



U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER: (kml)
FOLDER: K142282 - 373 pages
COMPANY: PRECEPTIS MEDICAL (PRECMEDID)
PRODUCT: TUBE, TYMPANOSTOMY (ETD)
SUMMARY: Product: HUMMINGBIRD(TM) TYMPANOSTOMY TUBE SYSTEM (TTS)
DATE REQUESTED: Nov 1, 2015
DATE PRINTED: Nov 1, 2015
Note: Printed





Preceptis
MEDICAL

19 September 2014

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – W066-G609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

K142282/AJ

FDA CDPM DMC

SEP 28 2014

Received _____

**RE: Traditional 510(k) Premarket Notification – 21 CFR 807.90(e)
Preceptis Medical, Inc.**

To Whom It May Concern:

Please find included an eCopy of the amendment to the traditional 510(k)
#K142282 submitted by Preceptis Medical, Inc.

The eCopy is an exact duplicate of the paper copy.

Sincerely,

Keith Leland



Preceptis
MEDICAL

FDA CDRH DMC

SEP 23 2014

Received

19 September 2014

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

RE: Traditional 510(k) Premarket Notification - 21 CFR 807.90(e)

#K142282 Preceptis Medical, Inc.

To Whom It May Concern:

The enclosed submission is an update to the 510(k) Pre-Market Notification #K142282 requesting clearance for the clinical use of the Hummingbird™ Tympanostomy Tube System (TTS). Two elements of the submission are being updated, the 510(k) summary and the clinical report.

1. The 510(k) summary performance data section has been updated to include additional information regarding the use of other surgical instruments with the TTS, and the number of TTS devices used per procedure. This update is being submitted because equivalent information was requested for the predicate device, and comparable updates to the predicate 510(k) summary were made.
2. The clinical report (appendix H1) section 12.4 has been updated to support the information updated in the performance data section of the 510(k) summary.

(b) (4)

Sincerely,

Keith Leland
VP of R&D



19 September 2014

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(b) (4)

Sincerely,

A handwritten signature in black ink, appearing to read "K Leland".

Keith Leland
VP of R&D

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Section 5 510k Summary

Submitter Information:	Preceptis Medical, Inc. 505 Highway 169 North, #365 Plymouth, MN 55441 763.568.7819
Contact:	Keith Leland, VP of R&D
Date Prepared:	12 August 2014
Trade Name	Hummingbird™ Tympanostomy Tube System (TTS)
Product Code	ETD (21 CFR Part 874.3880)
Common Name	Tympanostomy Tube Inserter with pre-loaded ventilation tube
Predicate Devices	Preceptis Tympanostomy Tube System, 510(k) K133921
Device Description	<p>The Hummingbird™ Tympanostomy Tube System (TTS) which includes a tympanostomy tube inserter (TTI) with a preloaded ventilation tube, is a single-use, sterile manual surgical instrument which is used to create a myringotomy in the tympanic membrane and place a ventilation tube. The TTS includes a handle with one or more tip assemblies which contain a sterile tympanostomy tube.</p> <p>Each tip assembly can be removably attached to the handle and includes a positioning rod and a ventilation tube pre-loaded inside the distal end of a sharpened sheath. Attaching the tip assembly to the handle also connects the sheath and actuator, allowing the user to retract the sheath by manually scrolling an actuator located on the handle.</p> <p>The user manually advances the sharpened sheath to create a myringotomy and simultaneously positions the ventilation tube within the myringotomy, always under direct visualization. The user then manually retracts the sharpened sheath away from the myringotomy using the manual actuator located on the handle. The retraction of the sheath releases the tube within the myringotomy.</p> <p>A first tip assembly can then be removed from the handle and replaced with a second preloaded tip assembly for bilateral procedures.</p>
Indications For Use	The Hummingbird™ Tympanostomy Tube System is intended to deliver a tympanostomy tube in tympanostomy procedures in which the patient is receiving a tympanostomy tube.

Section 5 510k Summary

Technological Characteristics	<p>The TTS is intended to deliver a tympanostomy tube (also referred to as a ventilation tube) through the tympanic membrane (TM) of the patient. It combines the separate functions of creating a myringotomy, positioning and placing a ventilation tube across the TM, and suctioning.</p> <p>The TTI is a manual surgical instrument. The actions of creating the myringotomy, positioning the ventilation tube, and retracting the sheath surrounding the ventilation tube are all performed manually by the user.</p> <p>A comparison between the TTS and predicate device shows that the devices are identical.</p>
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Section 5 510k Summary

Performance Data	<p>In two non-significant risk studies, a total of 69 children (mean age of 2.4 years, ranging from 8 months to 8.9 years) underwent tympanostomy procedures under moderate sedation using the Preceptis TTS to reduce surgical trauma for the patients. Results:</p> <ul style="list-style-type: none">• The IRBs at each institution designated the studies as Non-Significant Risk due to the low risk profile of the TTS and the fact that anesthetic regimen is determined and delivered by an anesthesia professional within the hospital.• This approach is presented as an additional option to the current standard of care under general anesthesia. It is also an extension of current tympanostomy medical practice in which children ages 12 and above are treated in the office with only topical anesthetic.• 100% of the children received ventilation tubes as planned. In 54 patients that were completed under moderate sedation, tympanostomy tubes were successfully delivered in 108 ears. In 99/108 ears (92%) only the TTS was used for the tympanostomy procedure. In 9/108 ears (8%), either a pick or alligator forceps was used to complete the tympanostomy procedure. In 5 of the 99 ears where only the TTS was used, a second TTS tip assembly was required.• There were <u>no intra-operative adverse events</u>, no unanticipated adverse events, and adverse event rates were well within normal reported rates.• There is no additional risk in converting cases from moderate sedation to general anesthesia since the conversion process simply involves turning off the nitrous oxide and turning on the flow of sevoflurane to the mask already in place over a child's nose and mouth. <p>Performing tympanostomy procedures in young children under moderate sedation in a hospital setting with anesthesia delivered by an anesthesia professional is safe and a well-reasoned alternative to the use of general anesthesia for caregivers and clinicians who are comfortable with this choice.</p>
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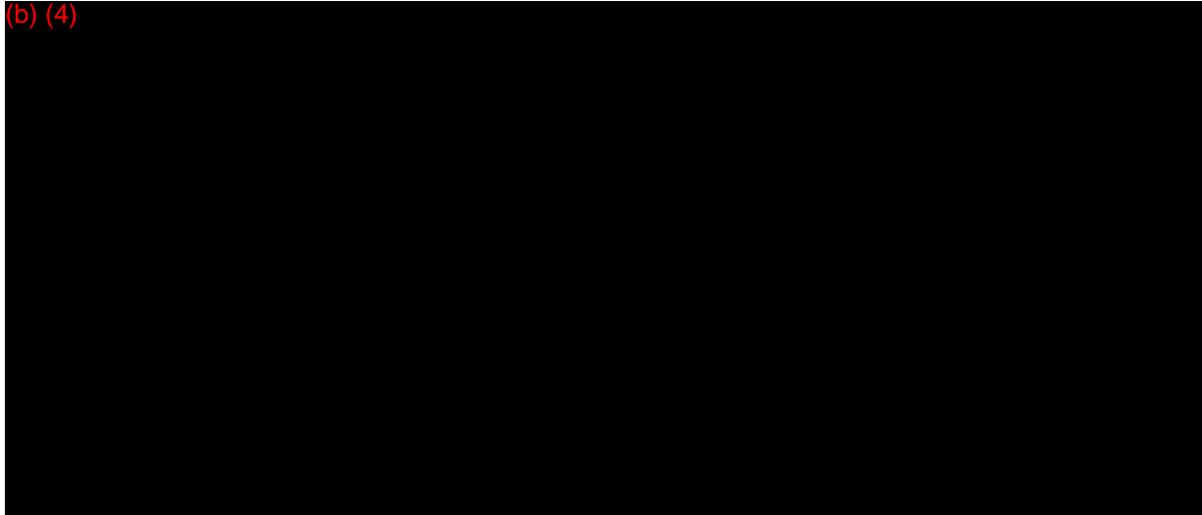
Appendix H1 Clinical Report – Hummingbird™ TTS

1.0 BACKGROUND

1.1 Device Name

The Preceptis Hummingbird™ Tympanostomy Tube System (HTTS)

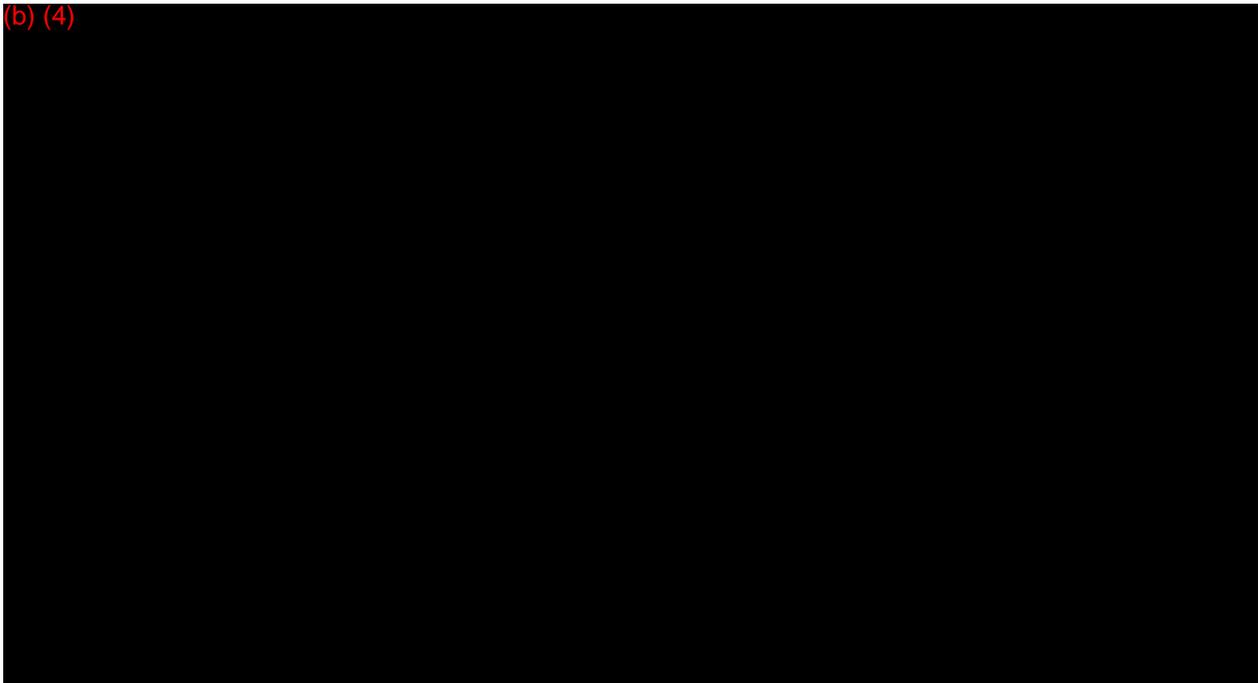
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1.3 Indications for Use and Intended Use

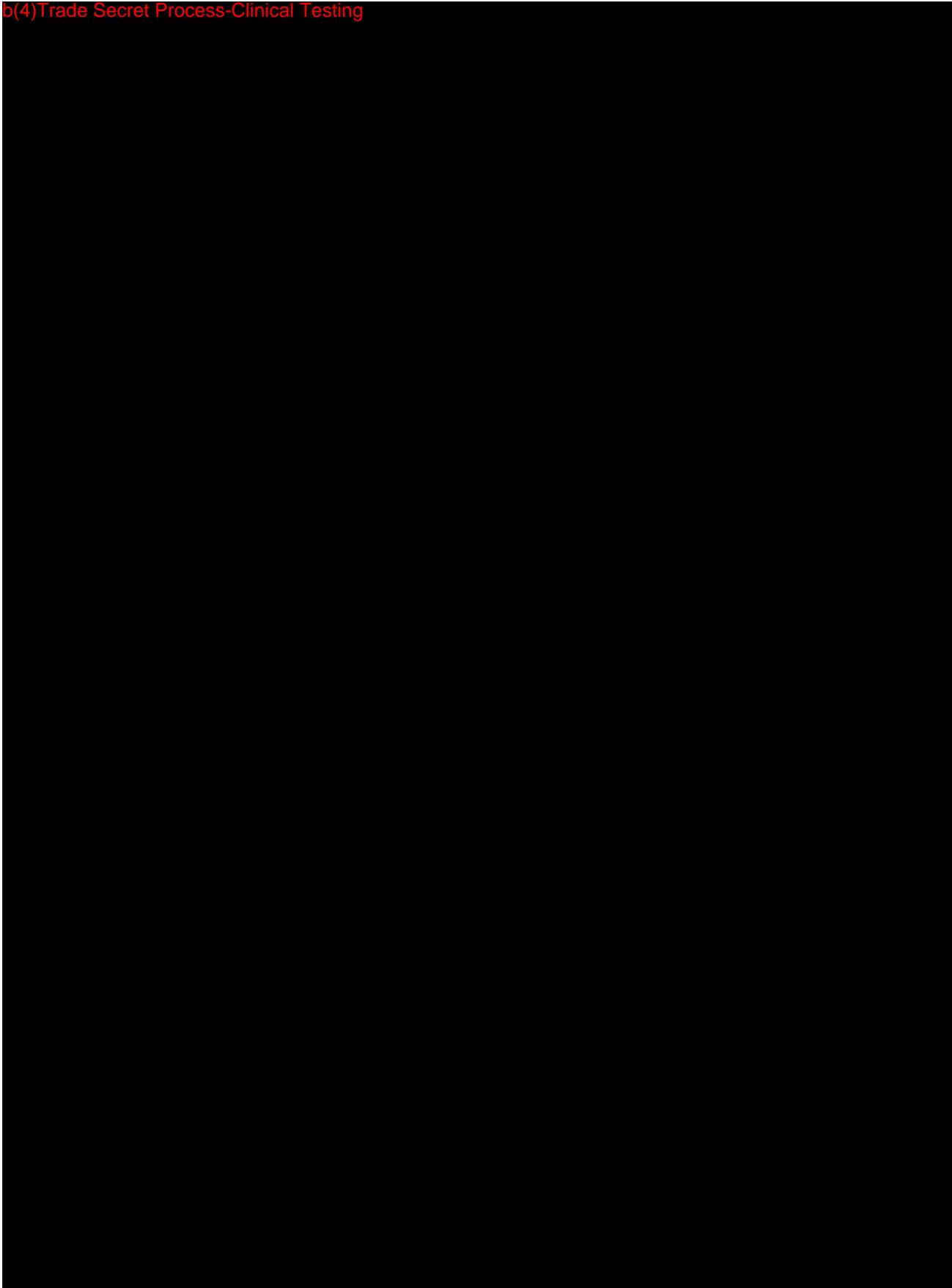
The HTTS is indicated for patients undergoing a tympanostomy procedure. The HTTS is intended to create a myringotomy incision and deliver a VT through the tympanic membrane of a patient.

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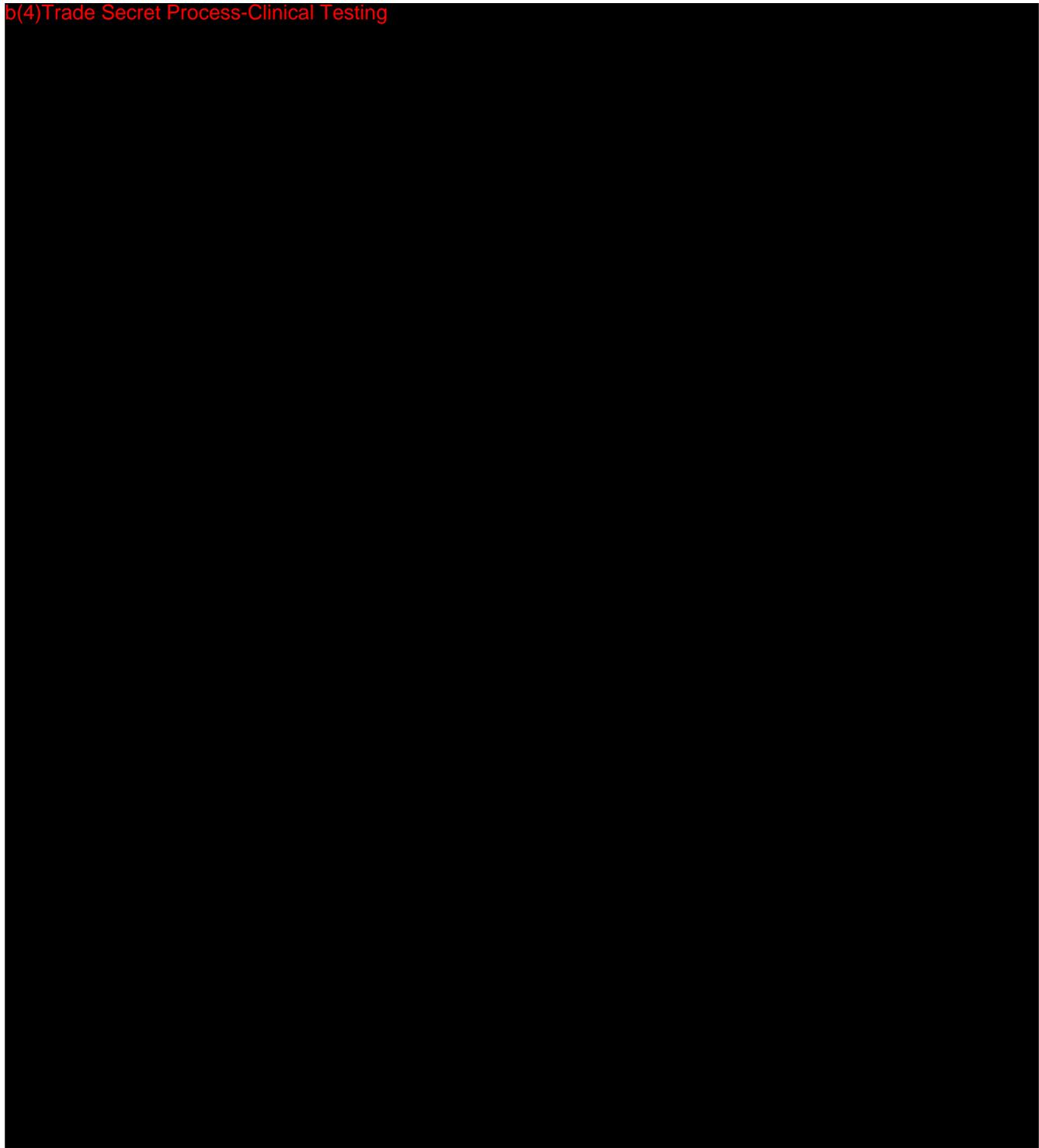
Appendix H1 Clinical Report – Hummingbird™ TTS

