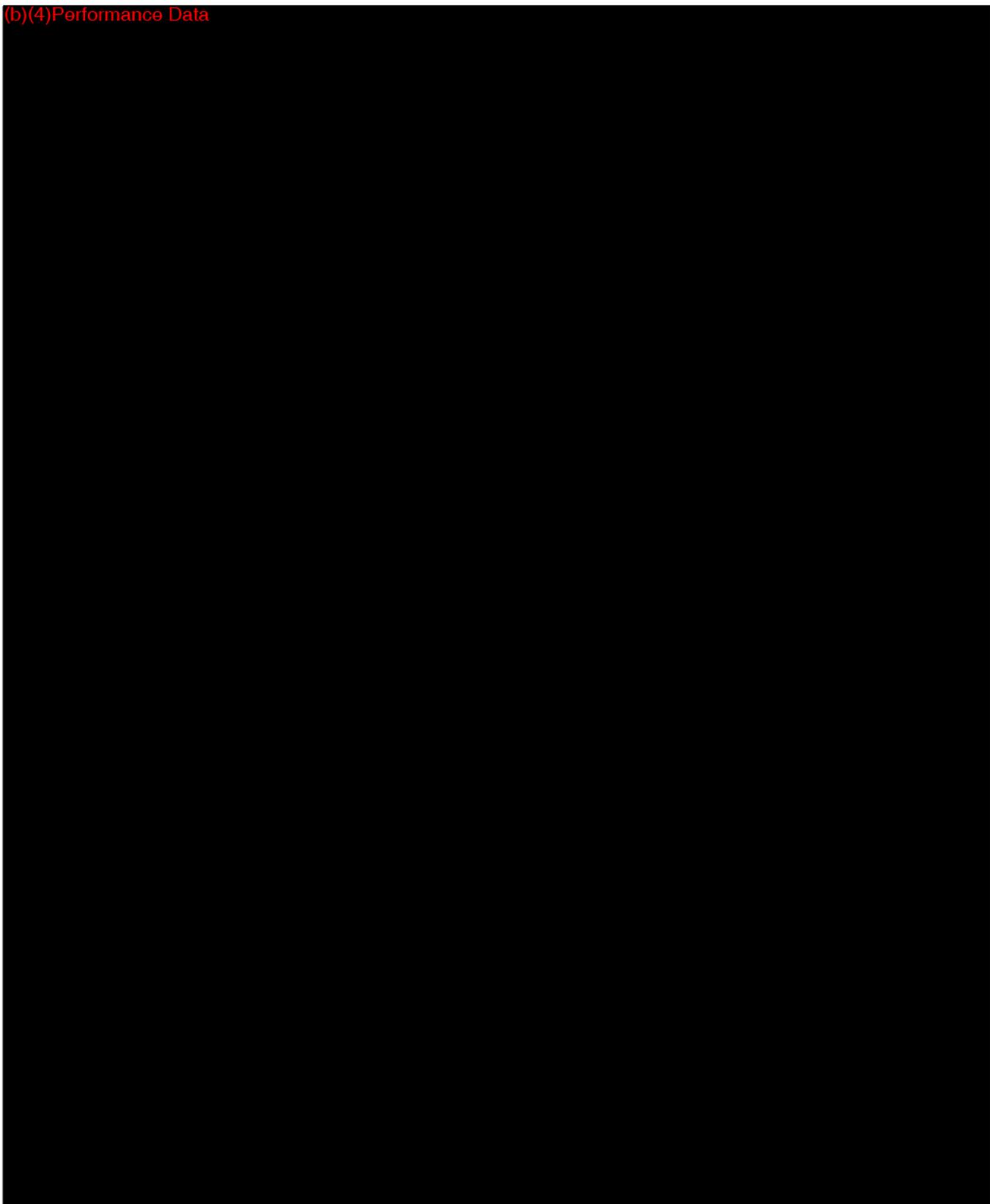
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*CONFIDENTIAL INFORMATION*

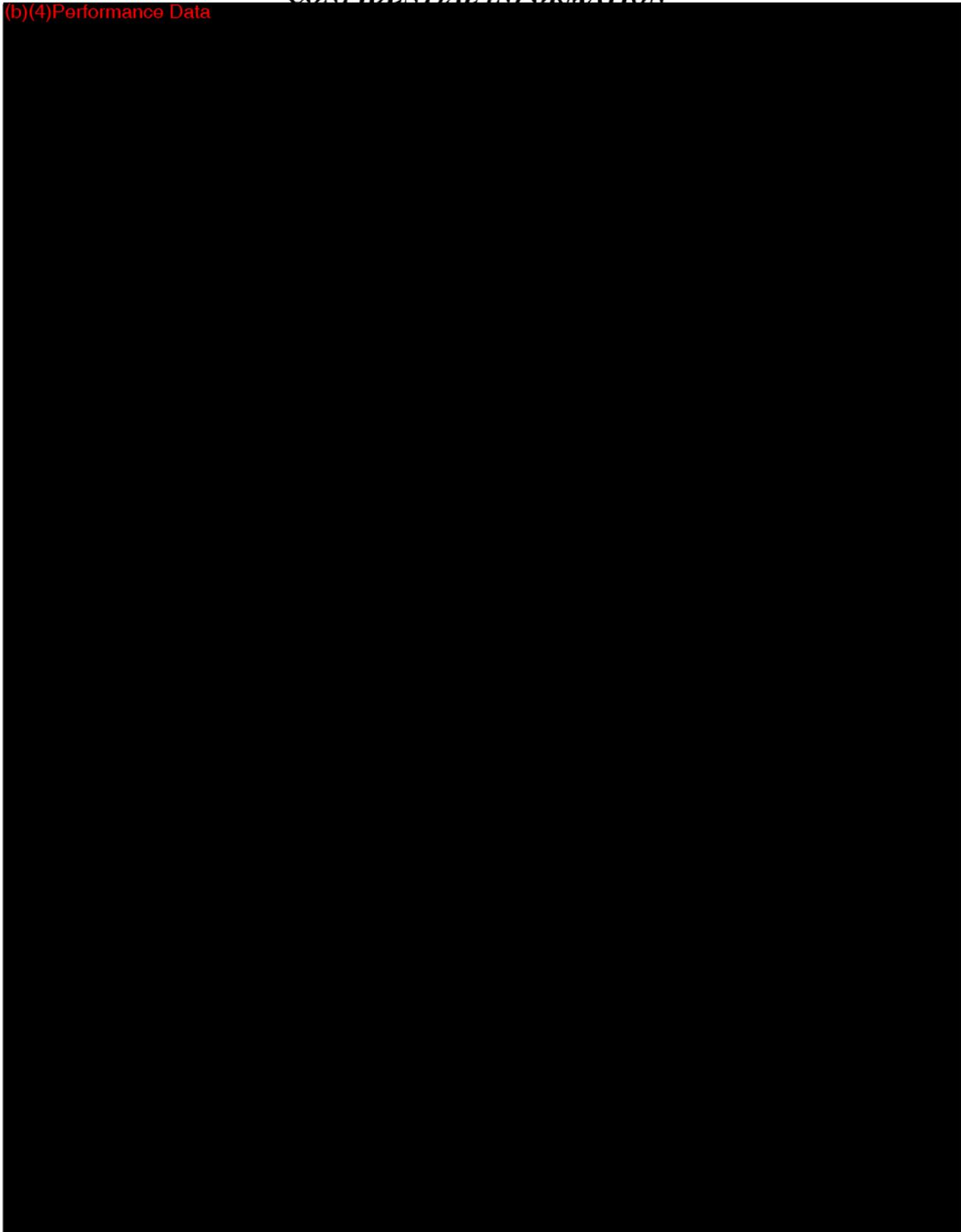
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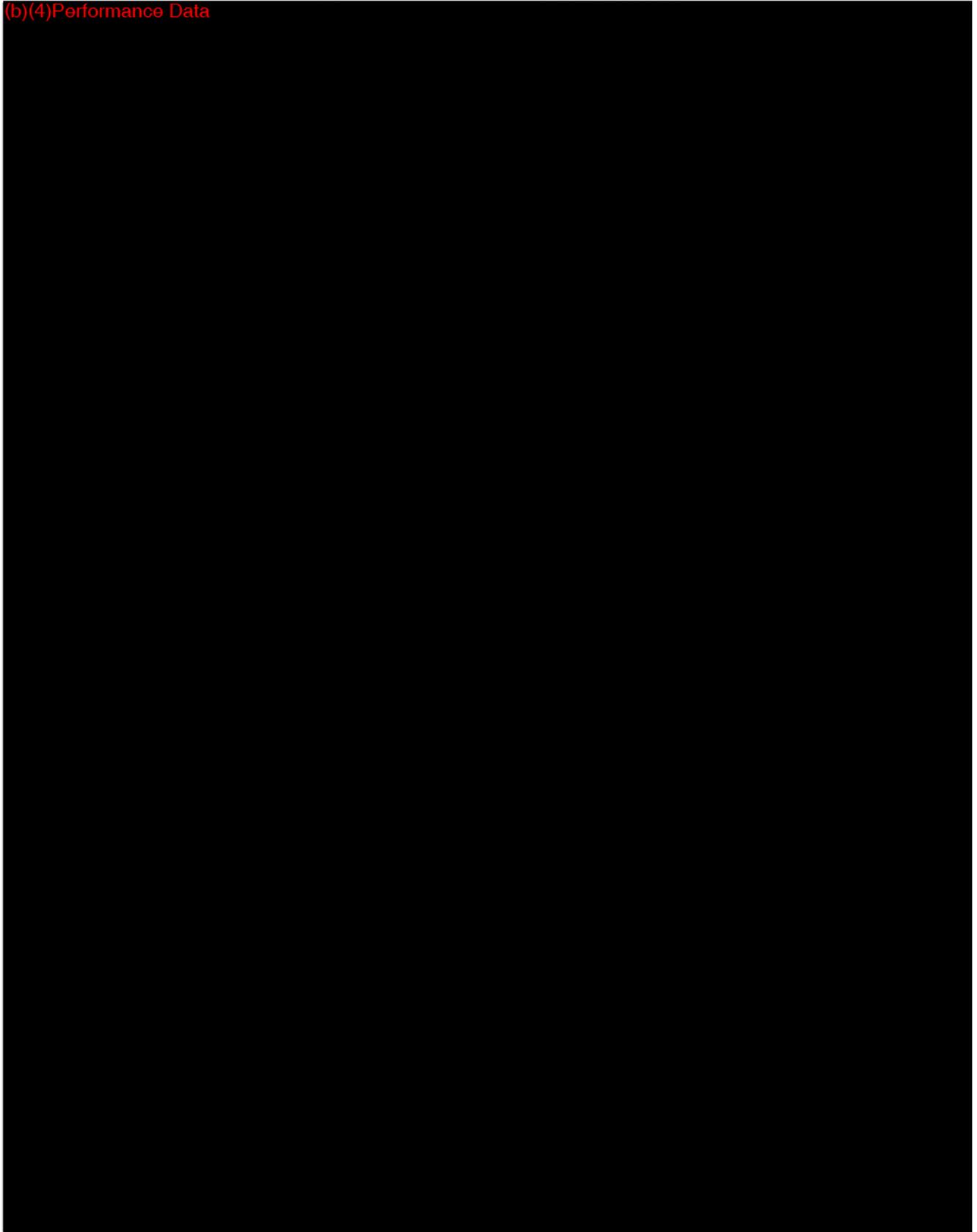
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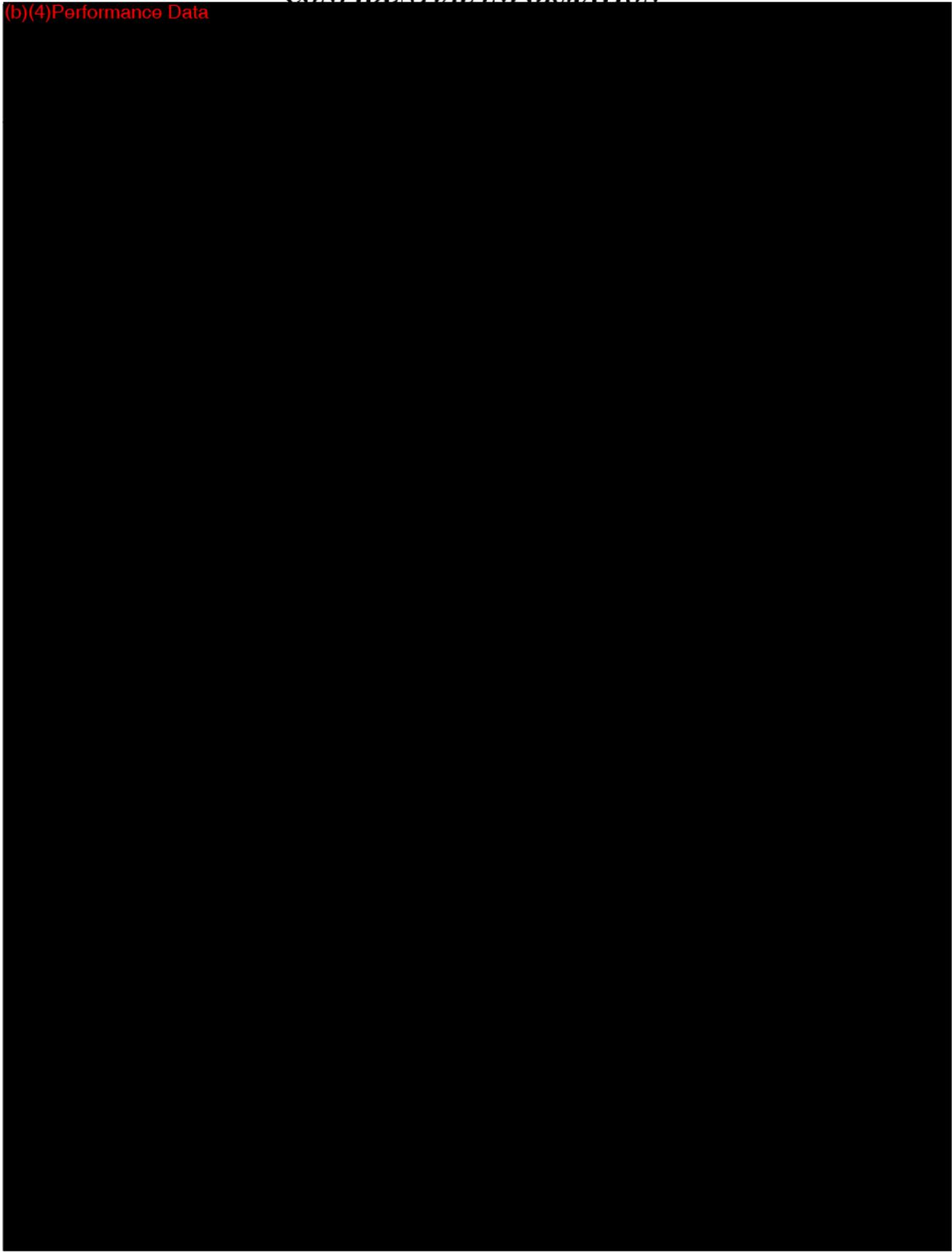