b(4)Trade Secret Process-Clinical Testing



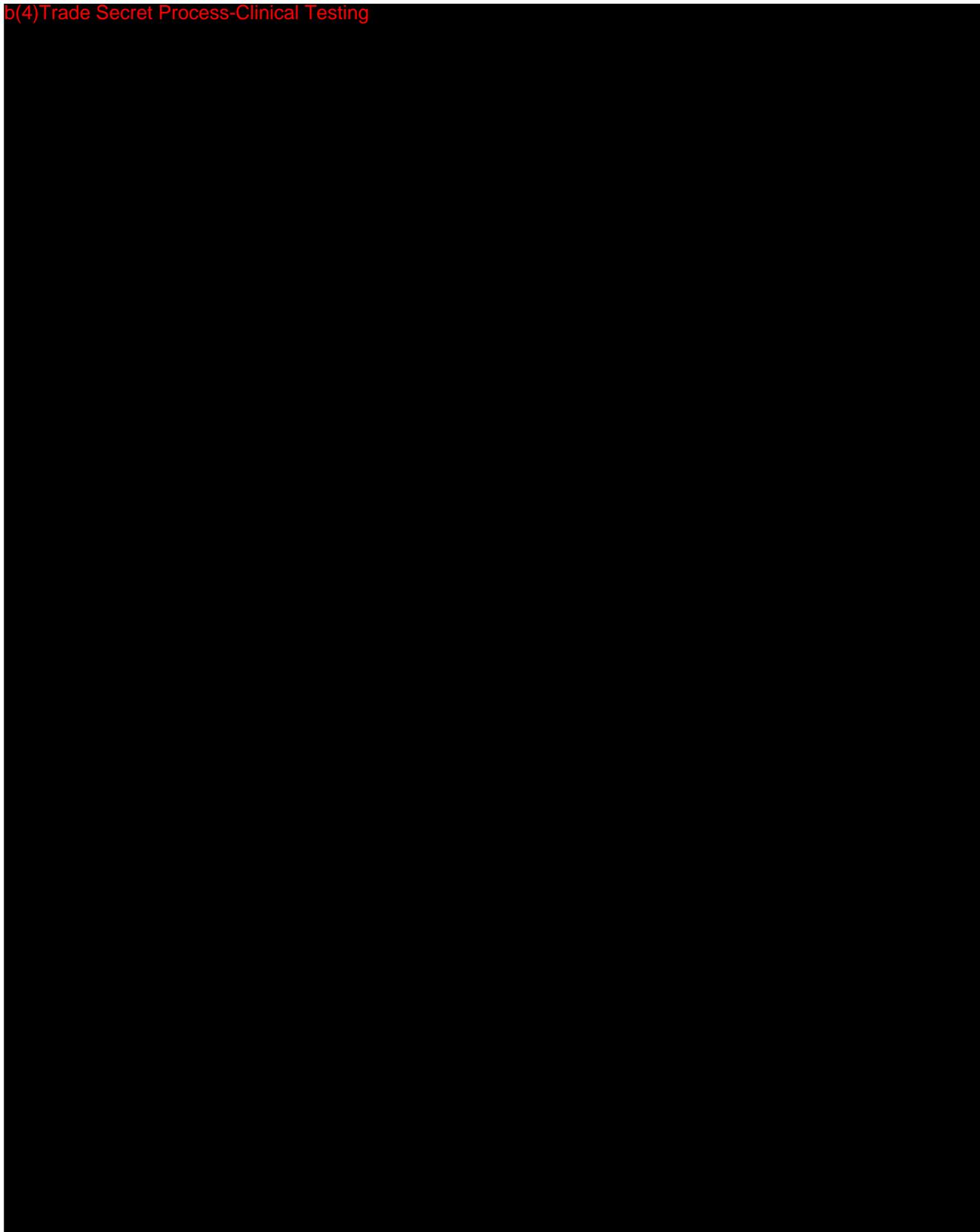
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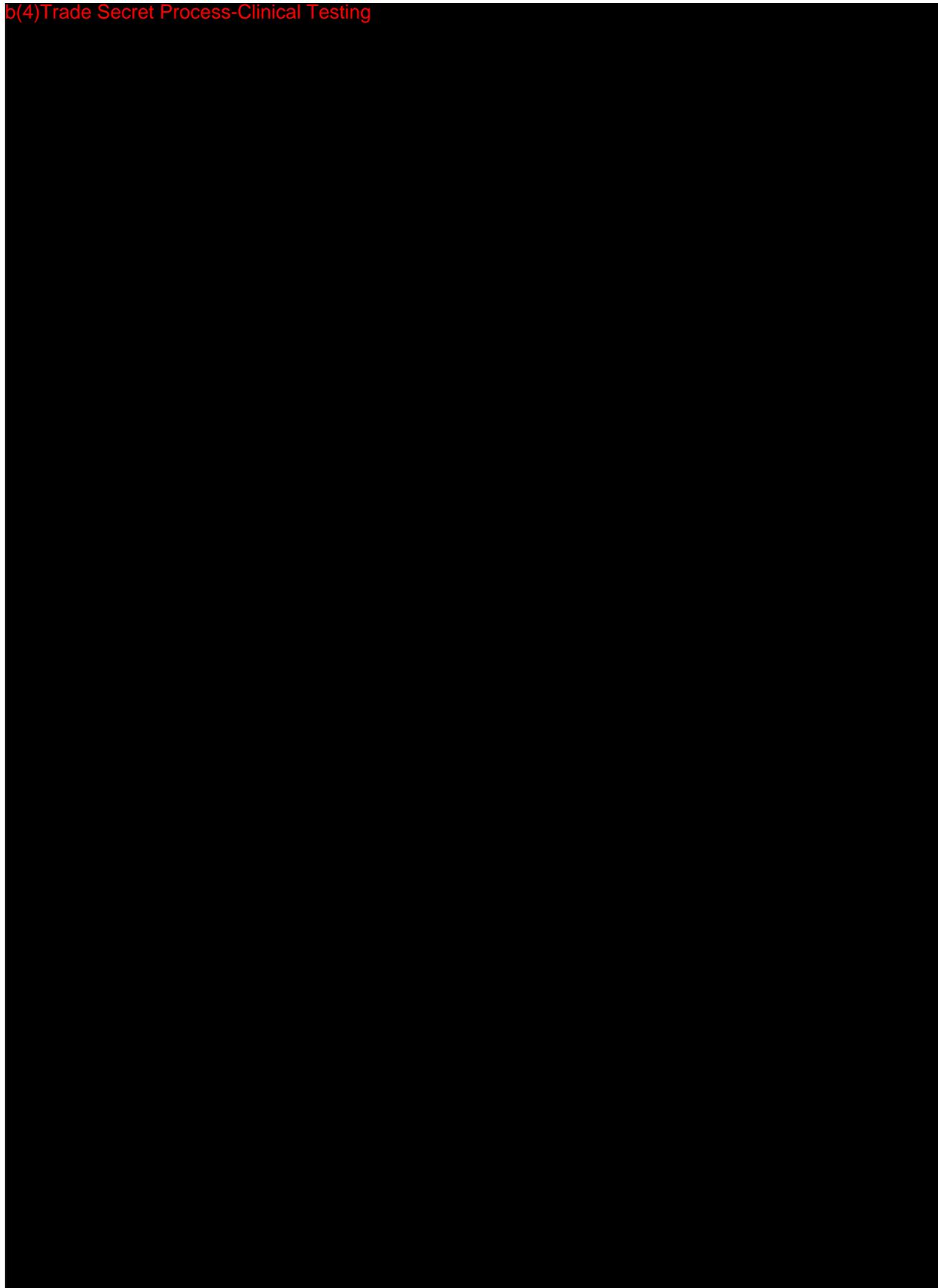
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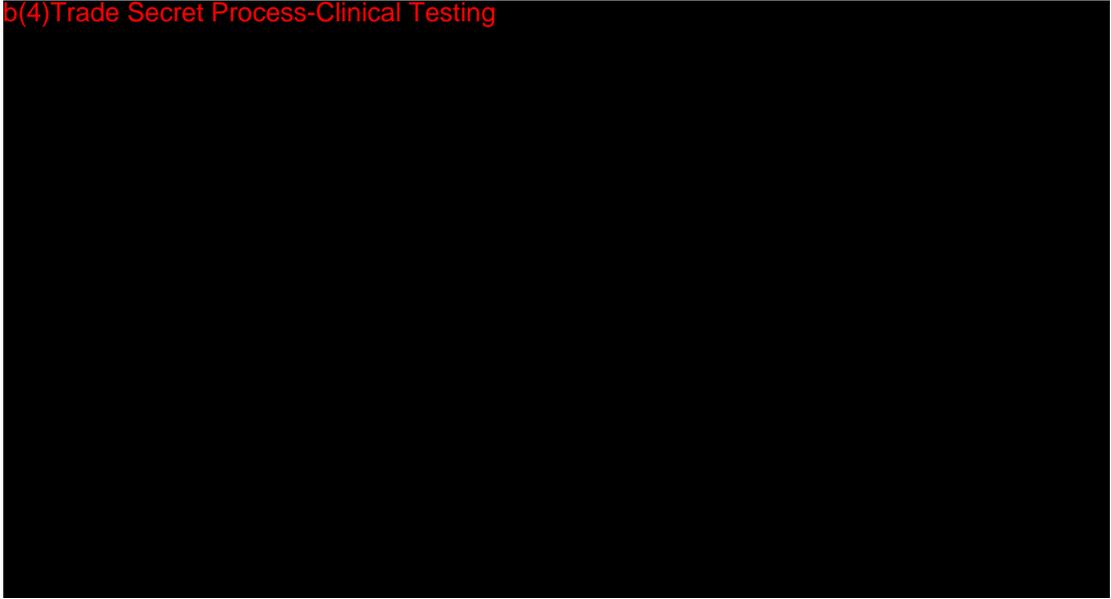
Table 1: Patient Age

Age (N=69)	Years
Mean	2.4
Median	1.7
Range	0.7 –8.9

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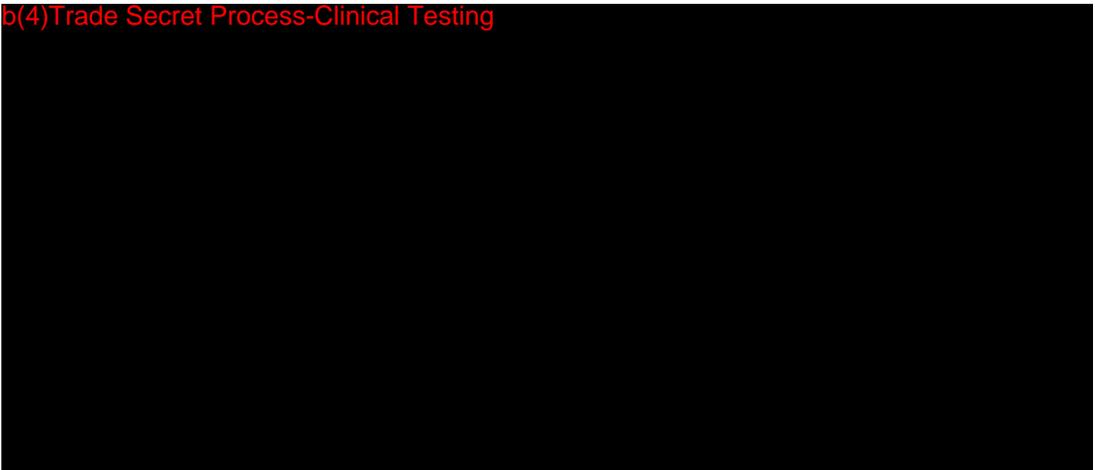
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12.3 Outcomes

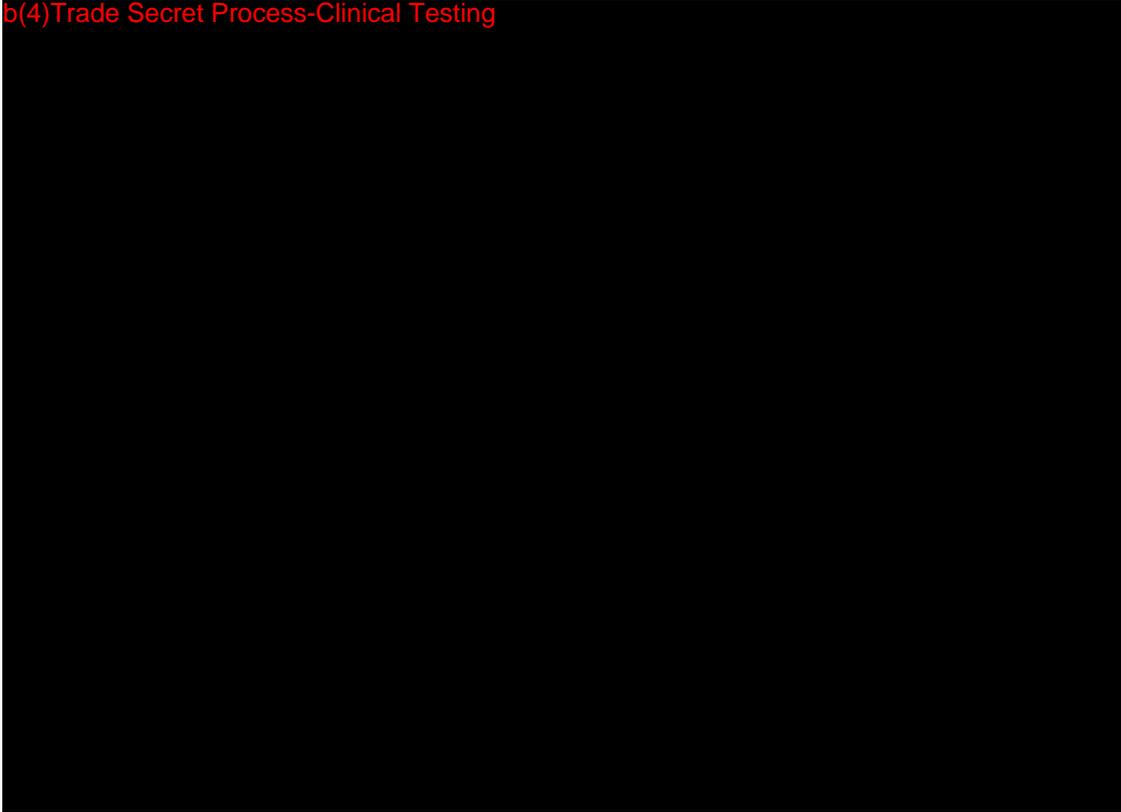
All 69 patients had successful procedures and received tubes as planned. Sixty-seven (67) had bilateral procedures, and two (2) patients had a unilateral procedure for a total of 136 ears treated. Fourteen patients (20% -- 12 Beta patients and 2 Alpha patients) were converted from moderate sedation to general anesthesia during the procedure. Conversion was accomplished by simply turning on the flow of sevoflurane to the mask already in place over a child's nose and mouth.

b(4)Trade Secret Process-Clinical Testing



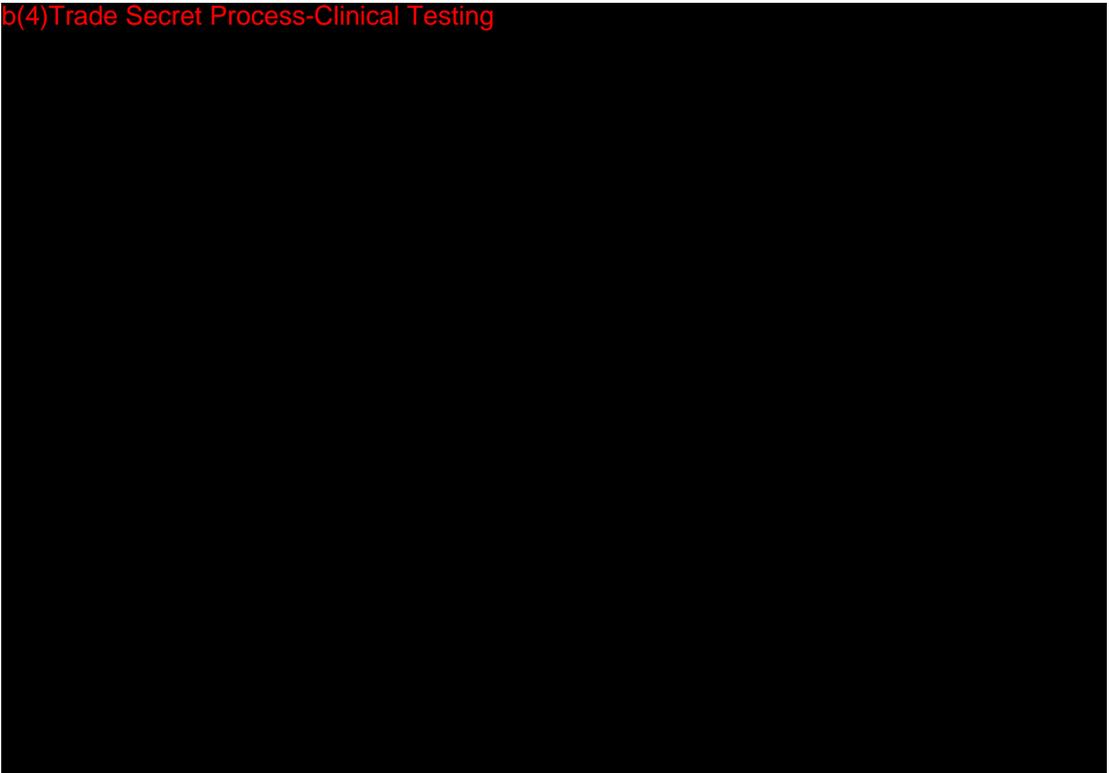
Appendix H1 Clinical Report – Hummingbird™ TTS

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12.4 HTTS Instruments and Procedure Time

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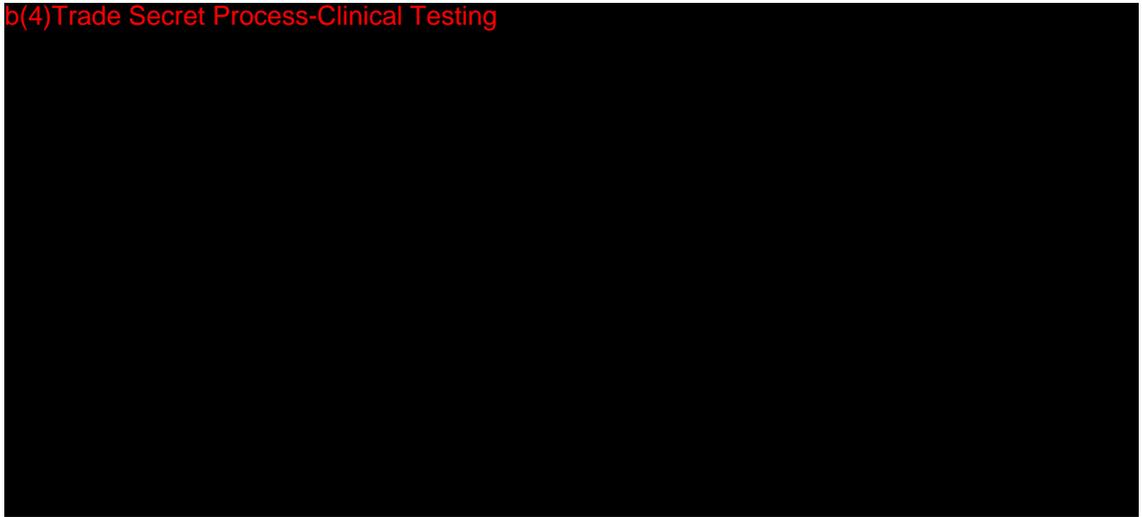


12.5 Adverse Events

Safety issues with using the HTTS to deliver tympanostomy tubes under moderate sedation would be identified intra-operatively. There were no intra-operative AE's.

The anticipated AE's for the study also included outcomes that are considered normal and expected within the standard of care for tympanostomy procedures, including otorrhea, chronic tube extrusion, and tube clogging. Preceptis and its investigators included these outcomes as AE's to be conservative when reporting results.

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12.5.3 Total AE Rates at 3-10 Weeks Follow-up

The rate of otorrhea was 4/136 ears (2.9%). The rate of occlusion was also 4/136 ears (2.9%). The rate of extrusion was 1/136 ears (0.7%). These rates are well within the range of rates reported in literature.

b(4)Trade Secret Process-Clinical Testing



Appendix H1 Clinical Report – Hummingbird™ TTS

b(4)Trade Secret Process-Clinical Testing



12.5.5 Conclusion

There were no intra-operative AEs. All AEs were anticipated, and none were serious or device-related. Therefore, these results unequivocally demonstrate that the safety profile of the HTTS when used under moderate sedation in children is safe and acceptable.

13.0 SUMMARY

The Preceptis HTTS is a disposable tool designed to create a myringotomy incision and place a VT across the tympanic membrane in one surgical pass, thereby reducing surgical trauma for the patient. Preceptis Medical, Inc. conducted prospective, treatment-only multicenter clinical studies to evaluate the performance and the safety of the HTTS. A total of 136 ears indicated for VT insertion were treated in 69 patients under moderate sedation by 3 investigators at 3 study sites.

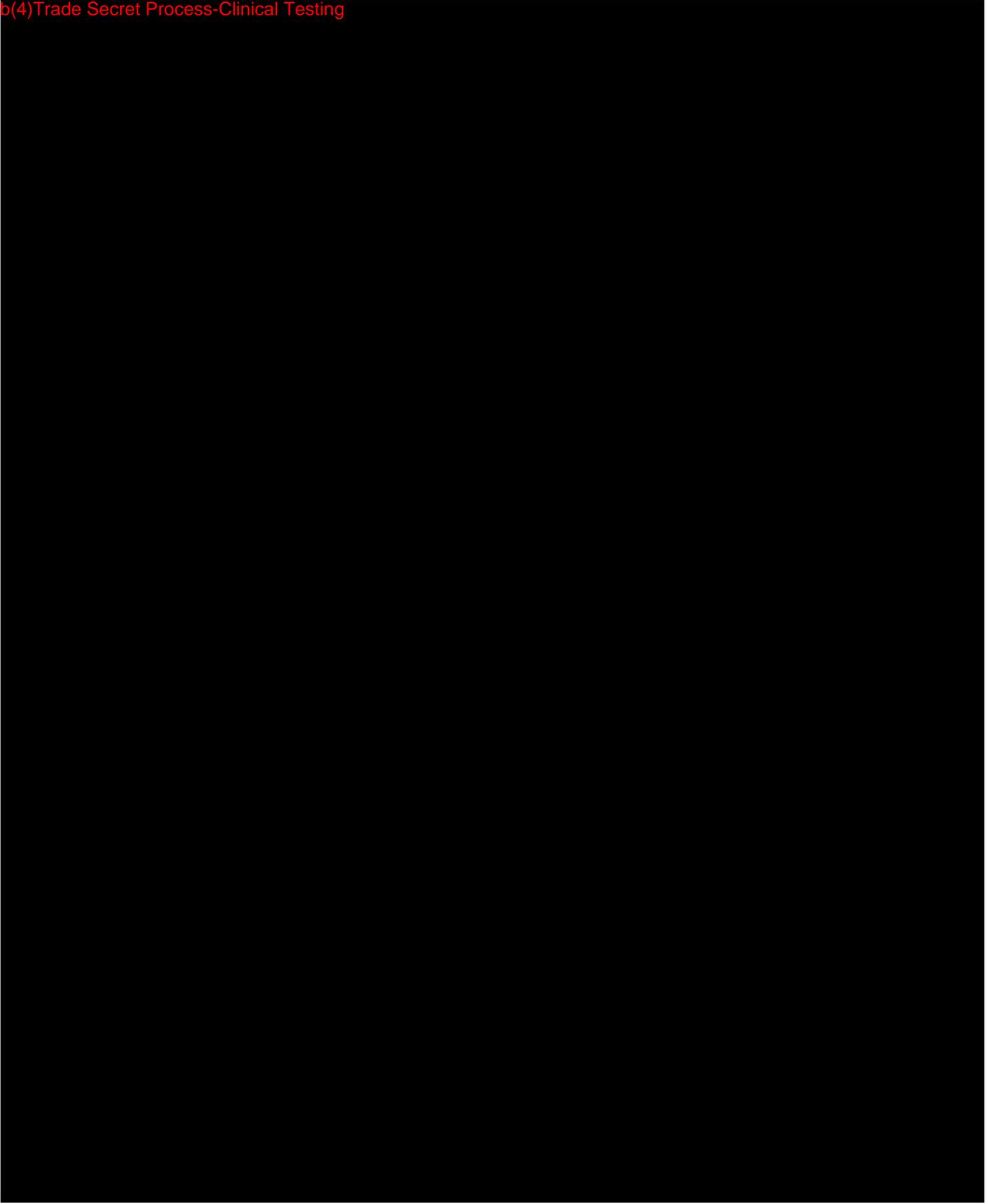
The success rate in performing the tympanostomy procedures was 100% (i.e., all patients received tubes as planned). There were no intra-operative AEs. The rate of AEs at the first follow-up visit was within normal rates. Additionally, an independent otolaryngologist reviewed all Beta results and determined that there were no safety issues associated with the HTTS. The HTTS met the study safety and performance criteria. As a result, the HTTS provides a potential option for otolaryngologists and anesthesiologists to safely perform tympanostomy procedures in children without incurring the risk of general anesthesia.