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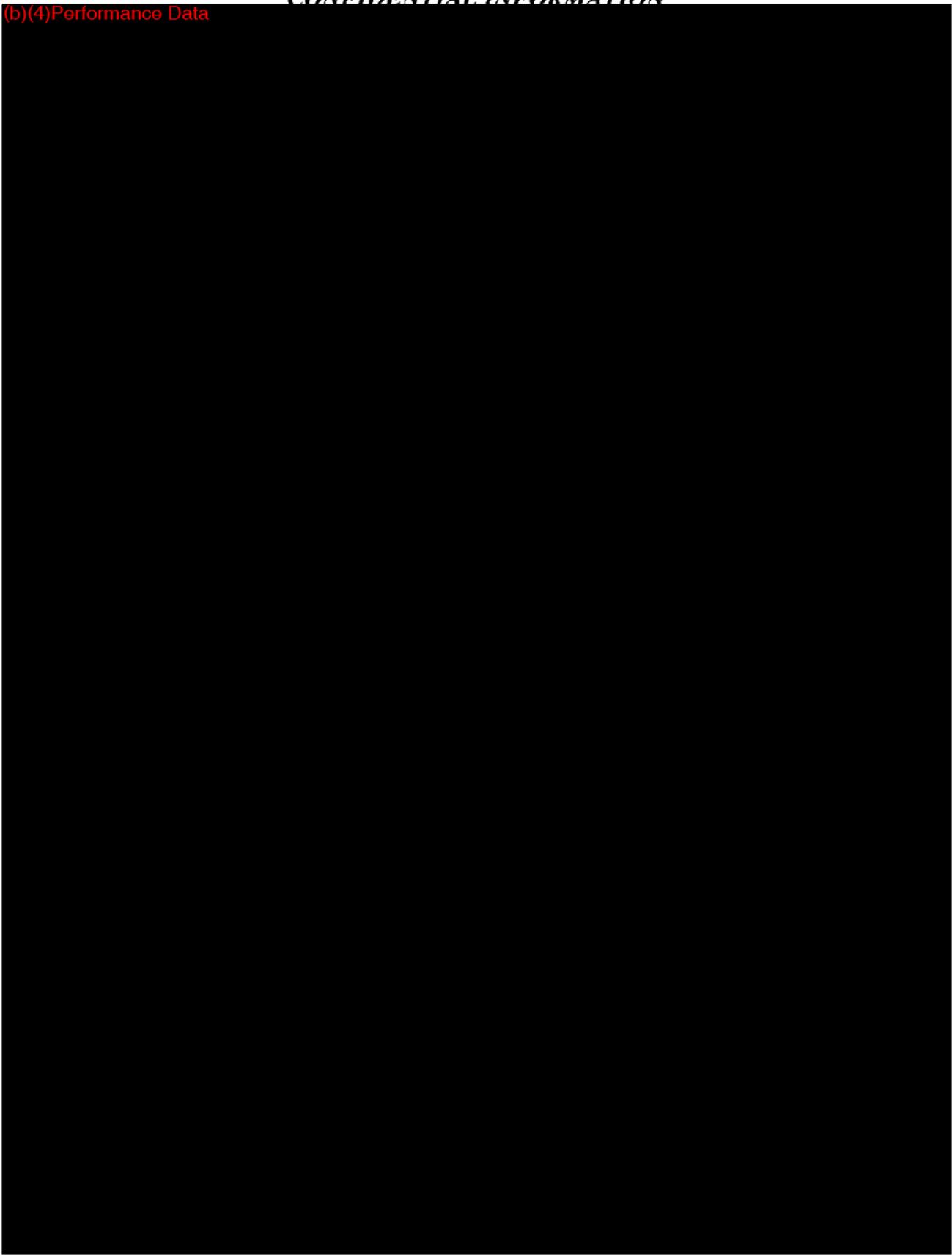
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*CONFIDENTIAL INFORMATION*

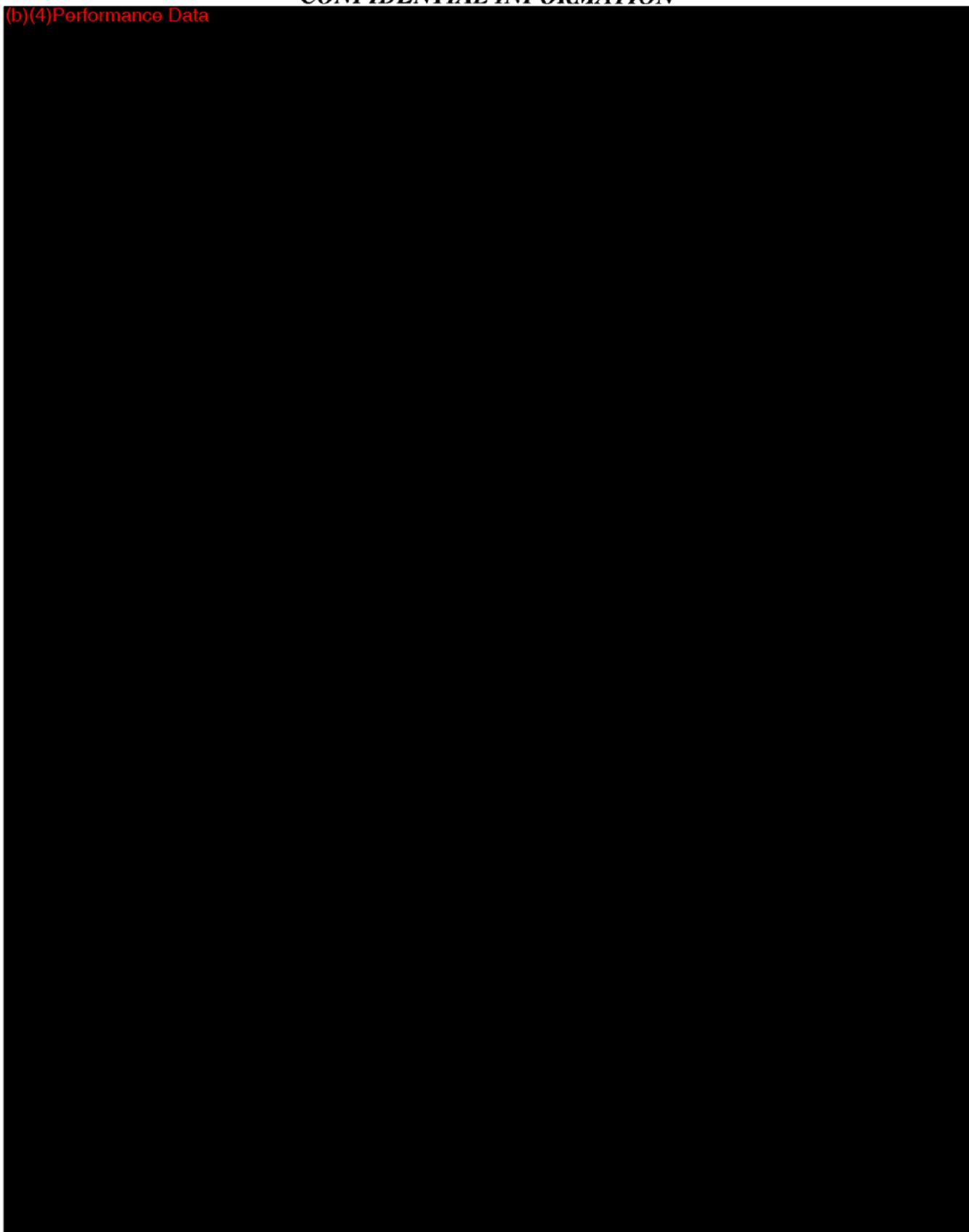
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