Appendix H1 Clinical Report – Hummingbird™ TTS

ATTACHMENT A CONSENT DOCUMENTS

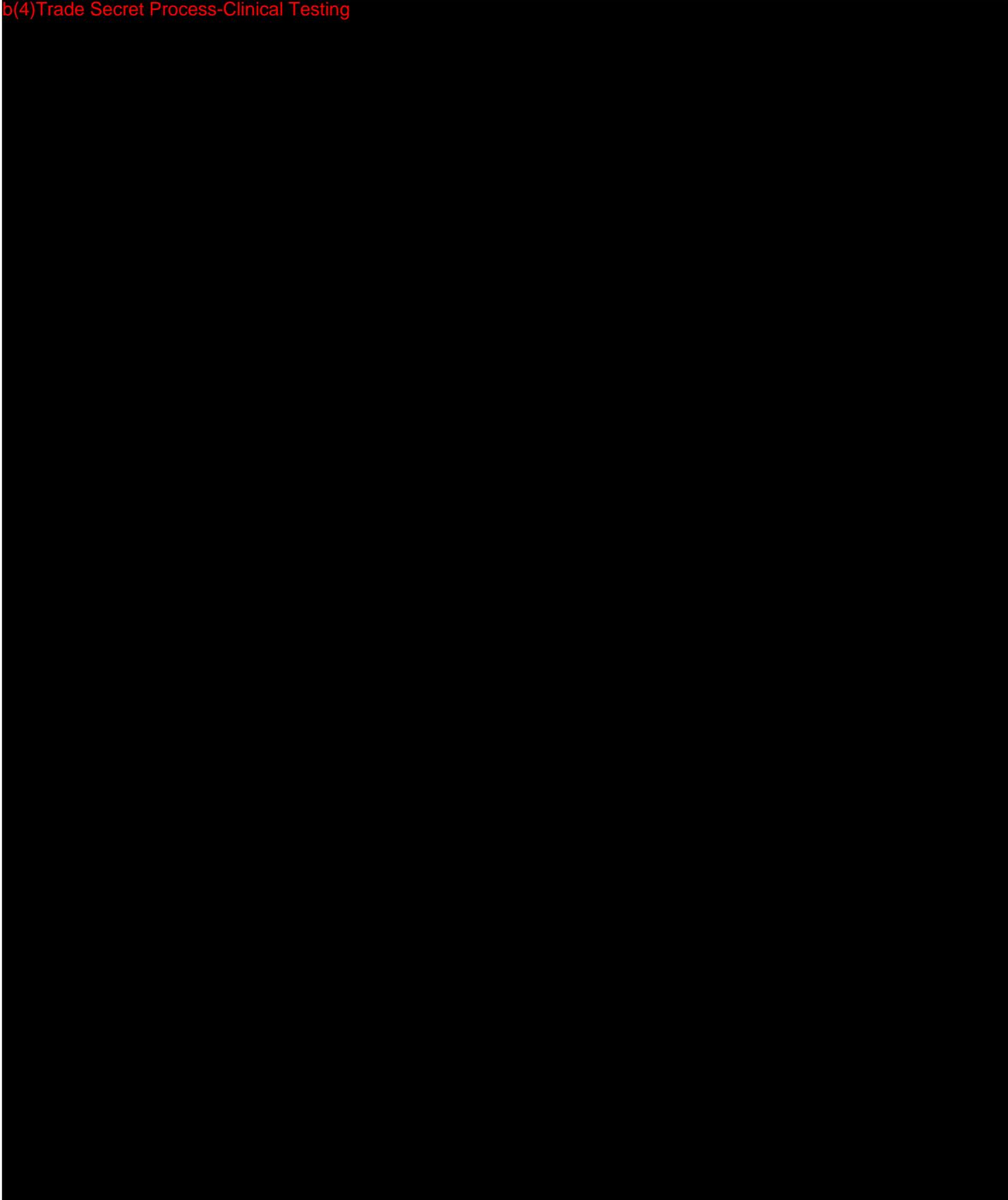
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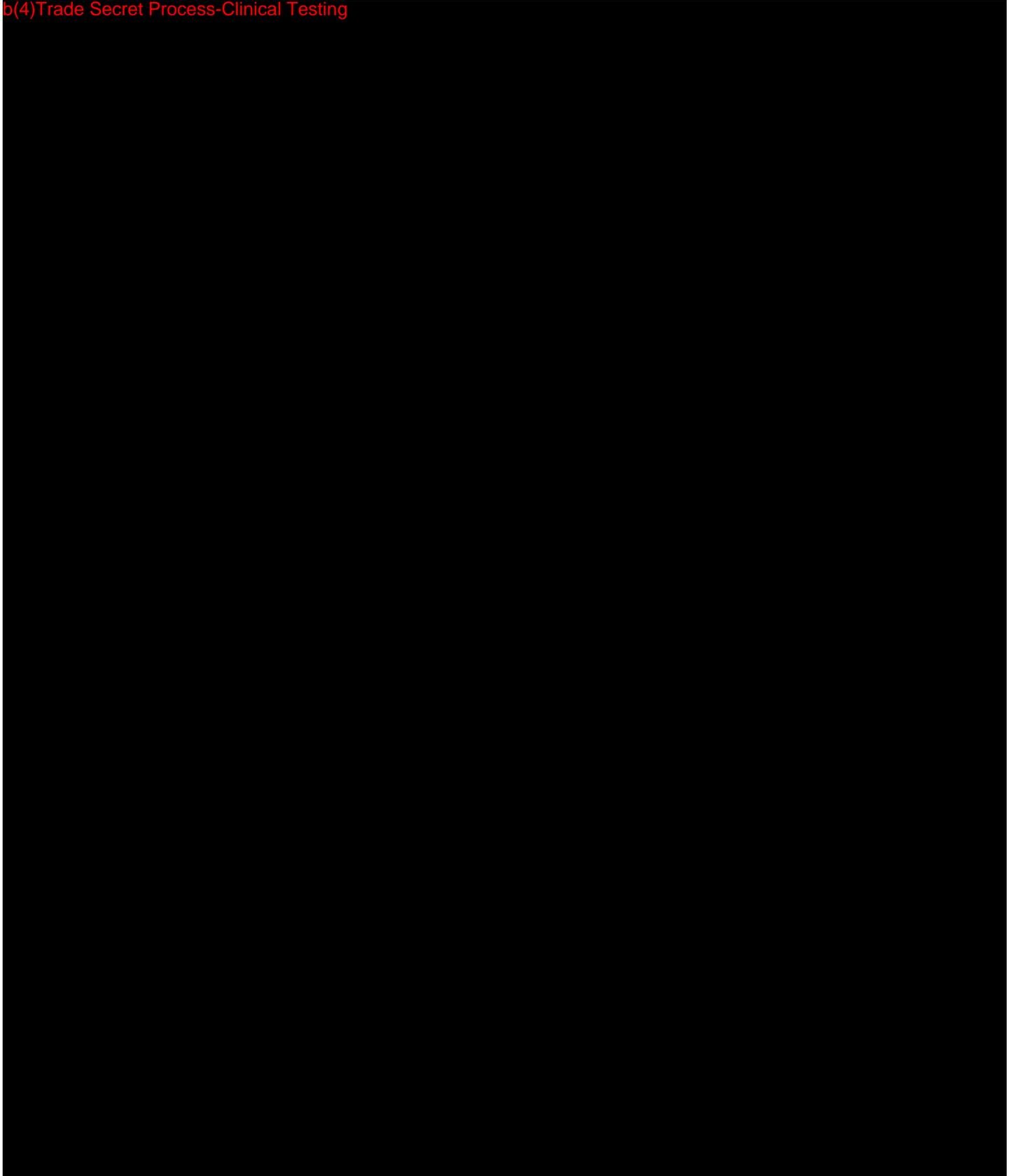
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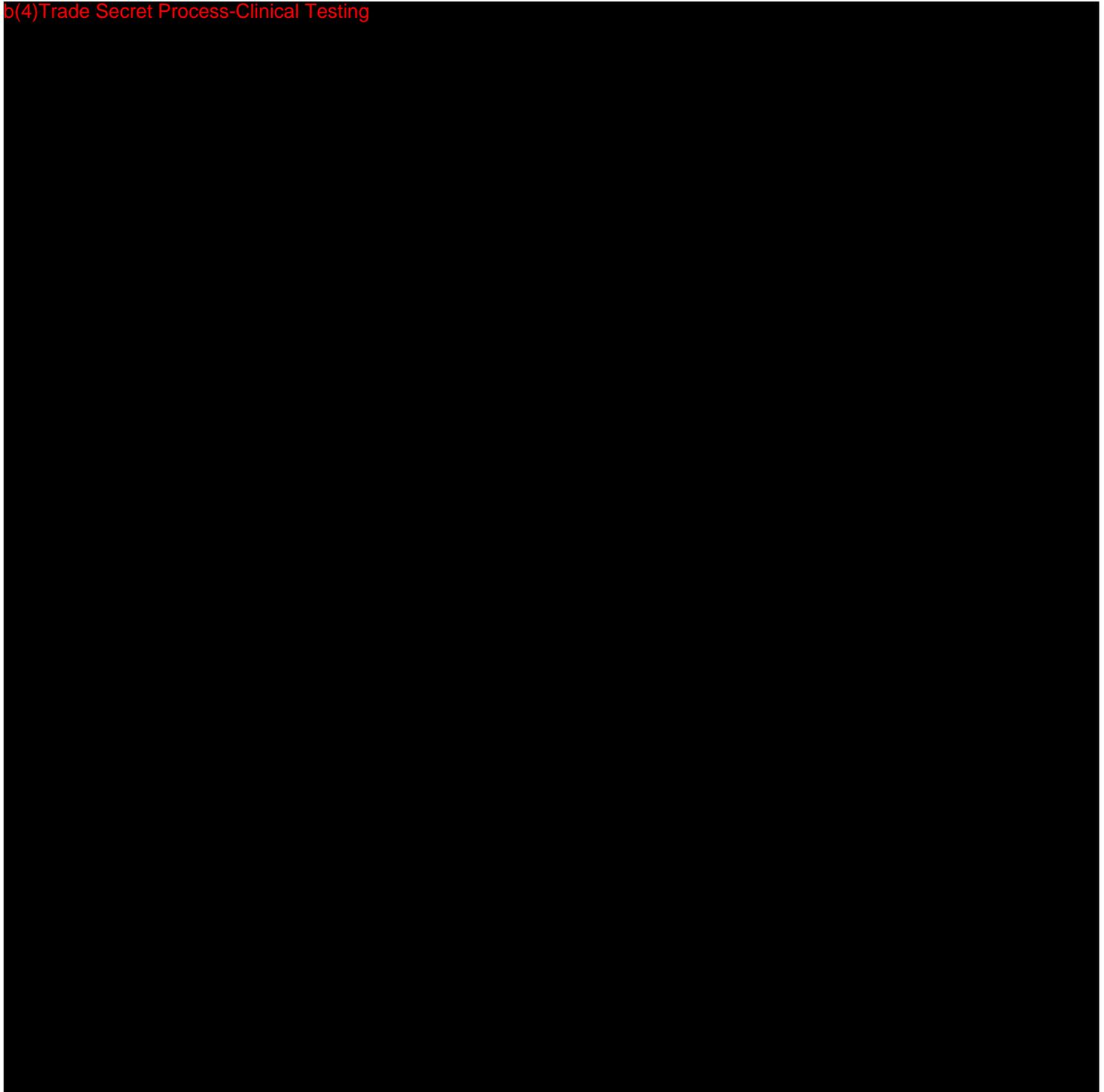
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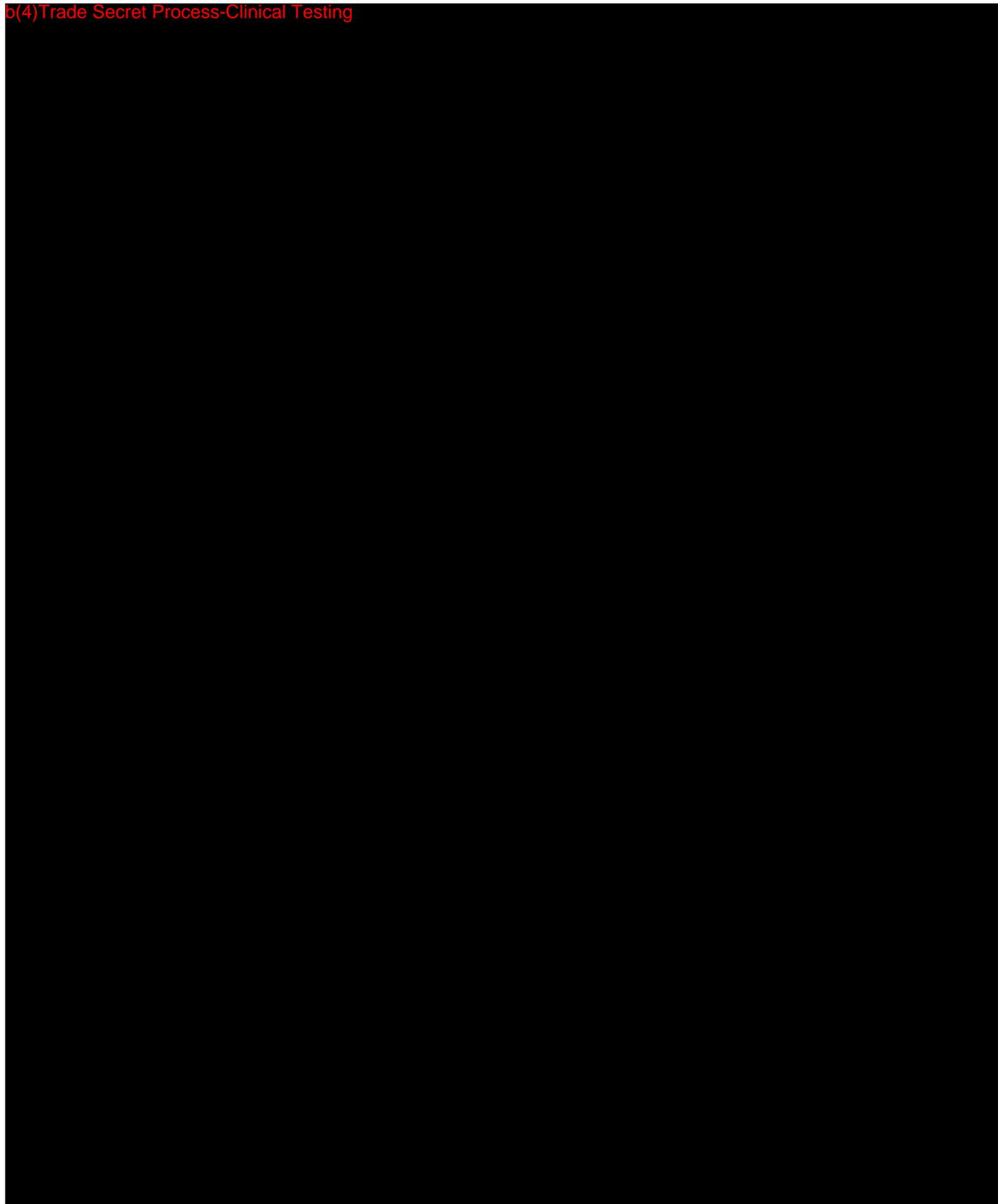
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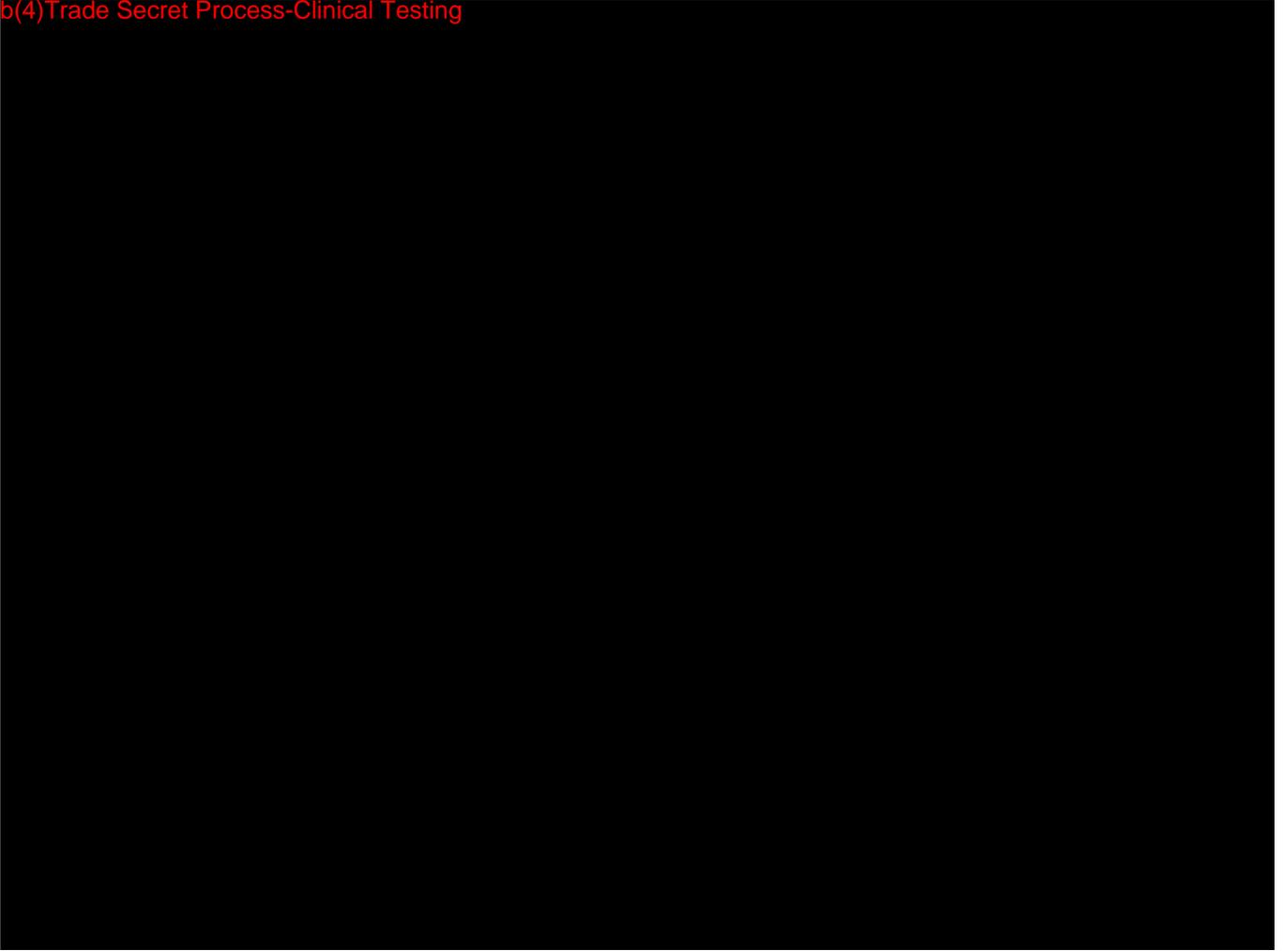
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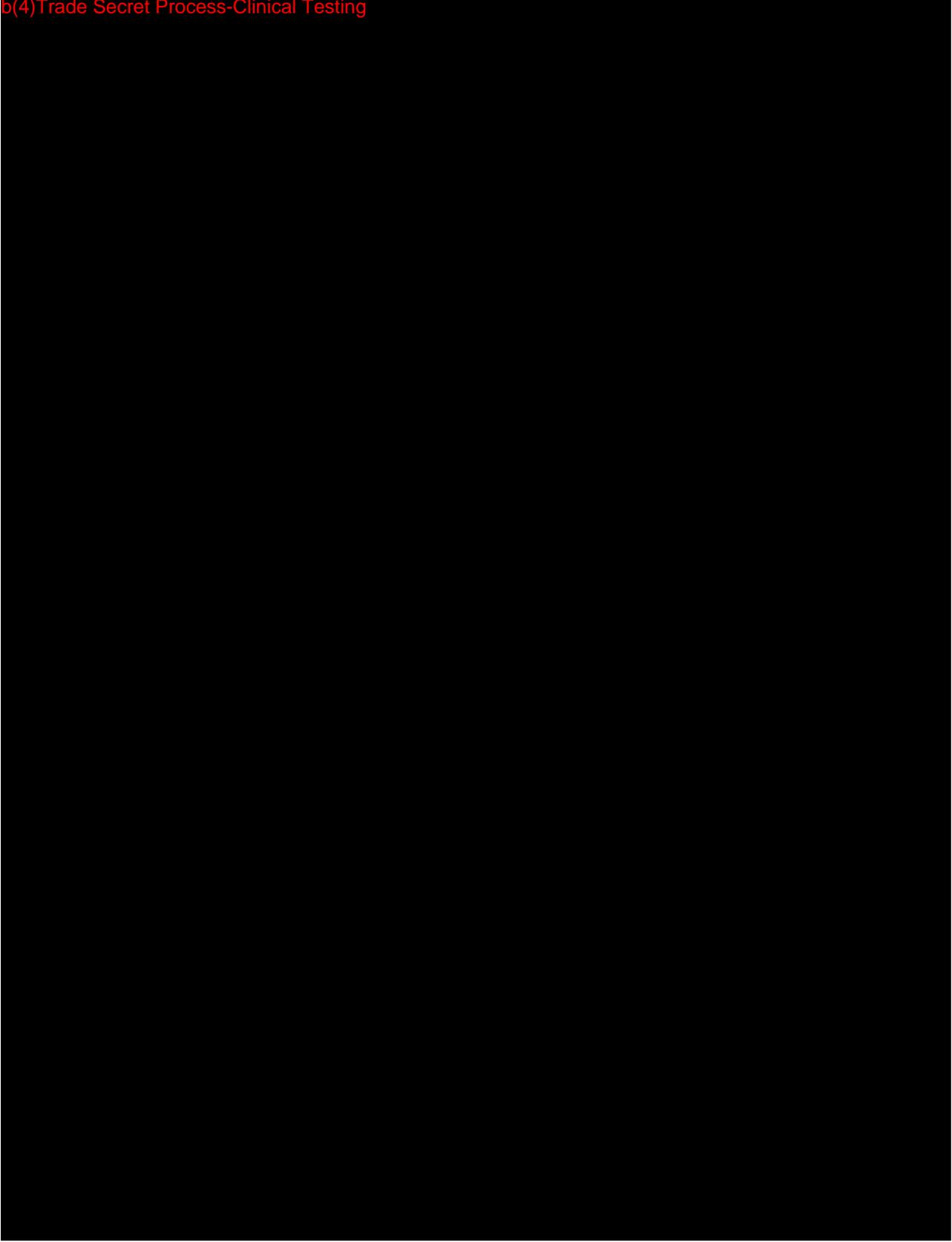
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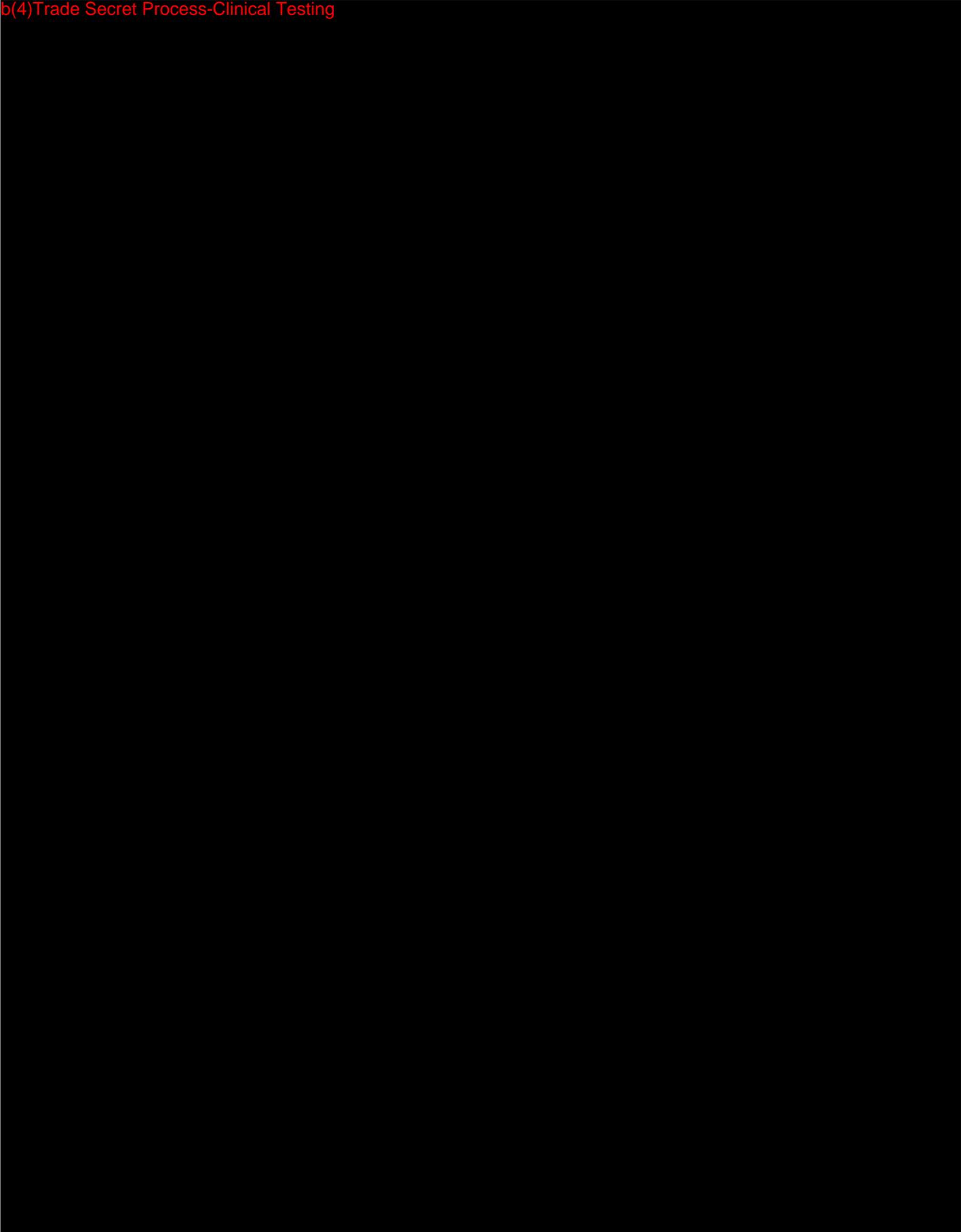
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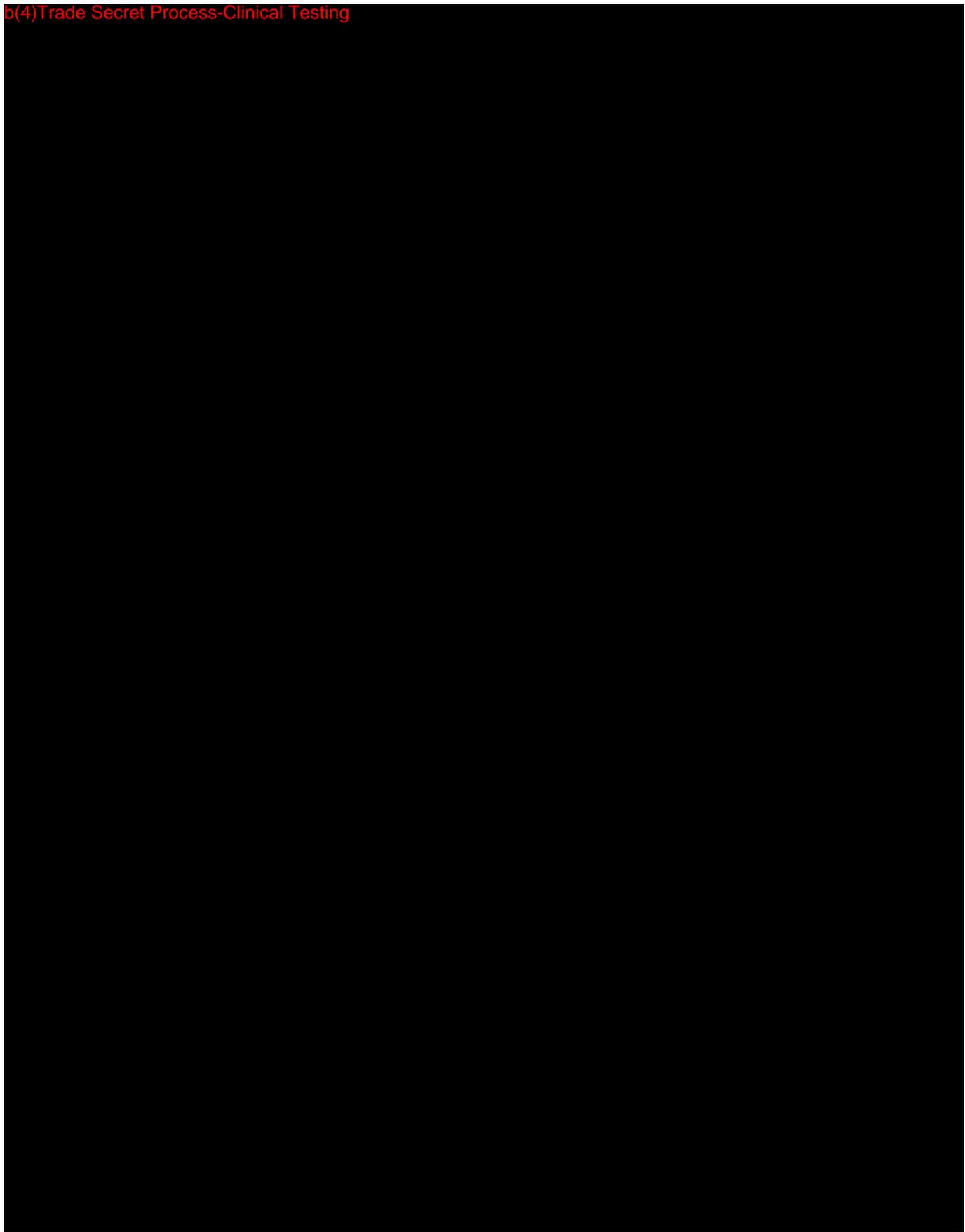
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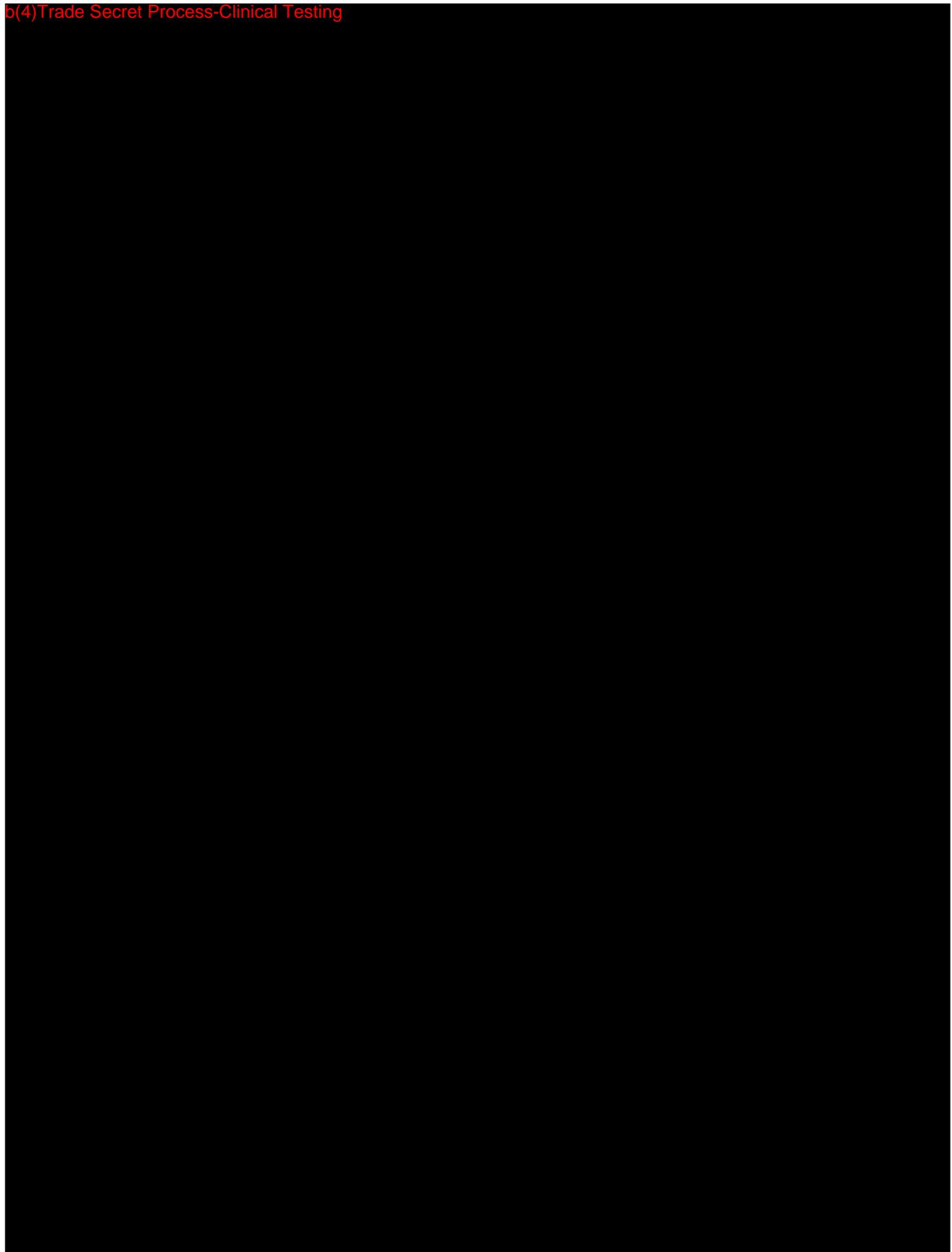
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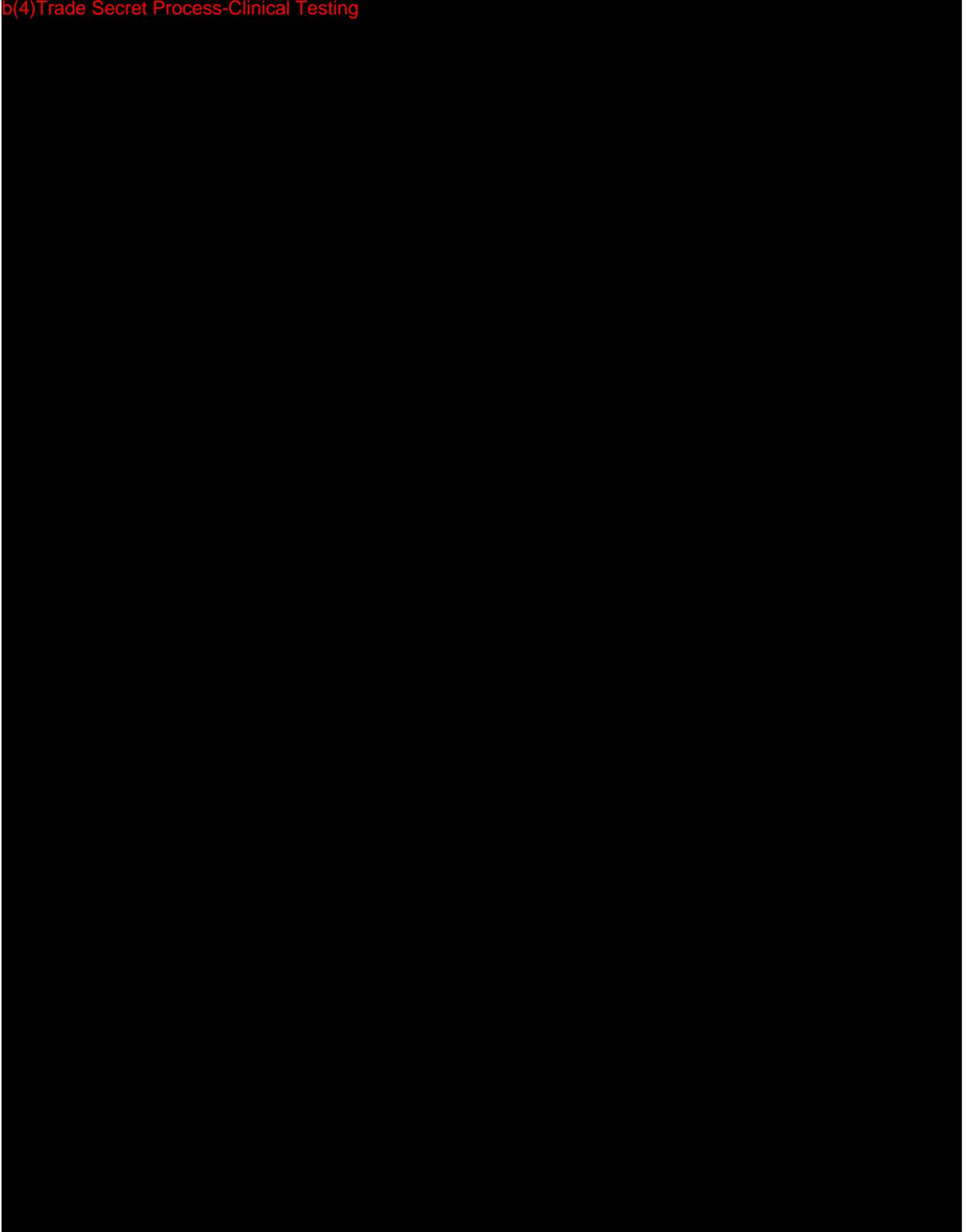
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Appendix H1 Clinical Report – Hummingbird™ TTS