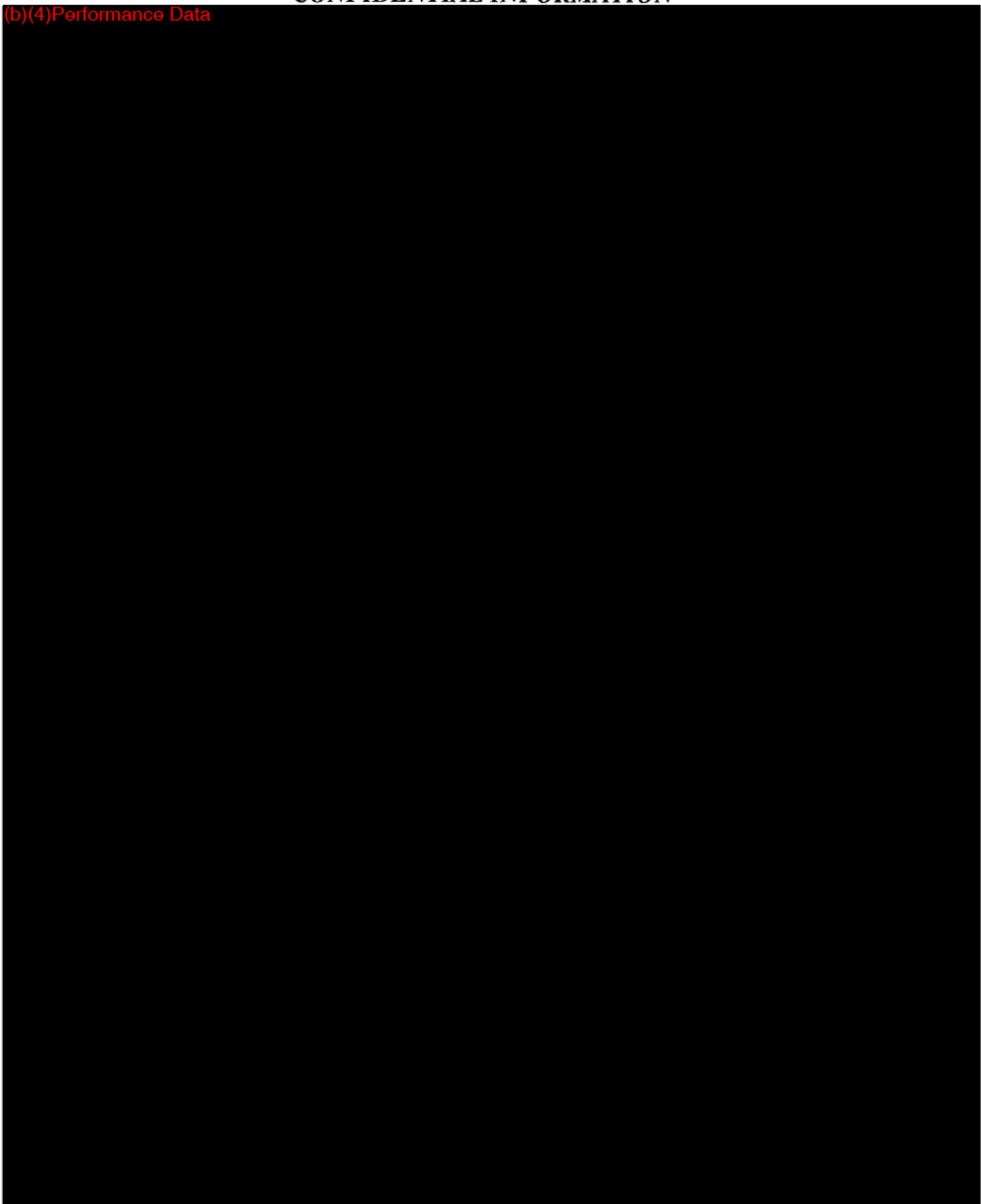
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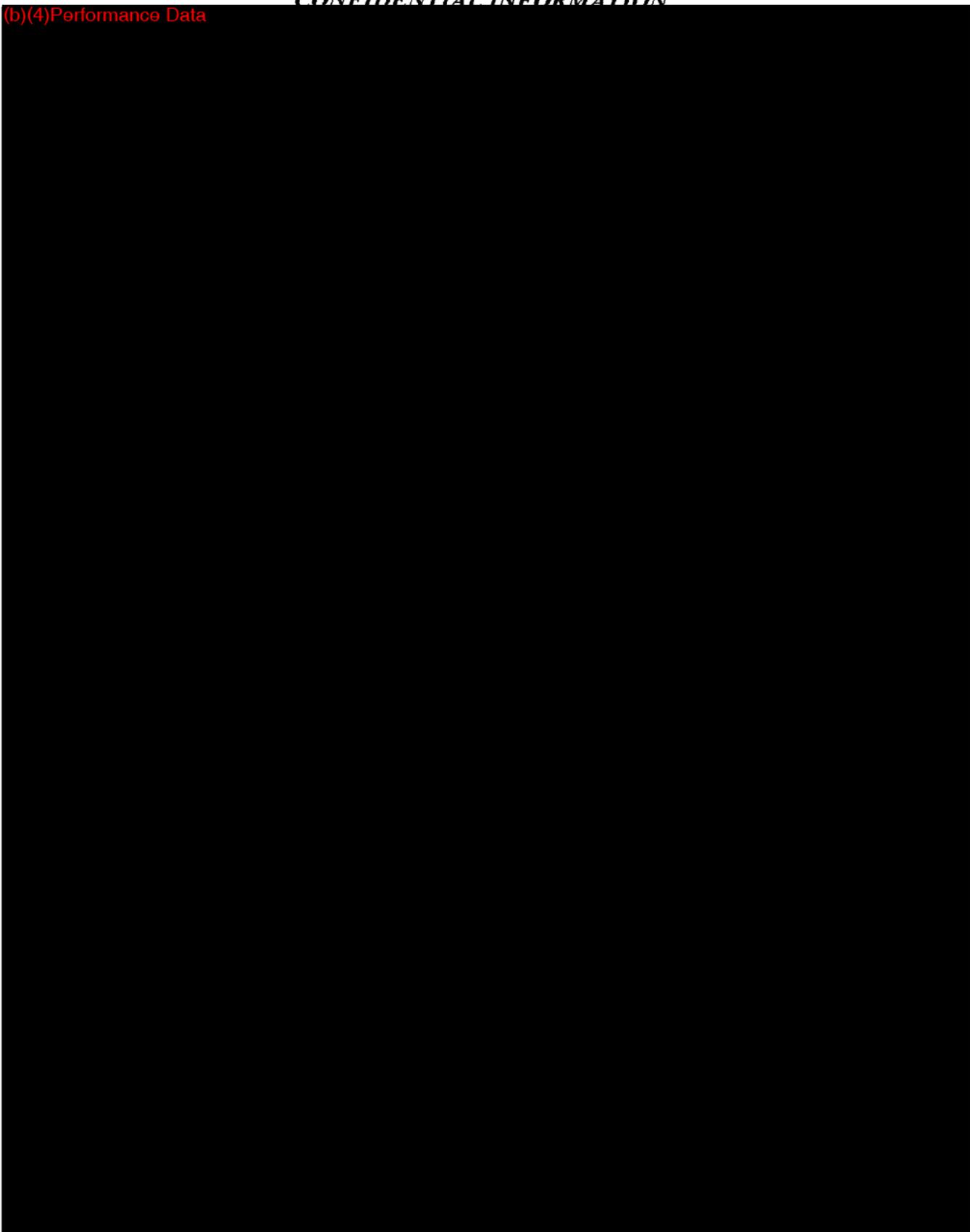
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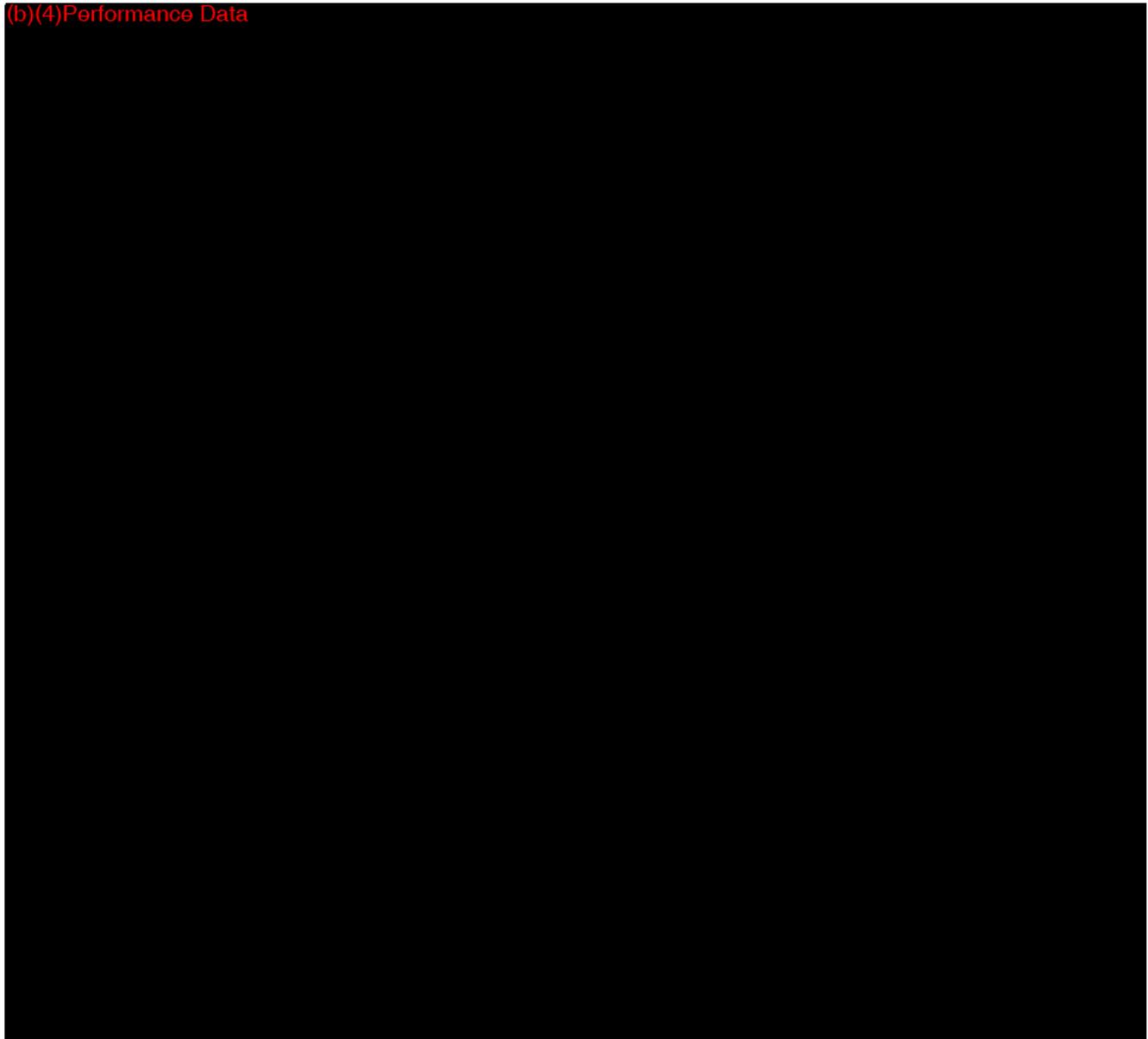