ATTACHMENT B REPORTABLE ANTICIPATED ADVERSE EVENTS

Appendix H1 Clinical Report – Hummingbird™ TTS

Appendix H1 Clinical Report – Hummingbird™ TTS

REPORTABLE ANTICIPATED ADVERSE EVENTS

Anticipated AE	Definition
Otorrhea	Fluid discharge from the middle ear.
Acute tube extrusion	During the surgical procedure, a myringotomy incision is completed but the TT will not stay in the tympanic membrane.
Chronic tube extrusion	At the follow-up visit, the tube is no longer in place in the tympanic membrane.
Tube dislocating into middle ear space	Tube passes completely through the tympanic membrane and falls into the middle ear cavity.
Tube clogging	Tube becomes clogged and fails to provide ventilation and drainage.
Bleeding	Bleeding in the ear canal, tympanic membrane, or the middle ear.
Vertigo	The patient experiences dizziness beyond 72 hours post-surgically.
Nausea	The patient experiences nausea and/or vomiting beyond 72 hours post-surgically.
Infection	Patient has fever ≥ 101 F beyond 24 hours post-surgically.
Hearing loss	Hearing loss ≥ 15 dB compared to baseline result in Pure Tone Average (PTA).
Facial nerve injury	Any weakness in face or altered perception of taste beyond 24 hours post-surgically.

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JAN 09 2015

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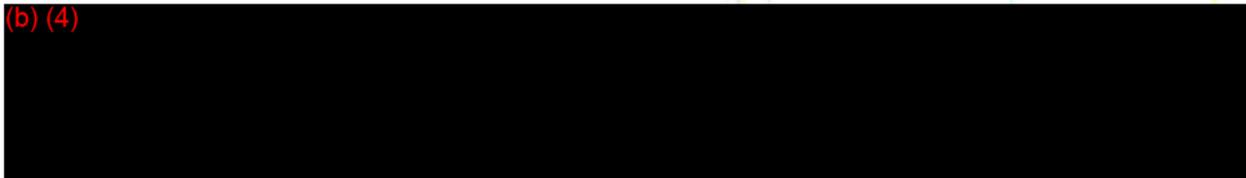
8 January 2015

William Maisel, M.D.
Acting Director, Office of Device Evaluation (ODE), and
Deputy Director for Science and Chief Scientist
Food & Drug Administration
Center for Devices and Radiological Health
Office of In Vitro Device Evaluation and Safety
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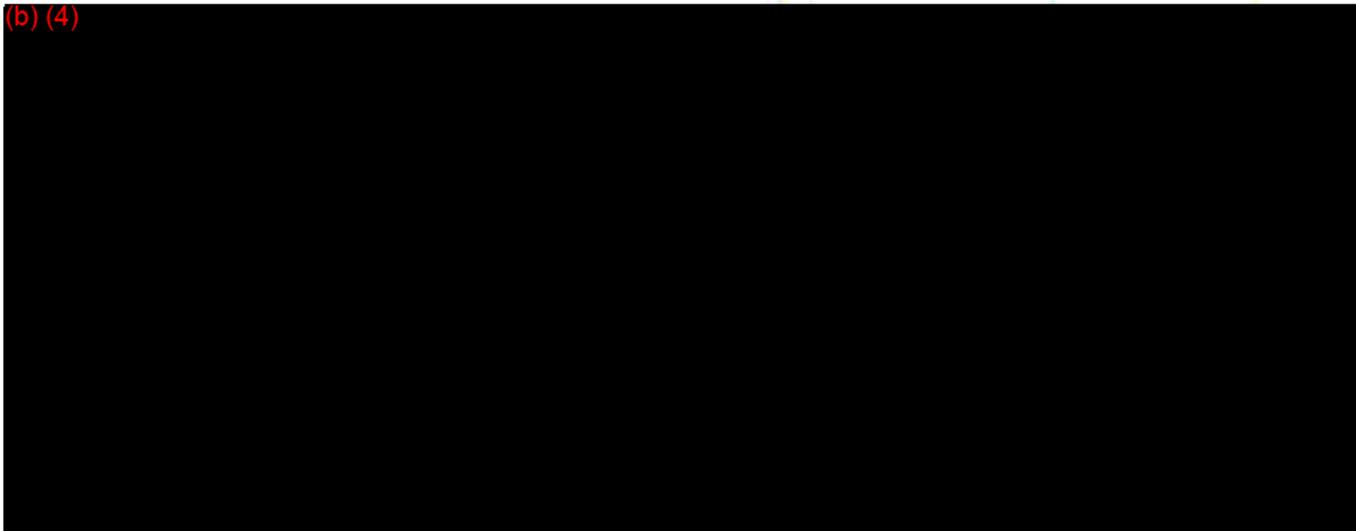
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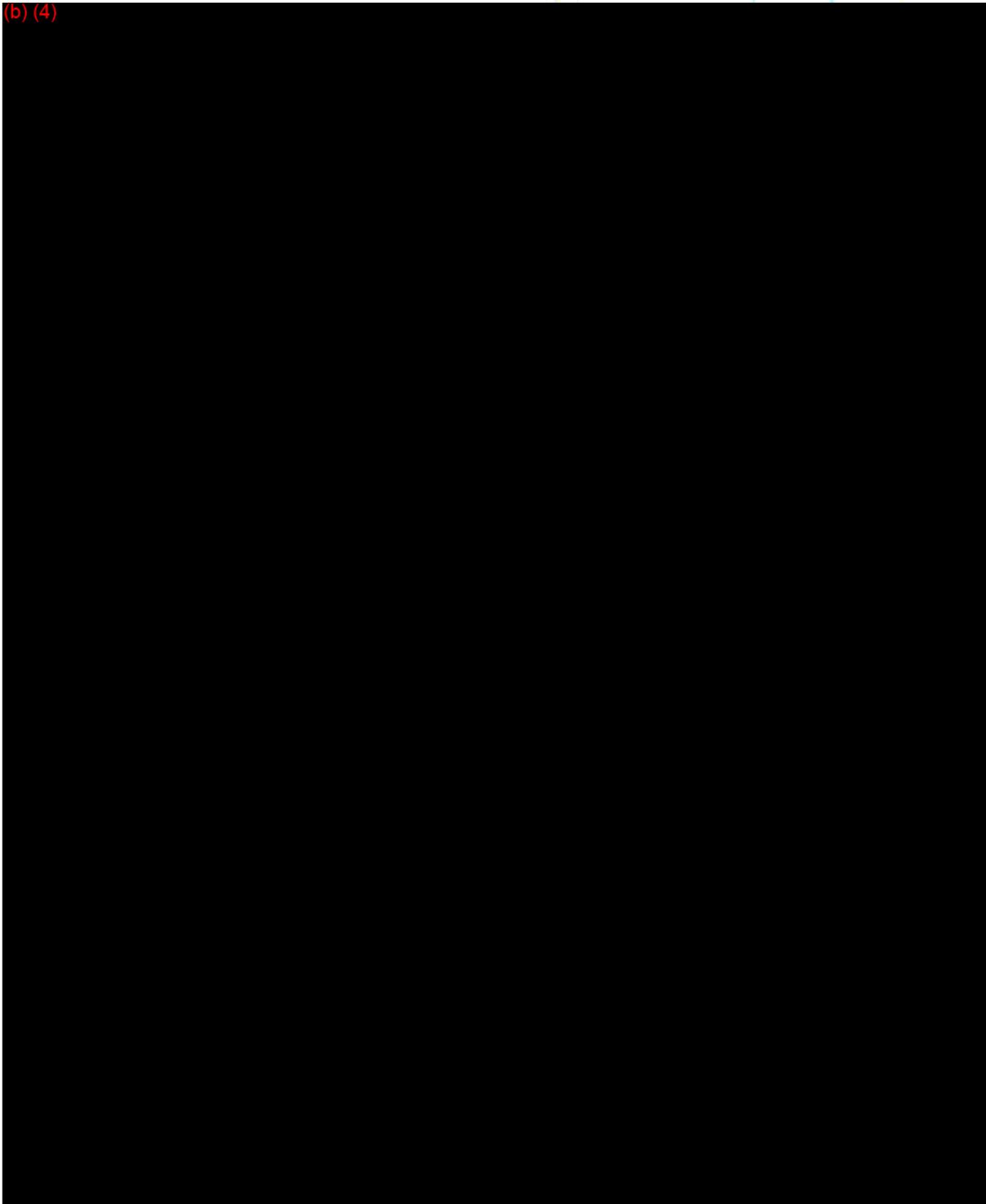
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INTRODUCTION/EXECUTIVE SUMMARY