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***CONFIDENTIAL INFORMATION***

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(b)(4) Performance Data



# Package Labeling

Manufactured by: <b>ORTHOFIX S.R.L.</b> Via delle Nazioni, 9 37012 Bussolengo VR ITALY	<b>DESCRIZIONE</b>	Distributed by: <b>DISTRIBUTORE</b> Indirizzo		
REF XX-XXXXX <span style="border: 1px solid black; padding: 2px;">LOT</span> XXX Use by  YYYY-MM				
Qty	Description			
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STERILE	R			
Single use only      See instructions prior to use				
CAUTION : Federal (U.S.A.) law restricts this device to sale by or on the order of a physician. Contents sterile unless package opened or damaged. Do not use if package is opened or damaged.				
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DISTRIBUTORE Indirizzo	REF XX-XXXXX  <span style="border: 1px solid black; padding: 2px;">LOT</span> XXX  YYYY-MM	DISTRIBUTORE Indirizzo		
DISTRIBUTORE Indirizzo	REF XX-XXXXX  <span style="border: 1px solid black; padding: 2px;">LOT</span> XXX  YYYY-MM	DISTRIBUTORE Indirizzo		
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DISTRIBUTORE Indirizzo	<b>DESCRIZIONE</b>	Manufactured by: <b>ORTHOFIX S.R.L.</b> Via delle Nazioni, 9 37012 Bussolengo VR ITALY		
		Distributed by: <b>DISTRIBUTORE</b> Indirizzo		
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Qty	Description			
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STERILE	R			
Single use only      See instructions prior to use				
CAUTION : Federal (U.S.A.) law restricts this device to sale by or on the order of a physician. Contents sterile unless package opened or damaged. Do not use if package is opened or damaged.				

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K961433

JUN 28 1996

510(k) Summary of Safety & Effectiveness

This 510(k) Summary of Safety and Effectiveness for the EBI X FIX™ DynaFix™ System and EBI DFS™ Distal Radius Fixator is provided as required per Section 513(l)(3) of the Food, Drug and Cosmetic Act.

1. **Submitter:** Electro-Biology, Inc.  
6 Upper Pond Road  
Parsippany, NJ 07054

**Contact Person:** Sharon A. Starowicz  
Telephone: (201) 331-3904

Date prepared: June 26, 1996

2. **Proprietary Name:** EBI X FIX™ DynaFix™ System - SC Bone Screws  
EBI DFS™ Distal Radius Fixator - SC Bone Screws

**Common Name:** External Fixation Bone Screws

**Classification Name:** Single/Multiple Component Metallic Bone Fixation Appliances and Accessories (888.3030)

3. **Predicate or legally marketed devices that are substantially equivalent:**

- EBI X FIX™ DynaFix™ System and DFS™ Distal Radius Fixator Bone Screws
- Vitaphore SilverFoam Wound Dressing
- Genetic Laboratories E-Z DERM™ Temporary Skin Substitute with Silver
- Arrow Antimicrobial Multi-Lumen Central Venous Catheter
- Vitaphore Pin Protection Device

4. **Description of the device:** The bone screws have a tapered thread diameter and are available in a variety of diameters and lengths in both cortical and cancellous thread patterns. The screws will be available with and without the additional proprietary silver coating which has been shown to significantly reduce bacterial colonization of the surface, and will be sold sterile and nonsterile.