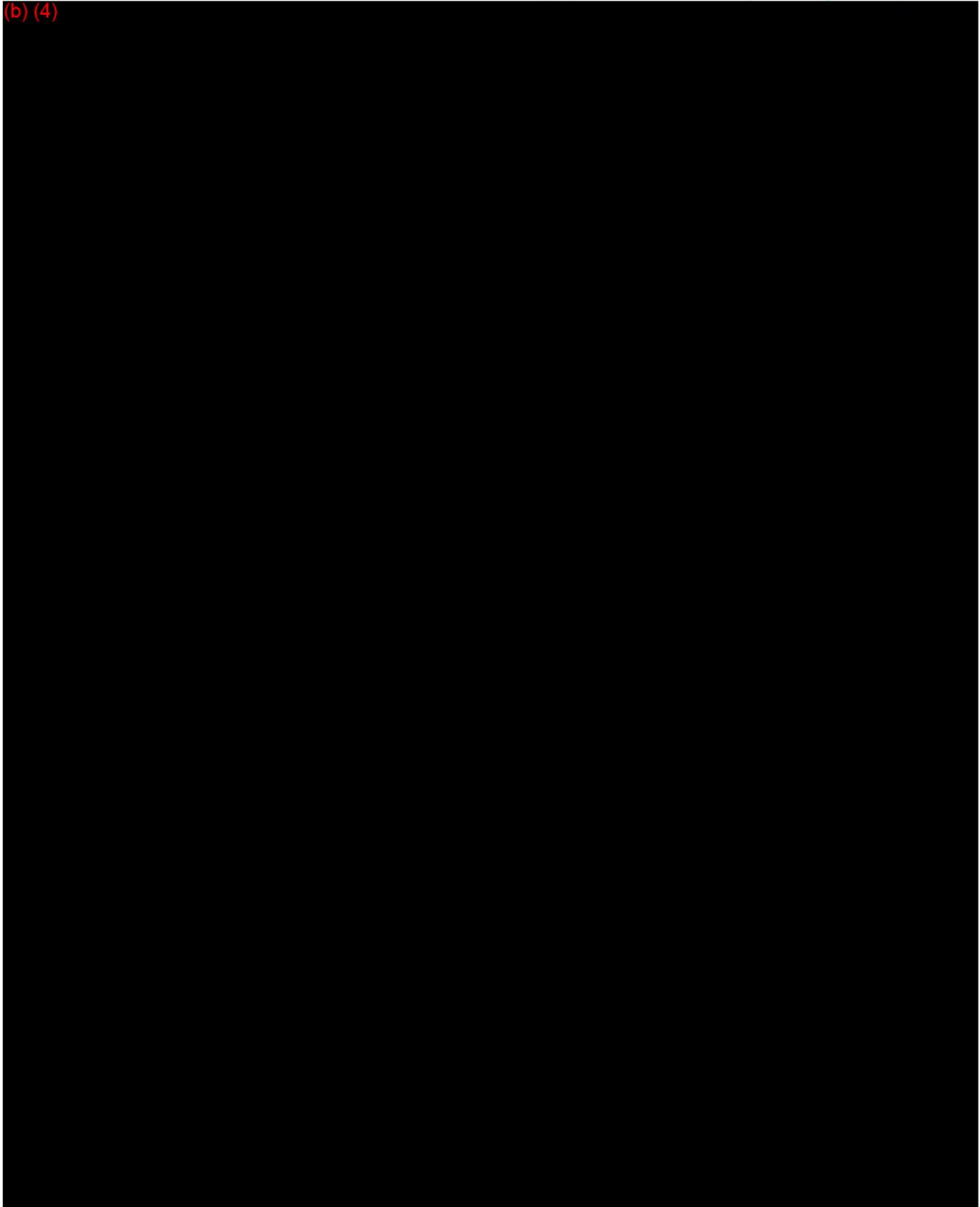
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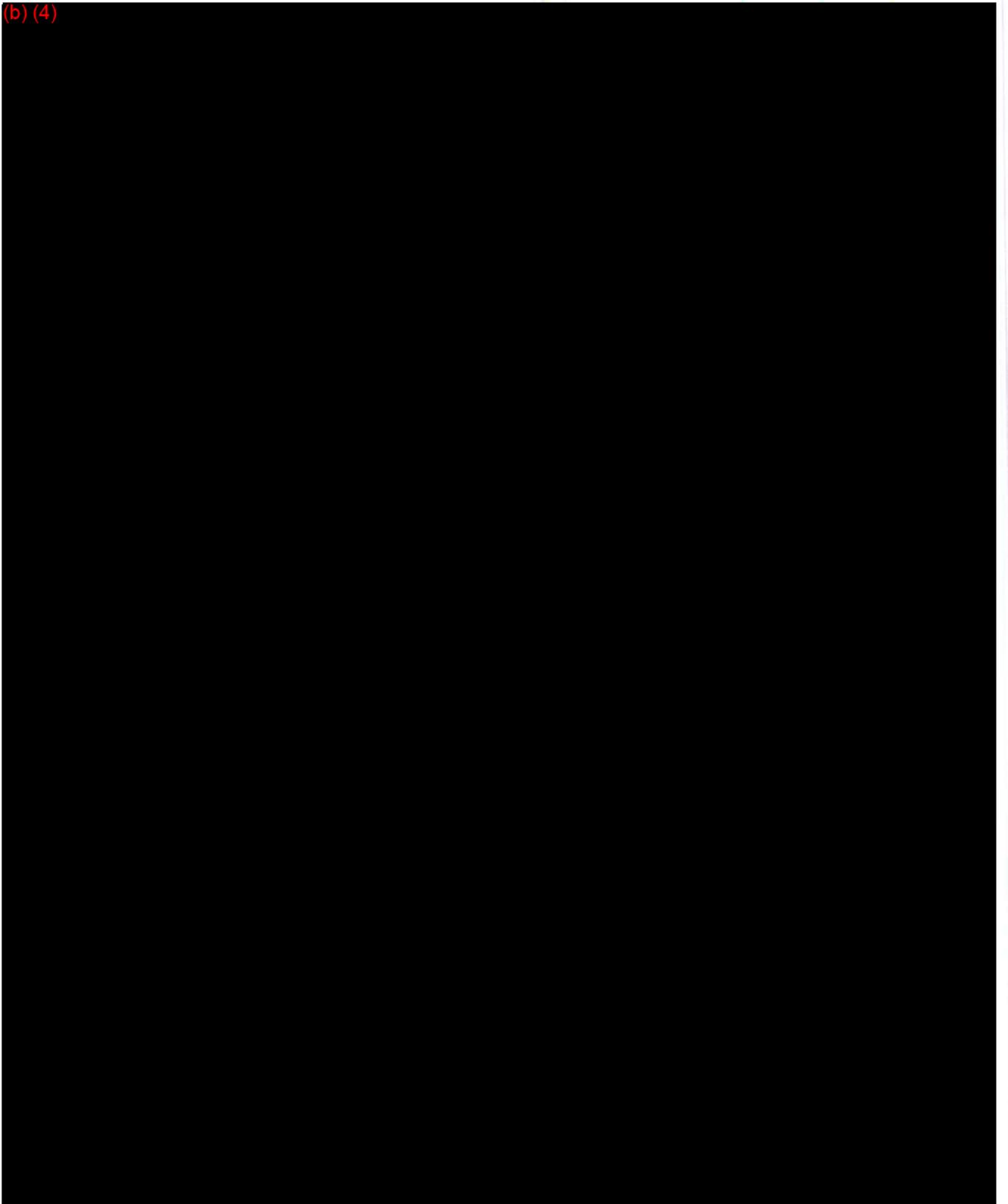
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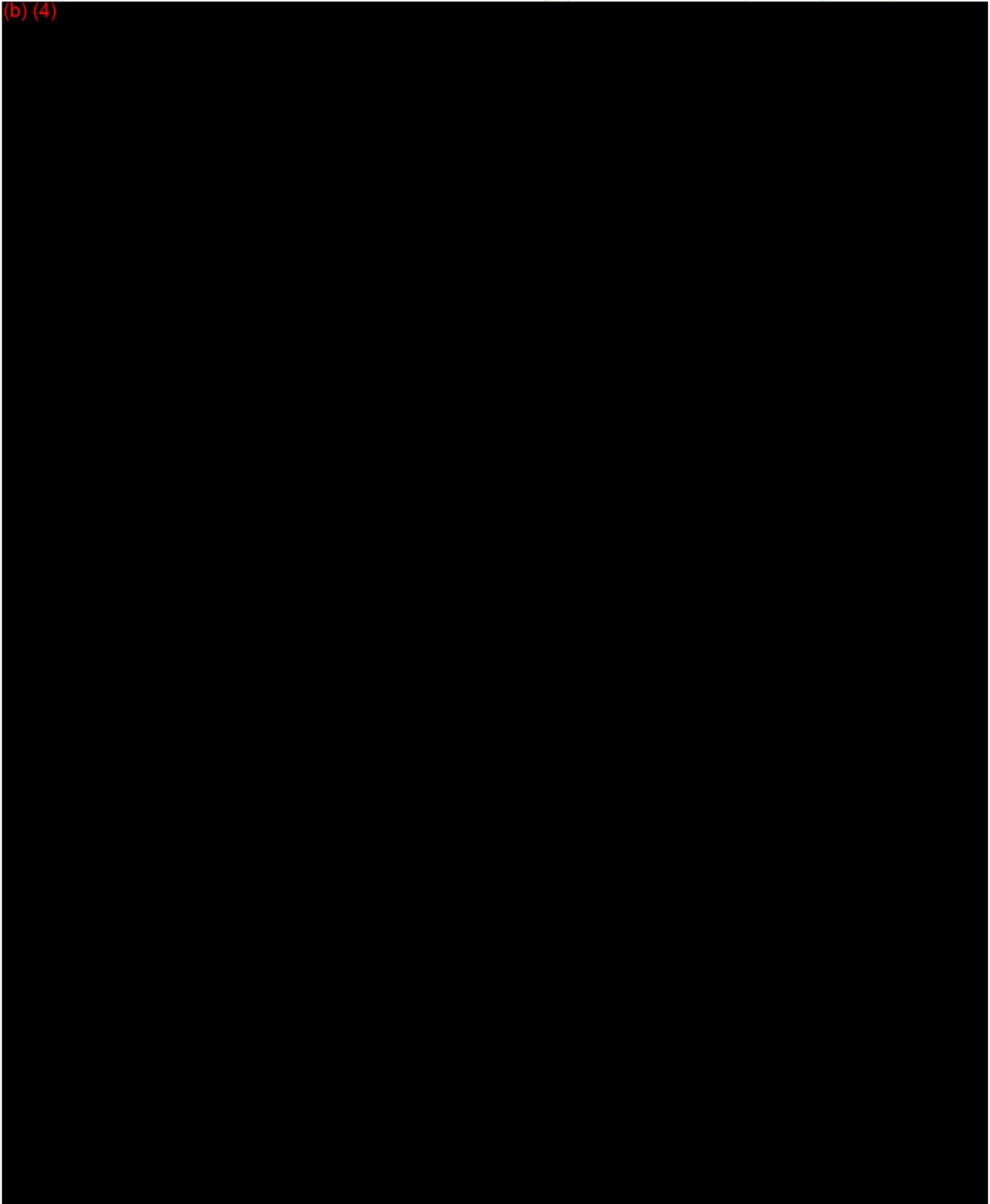
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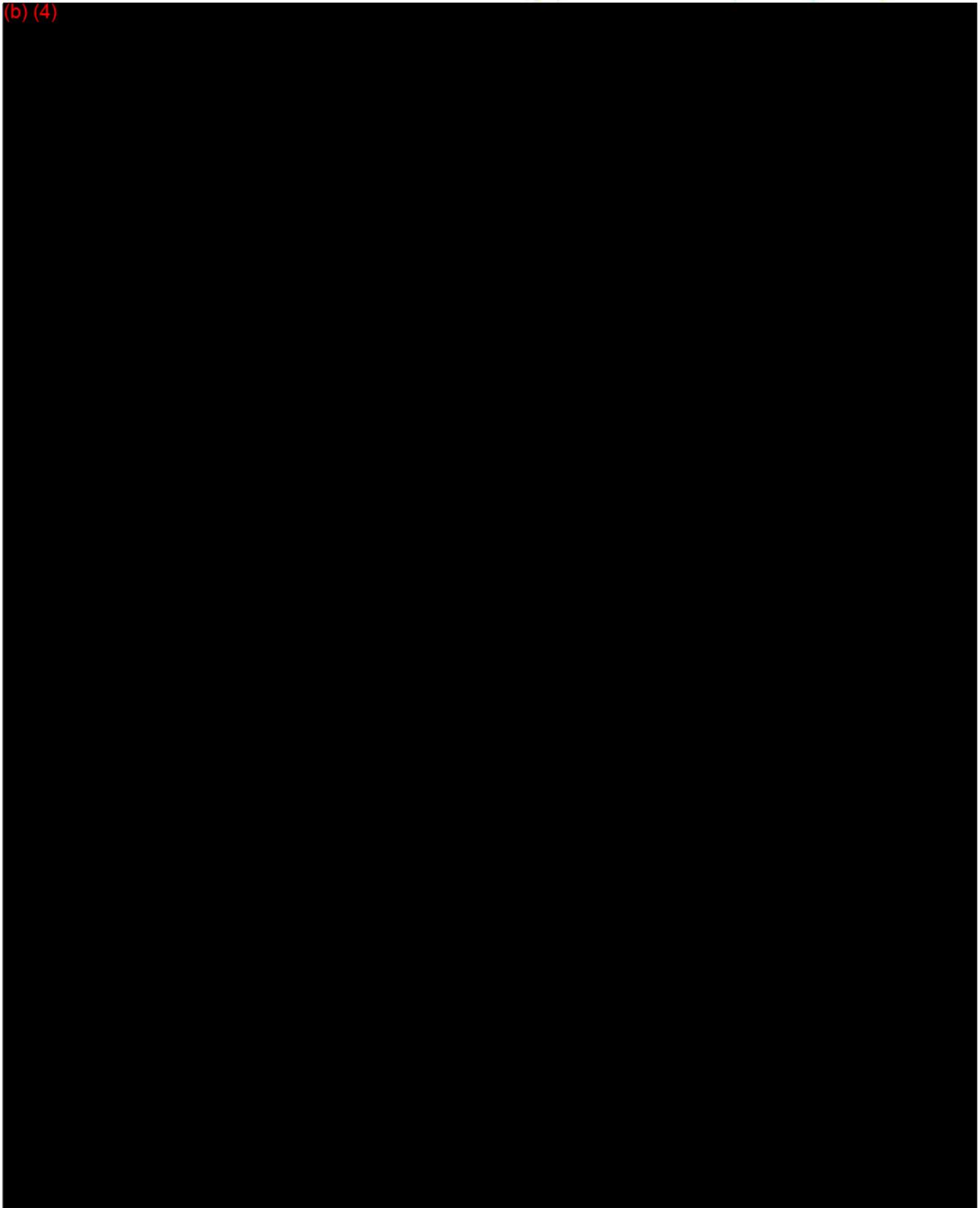
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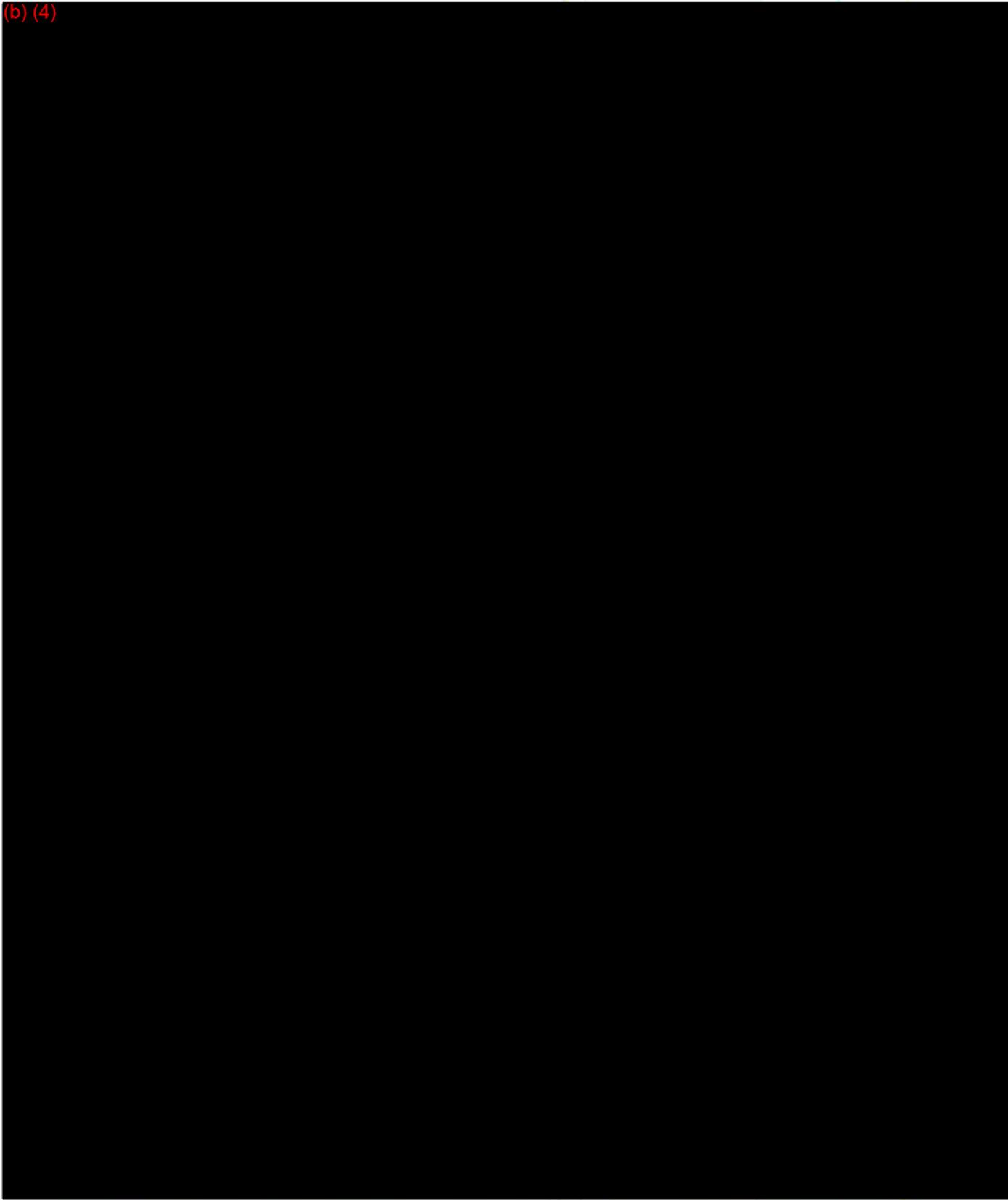
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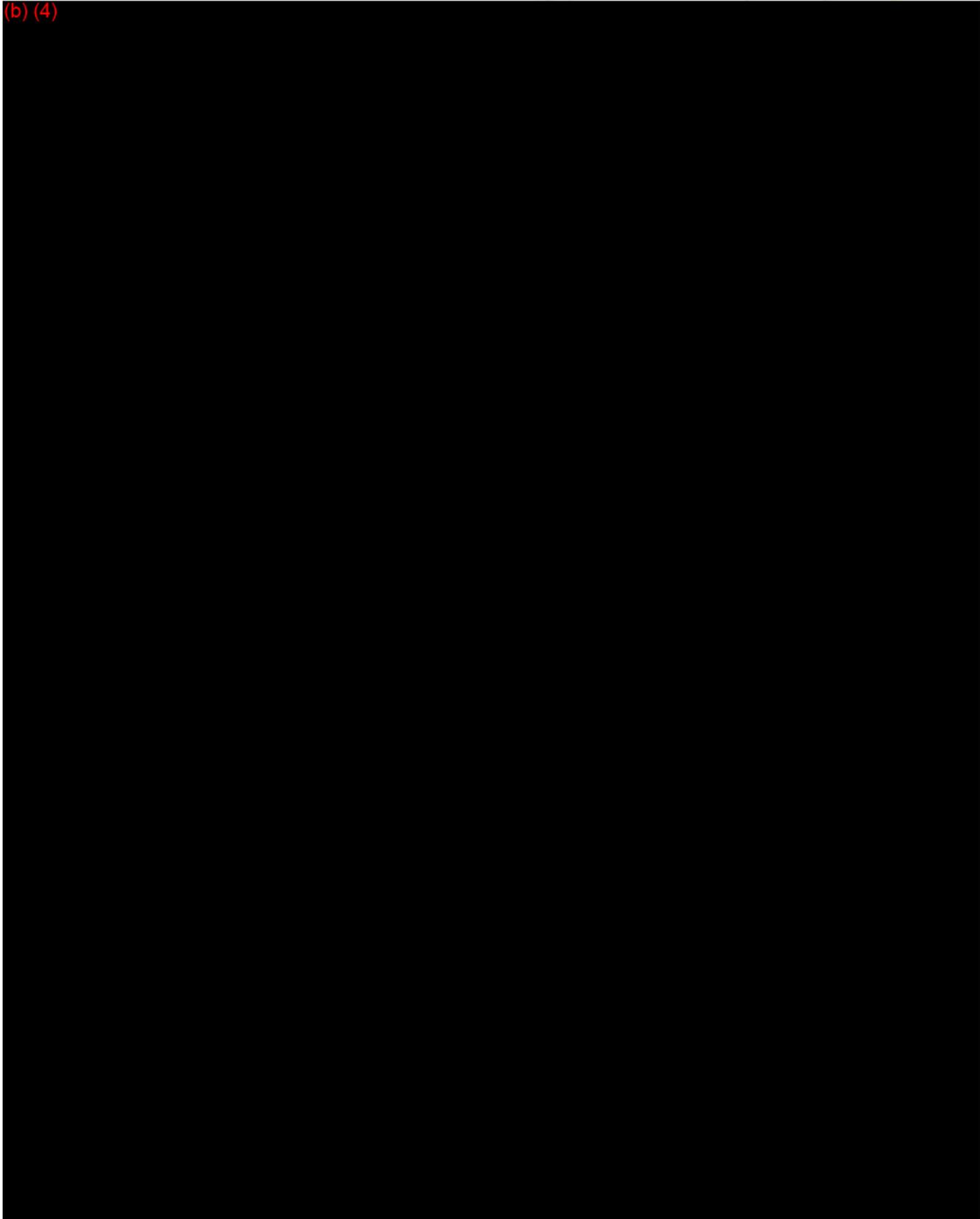
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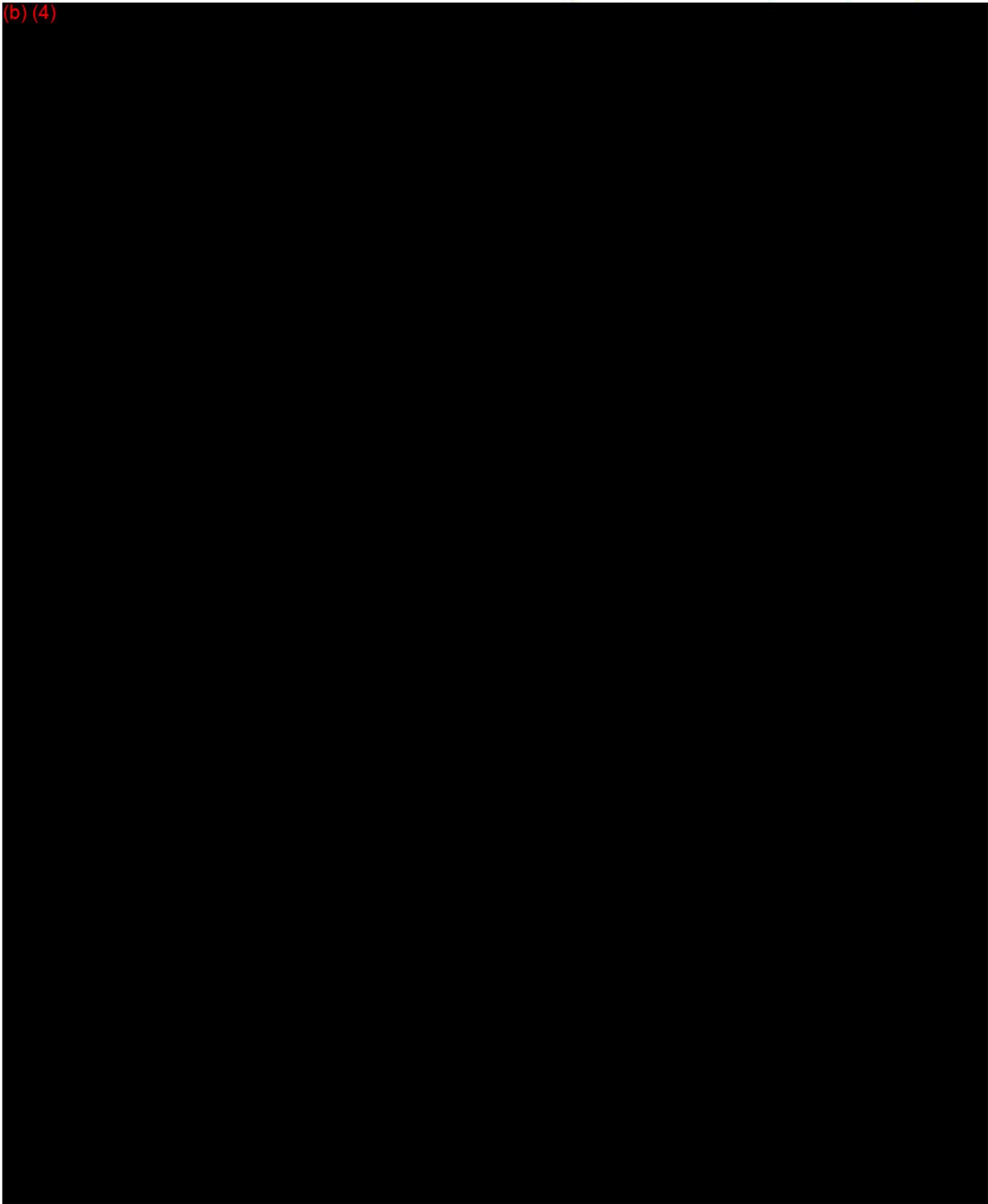
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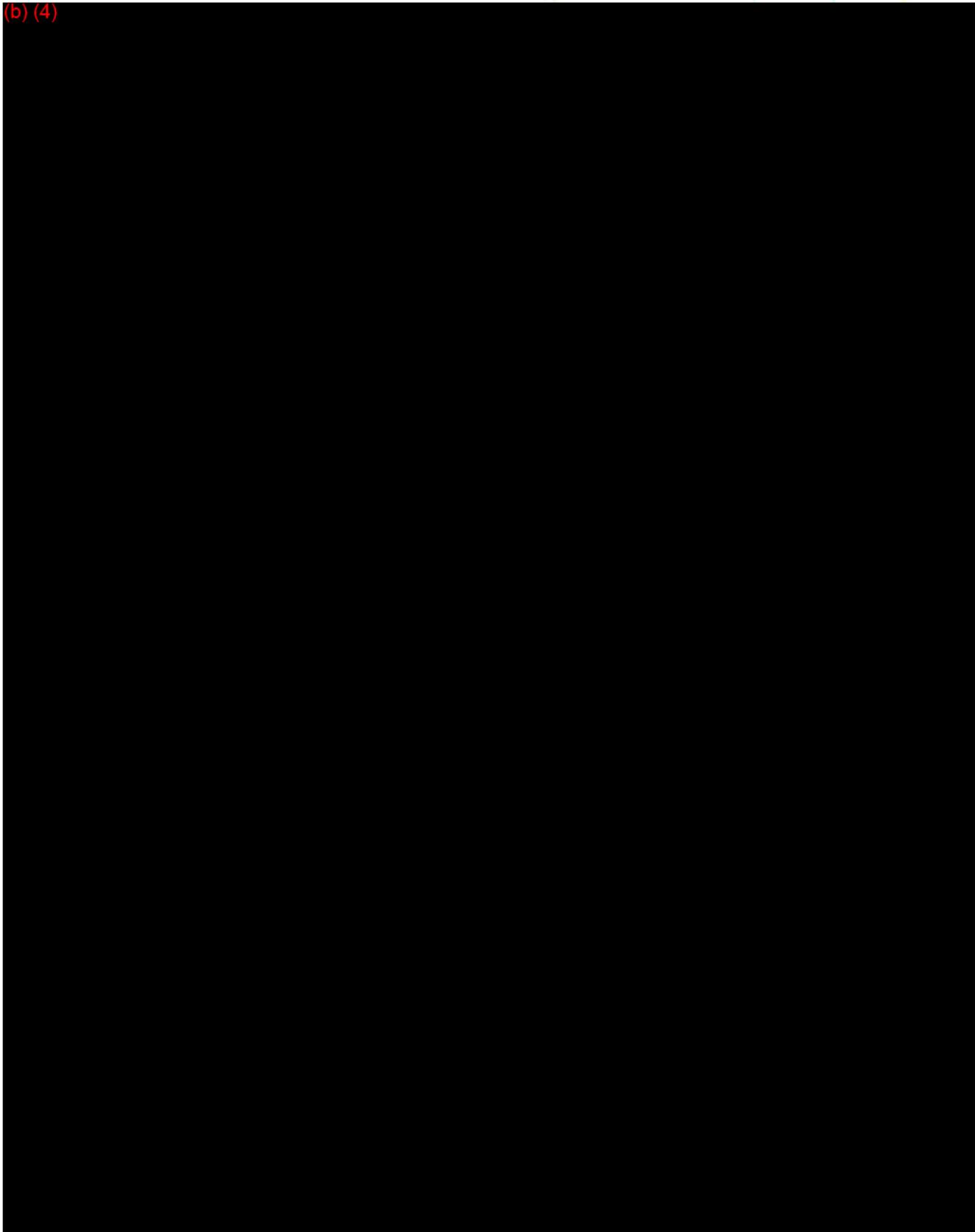
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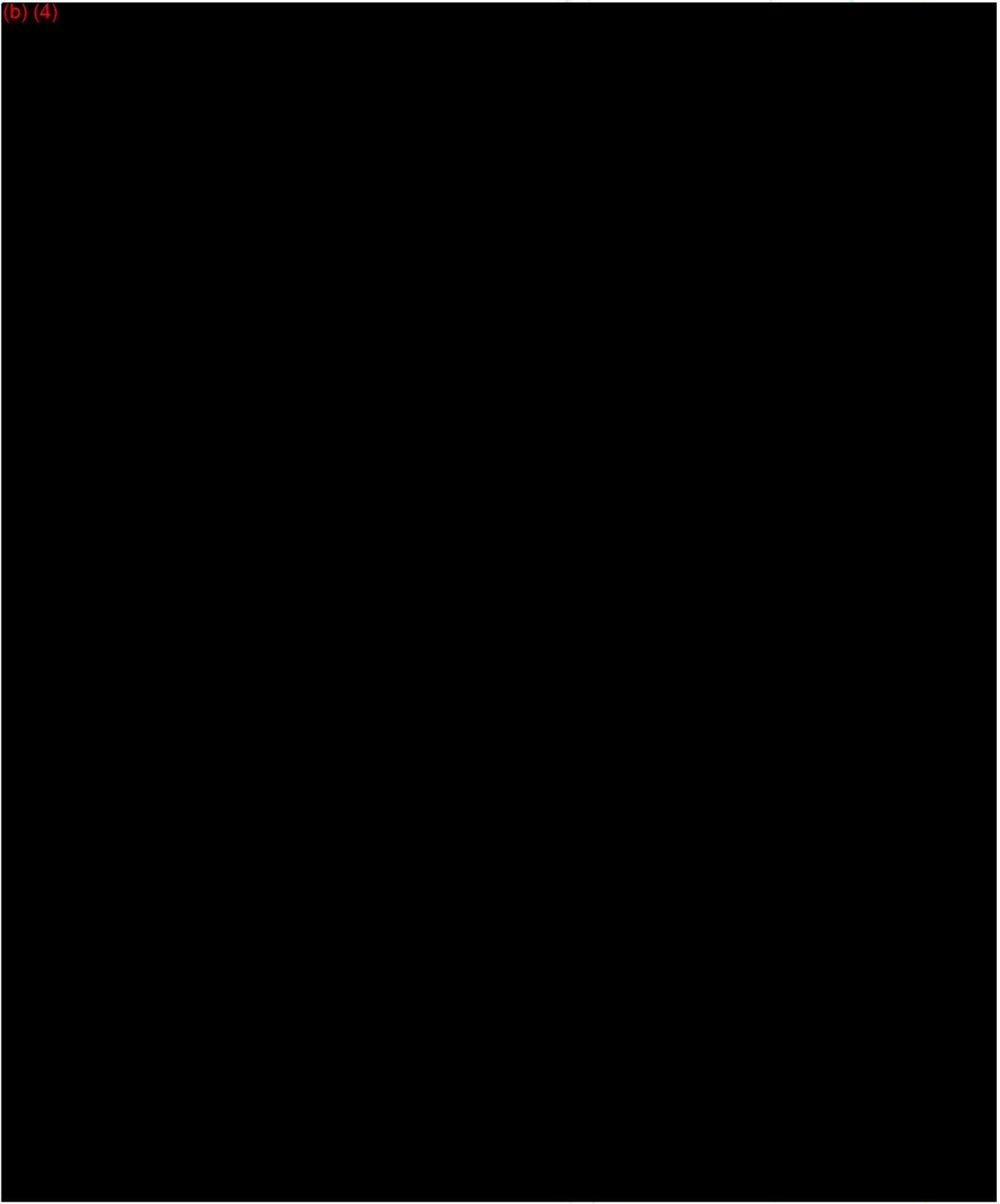
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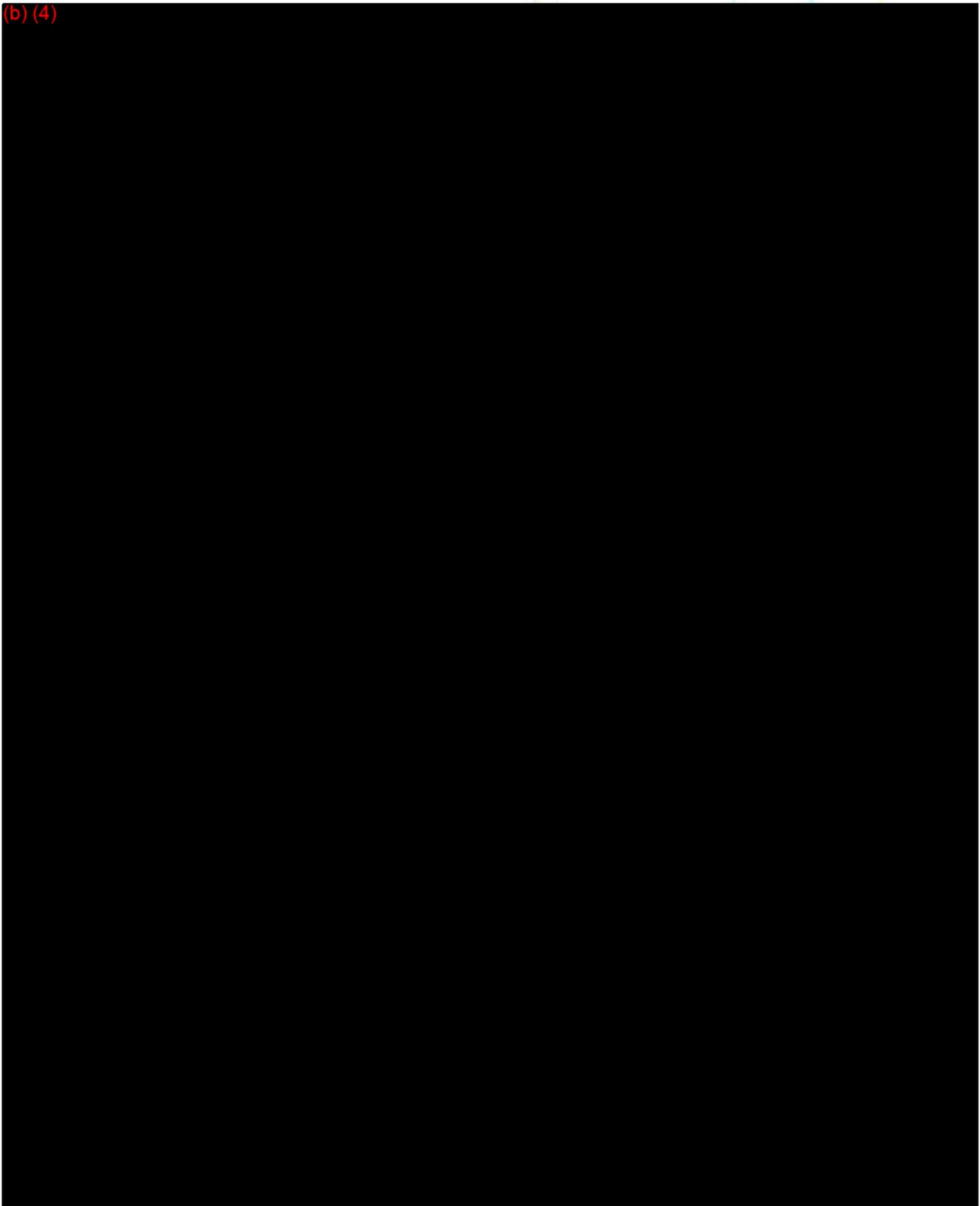
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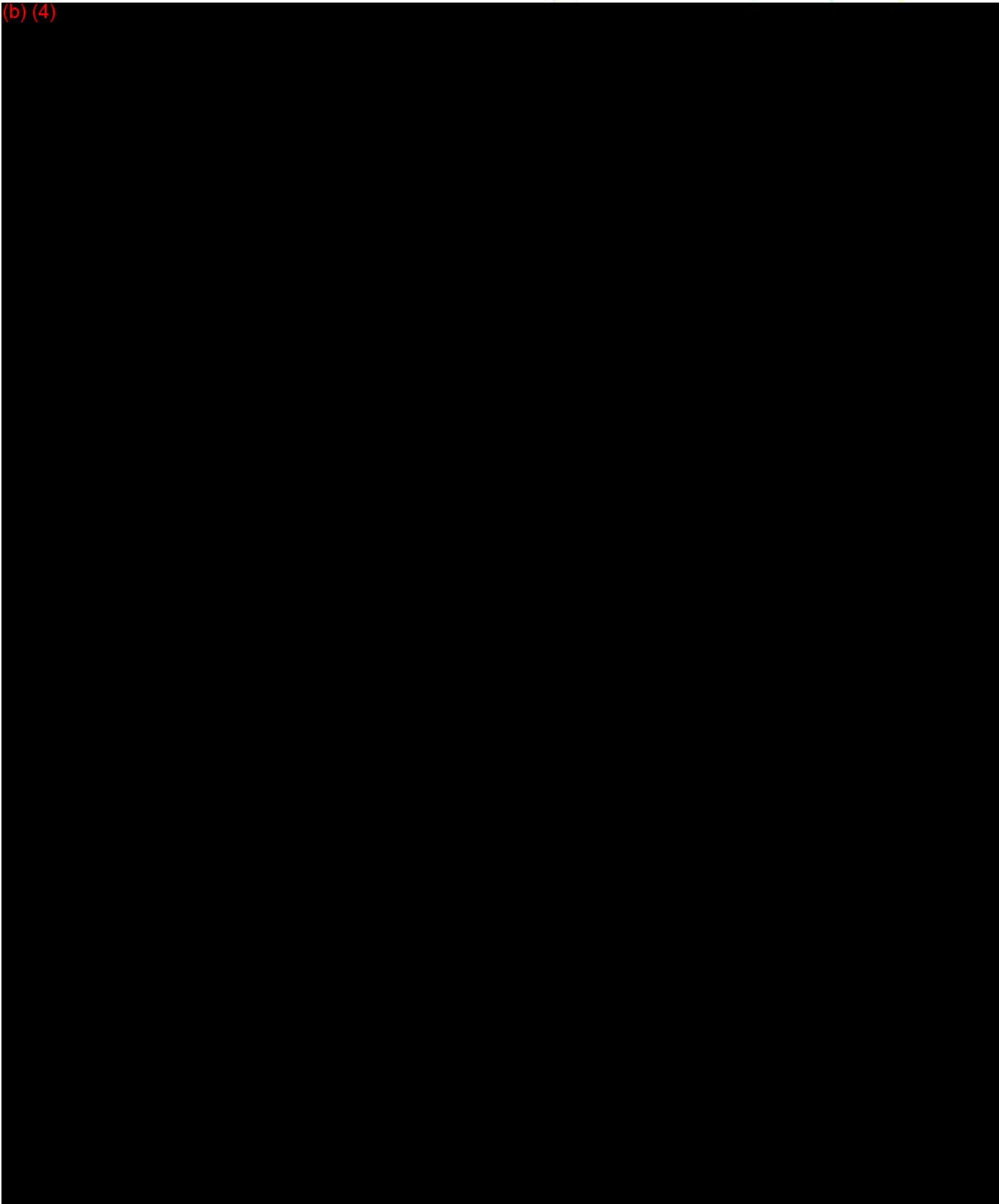
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Respectfully submitted,

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Mark DuVal, President
DuVal & Associates, P.A.