**Intended Use:** The EBI X FIX DynaFix System is intended for the treatment of bone conditions including leg lengthening, osteotomies, arthrodesis, fracture fixation, and other bone conditions amenable to treatment by use of the external fixation modality. The EBI DFS™ Distal Radius Fixator is intended for use in upper extremity applications for the reduction, alignment and stabilization of intra-articular and extra-articular fractures, corrective osteotomies, and soft tissue deformities.

5. **Materials:** The SC bone screws are manufactured from stainless steel, 316L per ASTM F138. The silver coating is applied by a proprietary process according to Device Master File MAF-480.

6. **Comparison of the technological characteristics of the device to predicate devices:** There are no significant differences between the SC bone screws and other currently marketed bone screws. The addition of the silver coating will not adversely affect the use of the bone screws. The coated screws underwent biocompatibility, fatigue, and direct inoculation testing. They are substantially equivalent\* to the predicate devices in design and function.

\*Any statement made in conjunction with this submission regarding a determination of substantial equivalence to any other product is intended only to relate to whether the product can be lawfully marketed without pre-market approval or reclassification and is not intended to be interpreted as an admission or any other type of evidence in patent infringement litigation. [Establishment Registration and Pre-market Notification Procedures, Final Regulation, Preamble, August 23, 1977, FR 42520 (Docket No. 76N-0355.)]

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**510(k) SUMMARY<sup>1</sup>**  
**Orthofix® External Fixation Screw**  
**November 6, 1997**

This summary is provided in accordance with the Safe Medical Devices Act of 1990 (SMDA). The information provided in the 510(k), premarket notification was in accordance with 21 CFR 807.87 and the SMDA.

**1. SUBMITTER OF 510(K)**

Robert L. Sheridan (Consultant)  
Vice President, Device Evaluation  
C.L. McIntosh & Associates, Inc.  
12300 Twinbrook Parkway, Suite 625  
Rockville, MD 20852

Telephone: (301) 770-9590  
Facsimile: (301) 770-9584

**2. NAME OF DEVICE**

**2.1 Trade/Proprietary Name**

Orthofix® External Fixation Screw (Pin) With Hydroxyapatite Coating

**2.2 Common/Usual Name**

External fixation pin

**2.3 Classification Name**

Smooth or threaded metallic bone fixation fastener (21 CFR 888.3040).

**3. APPLICANT/MANUFACTURER**

ORTHOFIX Srl.  
Via delle Nazioni 9  
37012 Bussolengo (VR), Italy  
Attention: Rolando Stanghellini, Director of Quality Assurance

Telephone: 011-39-45-6767030  
Facsimile: 011-39-45-6767135

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<sup>1</sup> Any statement made in conjunction with this submission regarding a determination of substantial equivalence to any other product is intended only to refer to whether the product can be lawfully marketed without pre-market approval or reclassification and is not intended to be interpreted as an admission or any other type of evidence in patent infringement litigation. (Establishment Registration and Premarket Notification Procedures, Final Regulation, Preamble, August 23, 1977, FR 42520 (Docket No. 76N-0355))

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**4. REASON FOR SUBMITTING THE 510(K)**

Orthofix intends to commercially distribute a modified version of its previously 510(k)-cleared external fixation pin.

Orthofix also wishes to distribute its pins with a very thin plasma sprayed coating of hydroxyapatite (HA).

**5. DEVICE DESCRIPTION**

The Orthofix HA coated pins are manufactured from surgical grade stainless steel AISI 316L. The pins are available in a variety of diameters and lengths. The threaded end is gradually tapered, over approximately the last third of the pin's length. The threaded portion of the pin is coated with a very thin plasma sprayed coating of HA. The HA powder used in the plasma spray coating process conforms to ASTM F 1185. The mechanical properties of the coating conform to ASTM F 1501.

**6. INTENDED USE**

The Orthofix external fixation screw (pin) with hydroxyapatite coating is indicated for use in the external fixation of bone.

**7. SUBSTANTIAL EQUIVALENCE**

The decision that the Orthofix HA coated pin is substantially equivalent to a legally marketed predicate device is reached through consideration of the requirements for substantial equivalence determinations. These requirements are set forth in the document published on June 30, 1986 by the Center for Devices and Radiological Health (CDRH), entitled "Guidance on the Center for Devices and Radiological Health's Premarket Notification Review Program."

FDA guidance documents relevant to this application were used in its preparation. In particular, the guidance document "510(k) Information Needed for Hydroxyapatite Coated Orthopedic Implants" (revised February 20, 1997), was followed in the preparation of this 510(k). The physical, mechanical and chemical tests prescribed by FDA in its guidance document to characterize the HA coating and HA/substrate interface were conducted.

The substantial equivalence of the Orthofix HA coated pins is supported by the extensive laboratory, animal and clinical testing data presented herein. The preclinical and clinical data presented herein demonstrate that the use of the HA coating enhances fixation at the pin/bone interface. The coated pins demonstrate statistically significantly better stability or fixation at the time of removal or extraction than the uncoated pins.

In summary, the information and data provided in this submission are consistent with FDA's guidance documents for HA coated orthopedic implants and demonstrate that the Orthofix HA coated pin is substantially equivalent to legally marketed predicate devices.

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