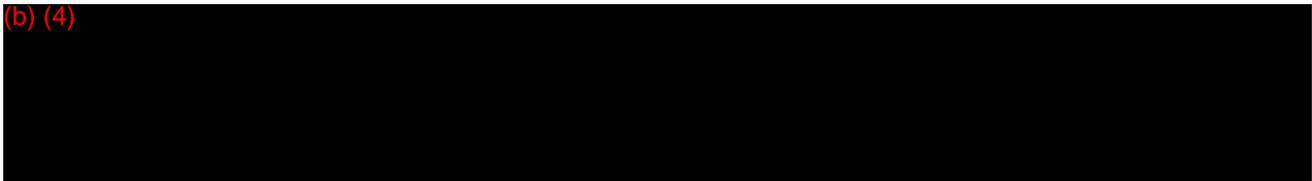
Cc: Preceptis Medical, Inc.

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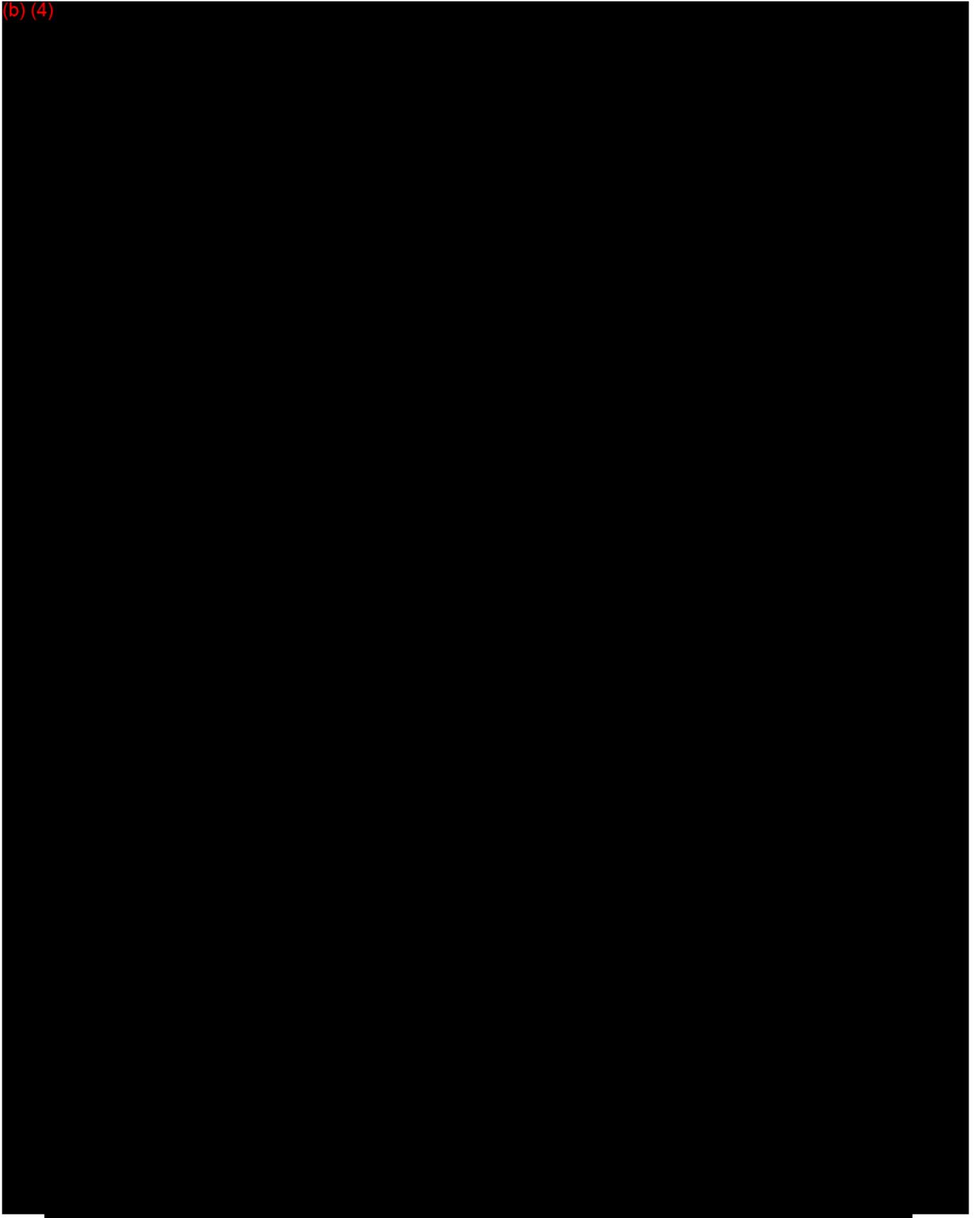
Dear Dr. Maisel:

INTRODUCTION/EXECUTIVE SUMMARY

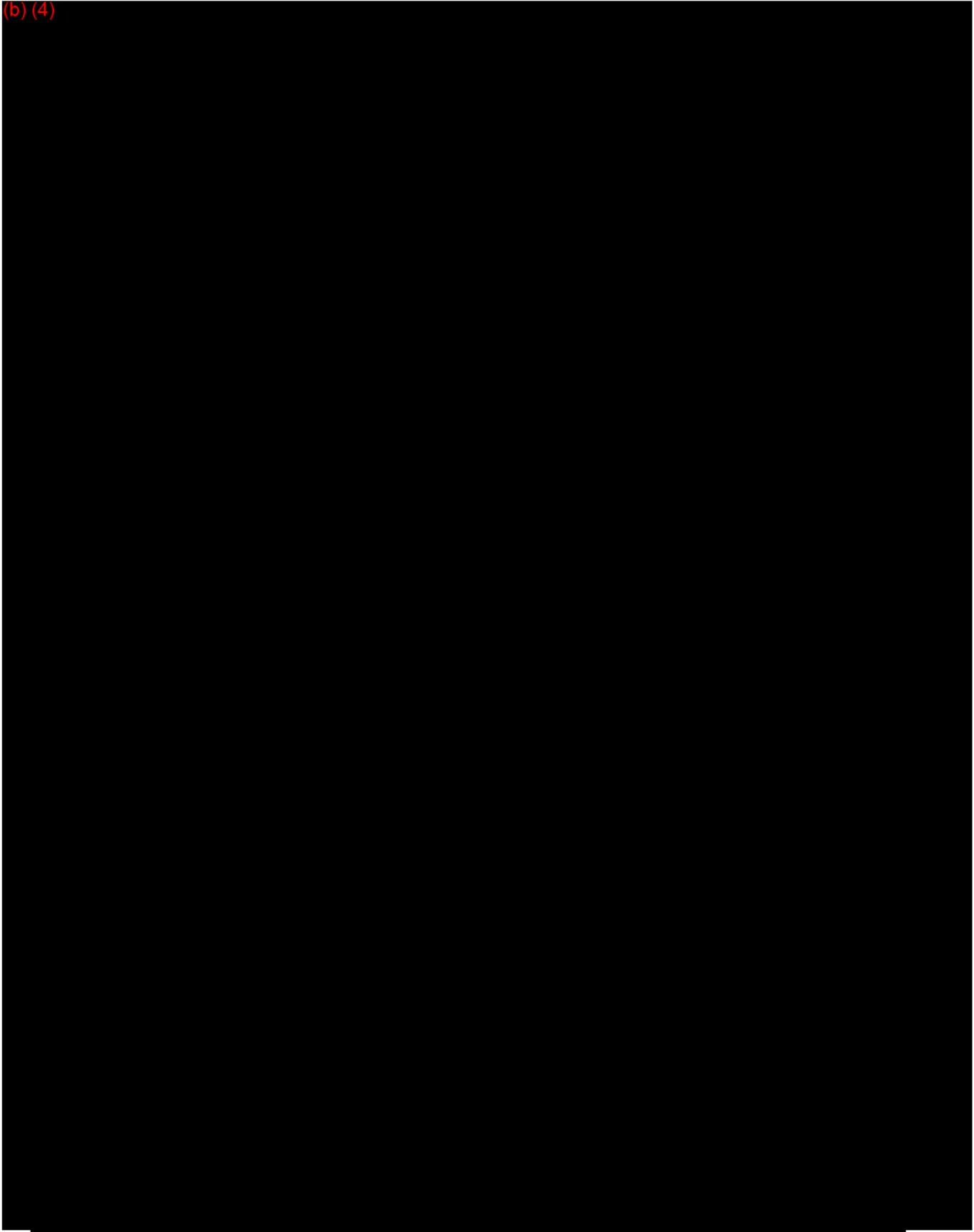
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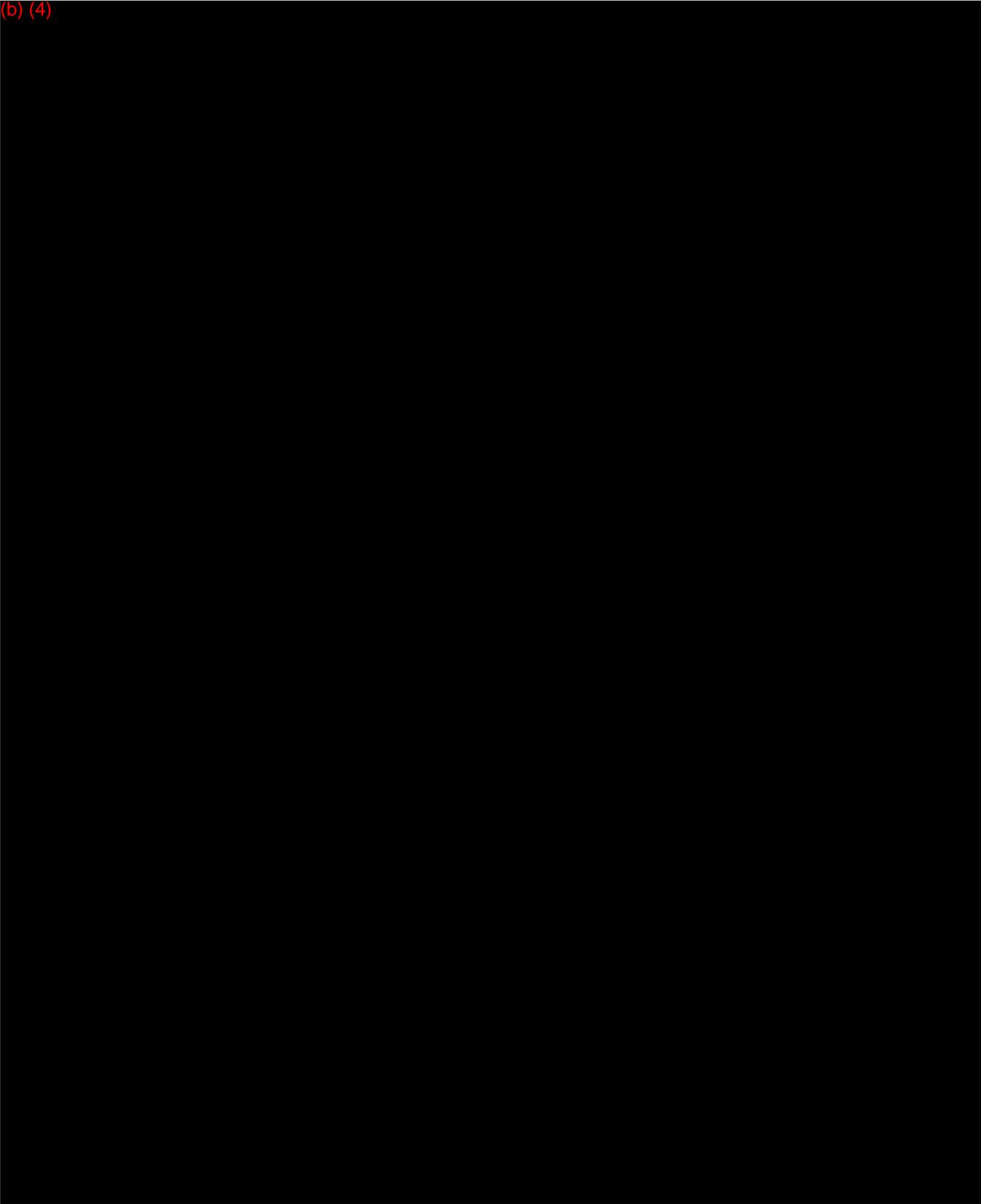
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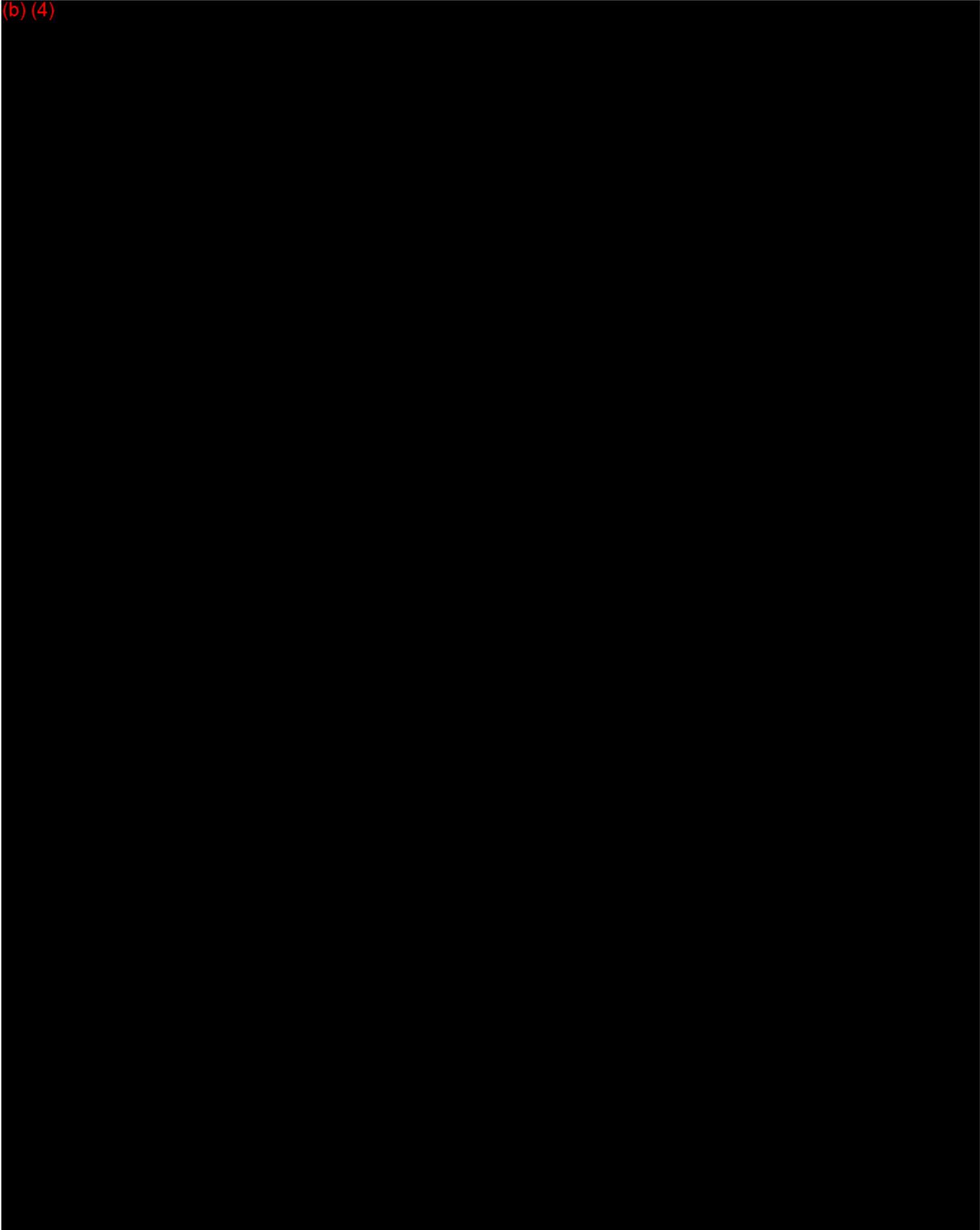
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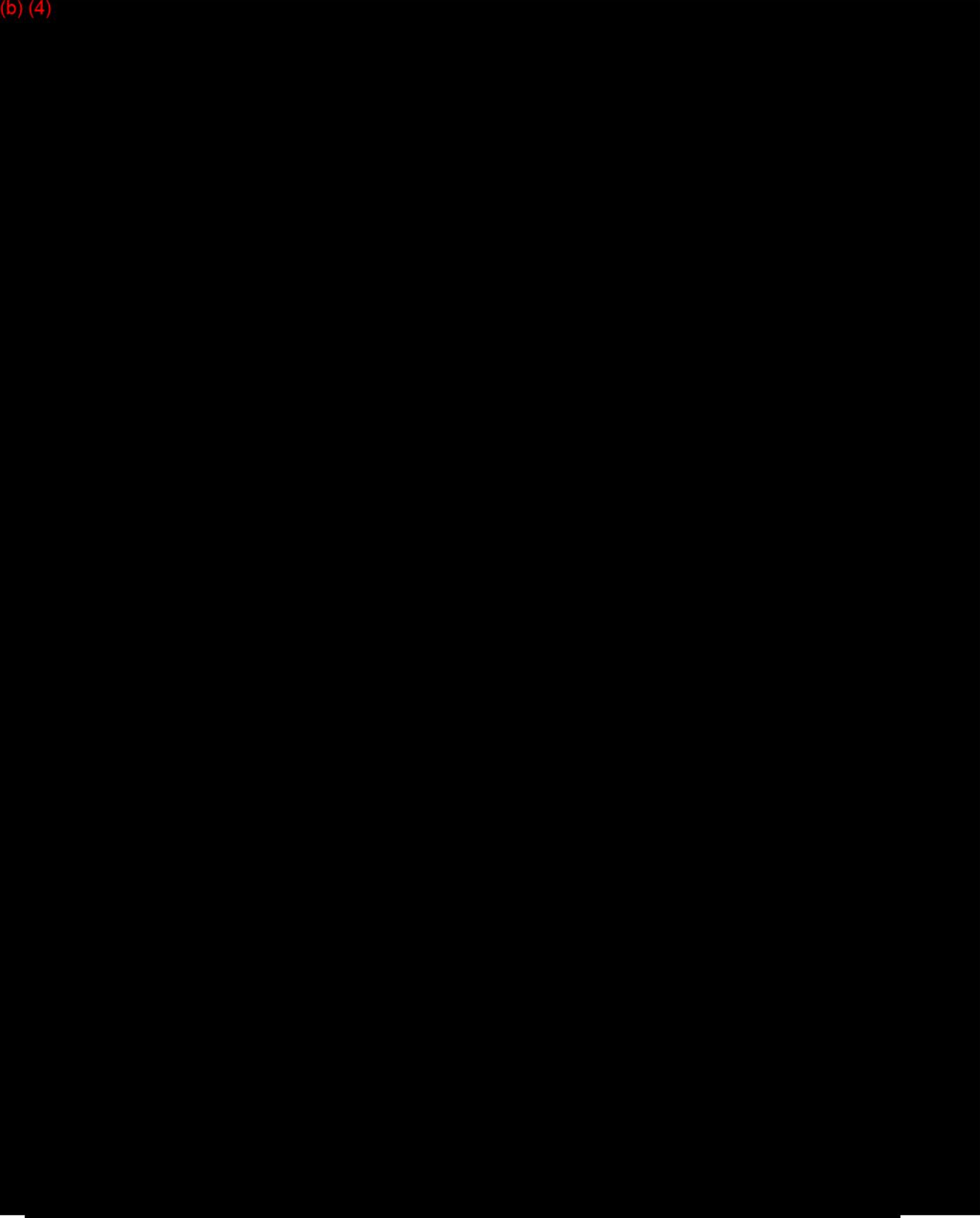
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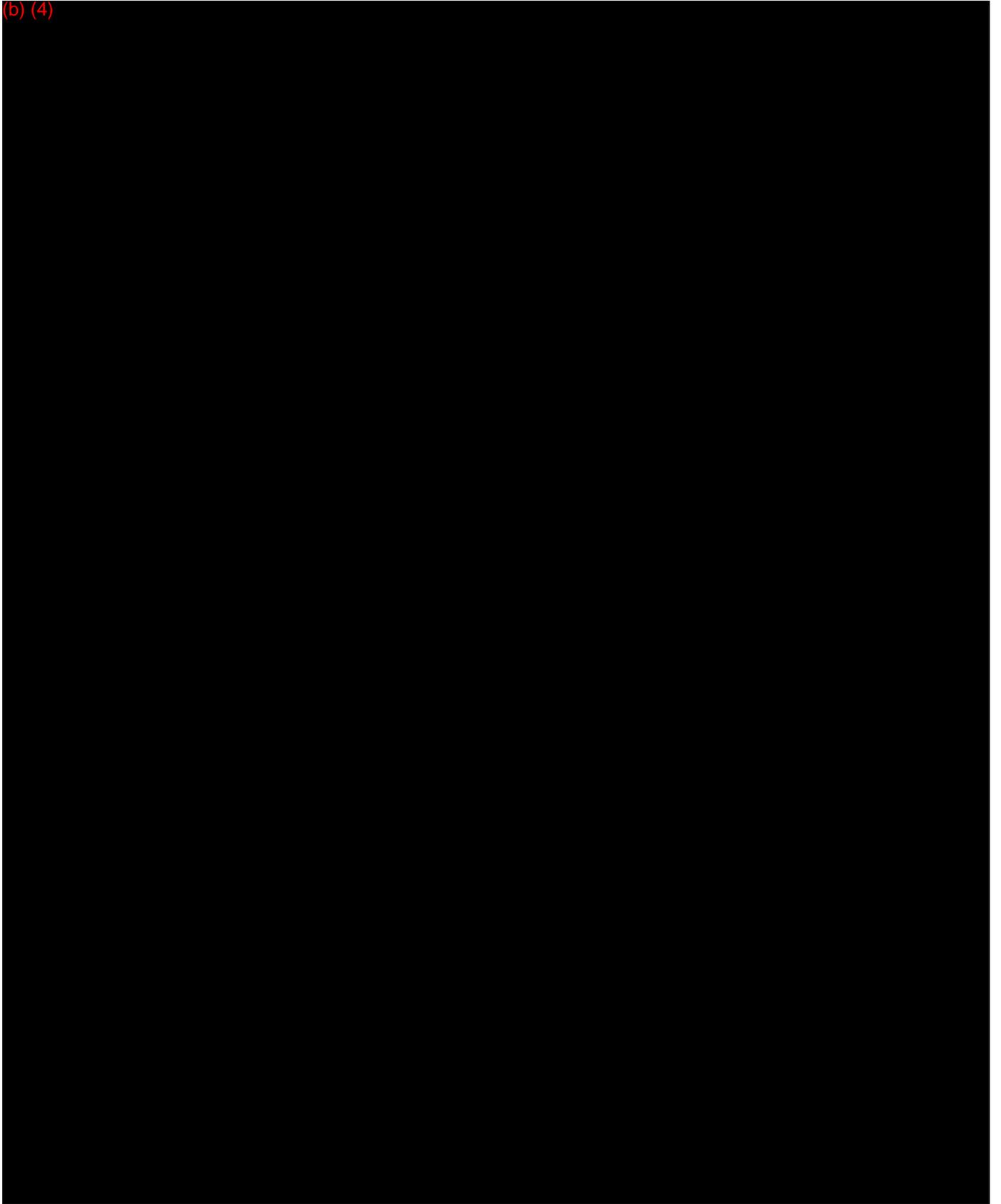
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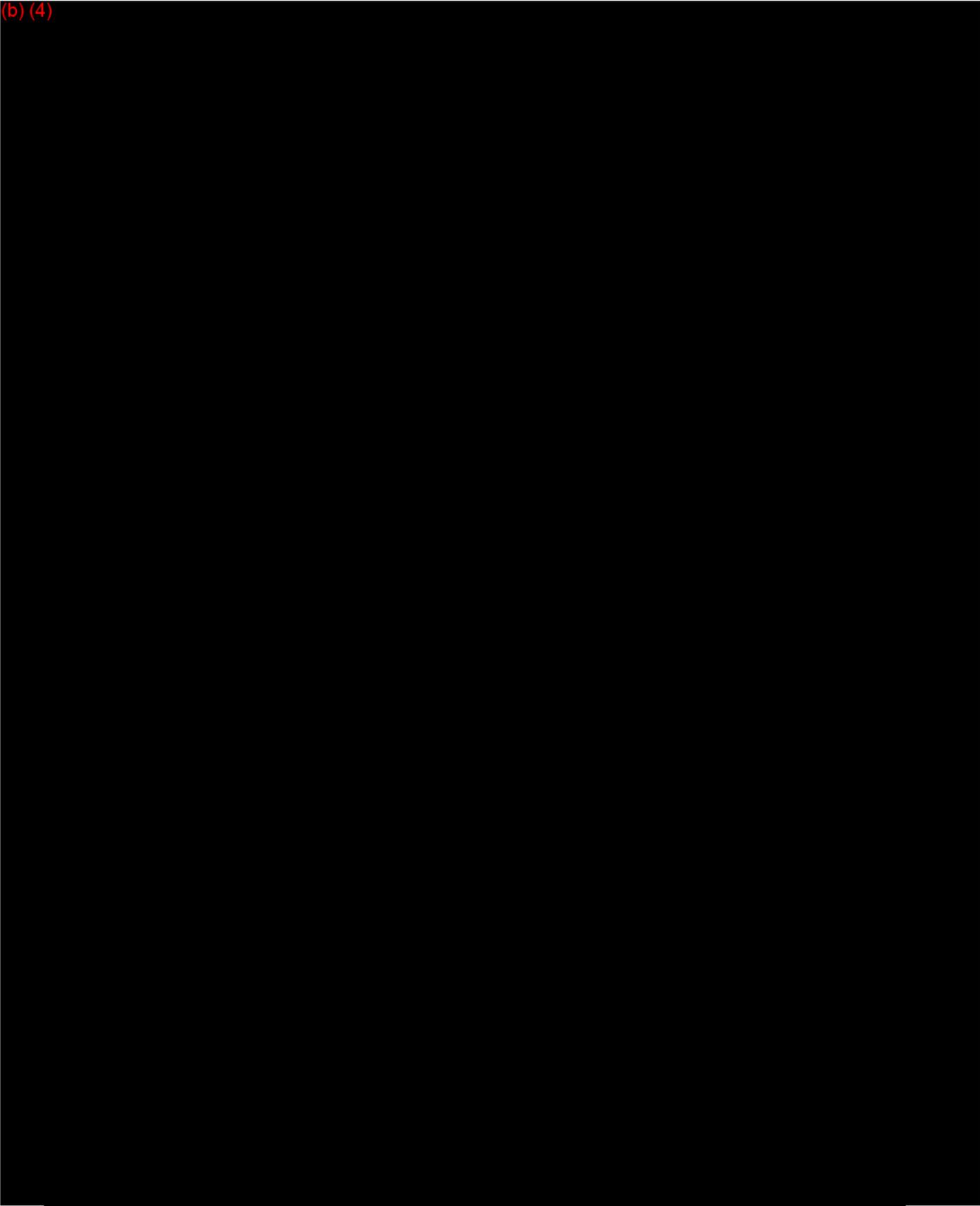
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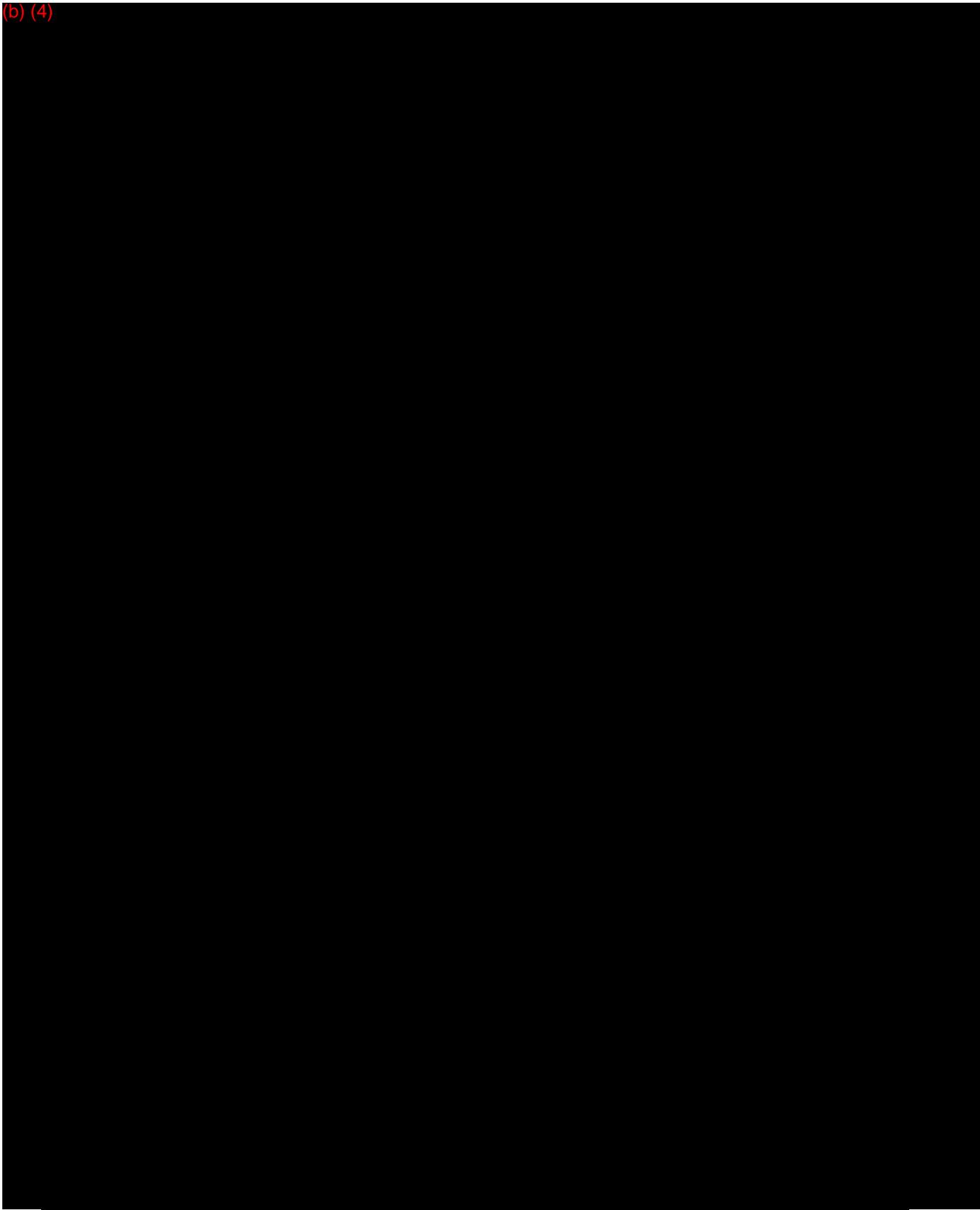
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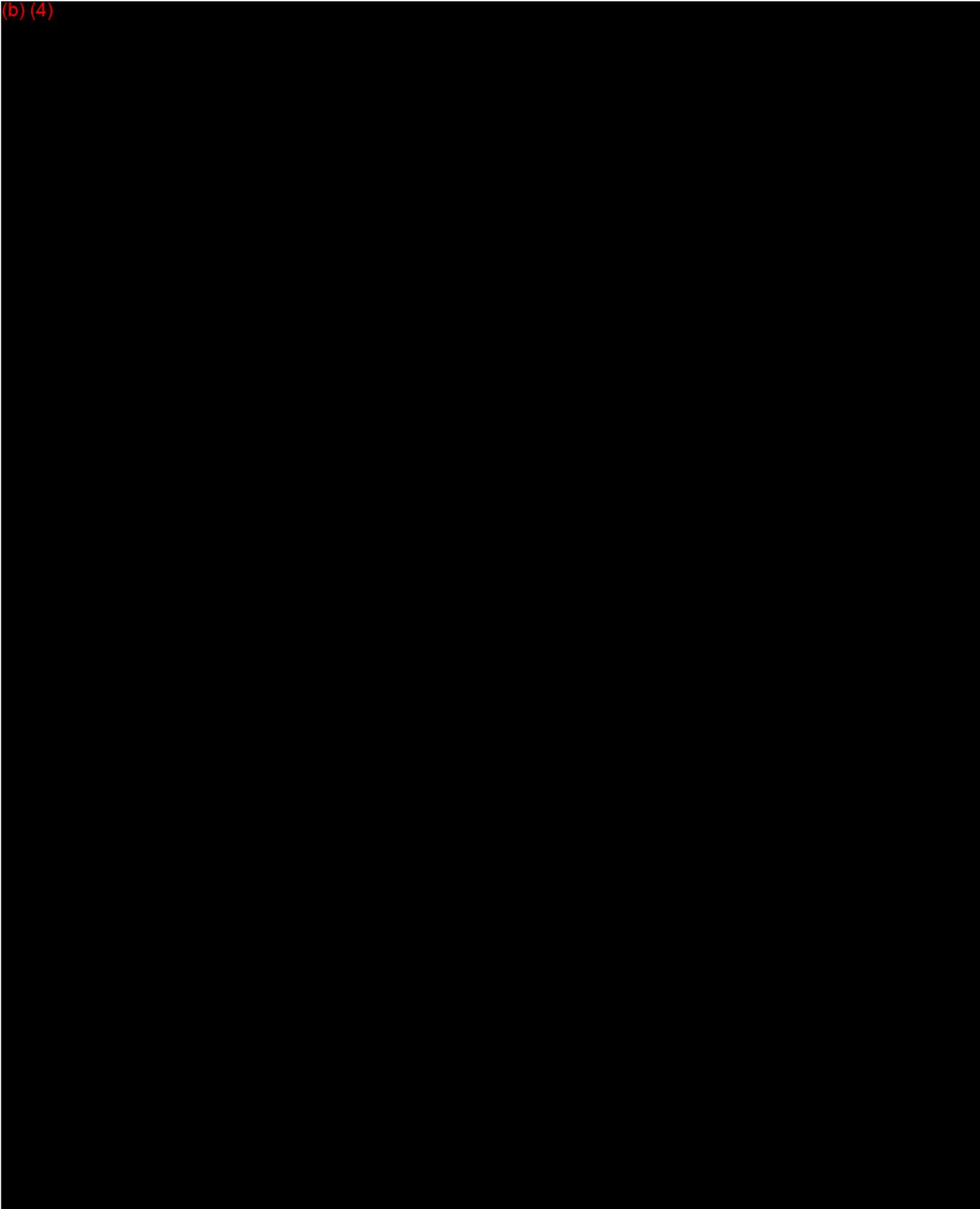
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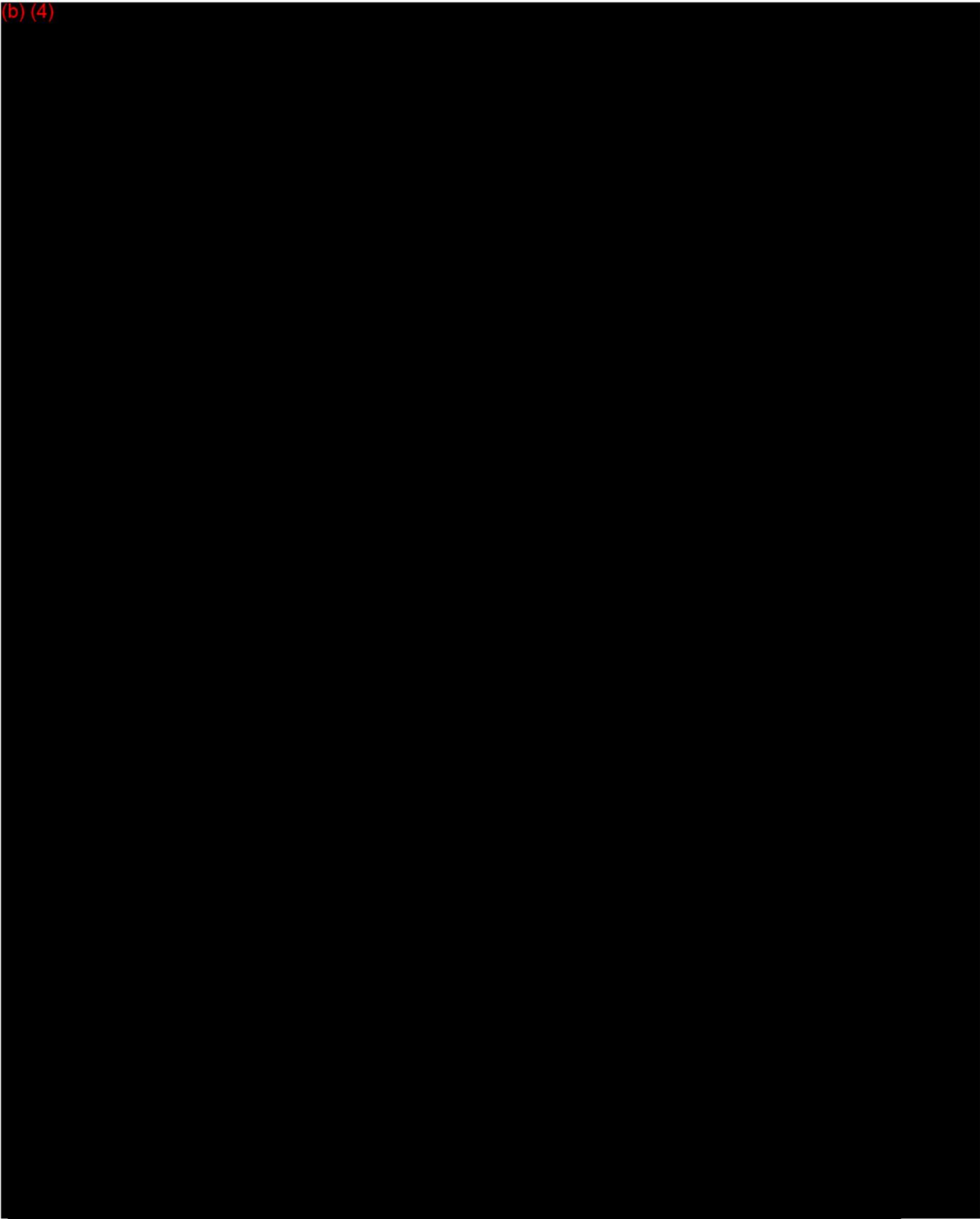
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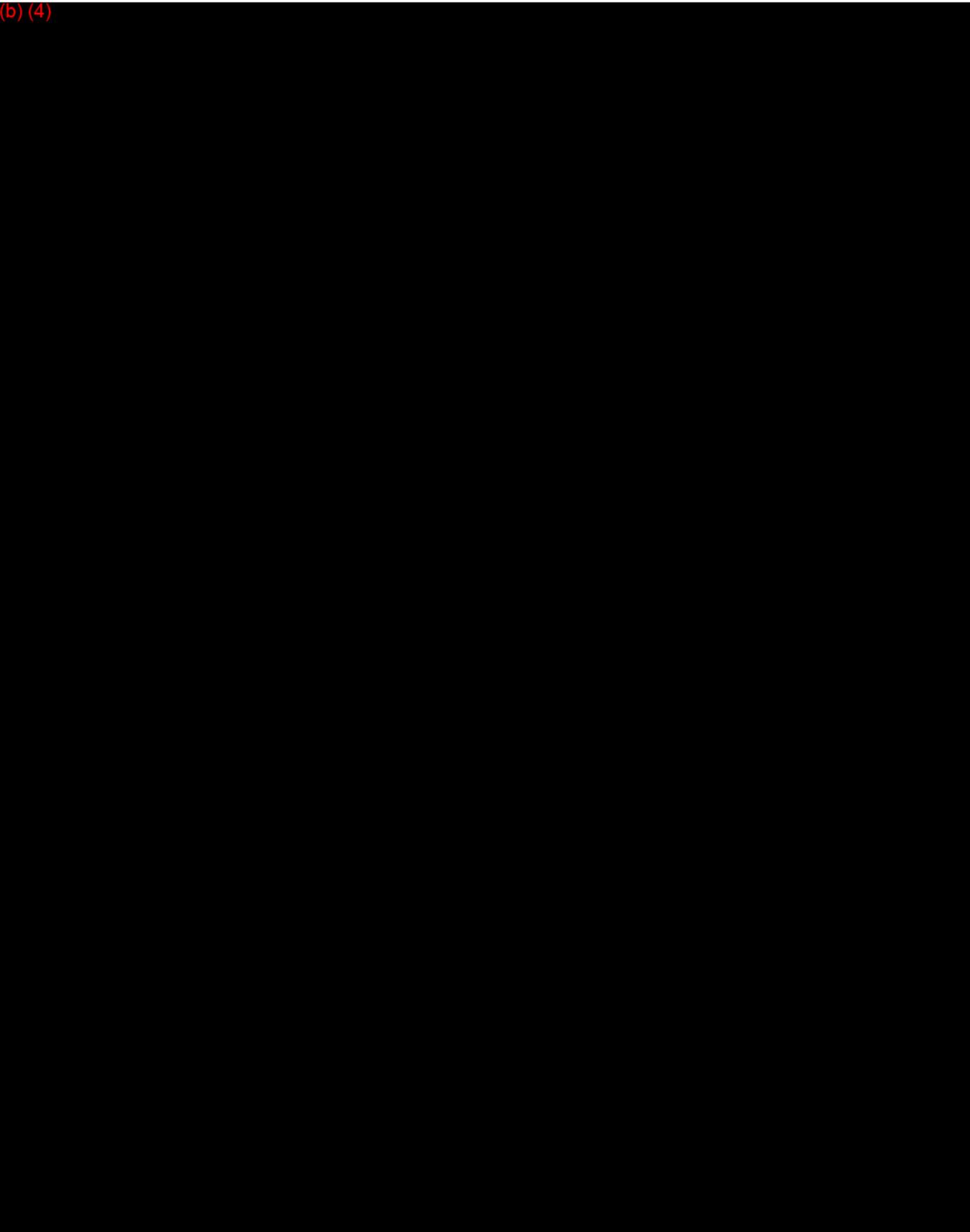
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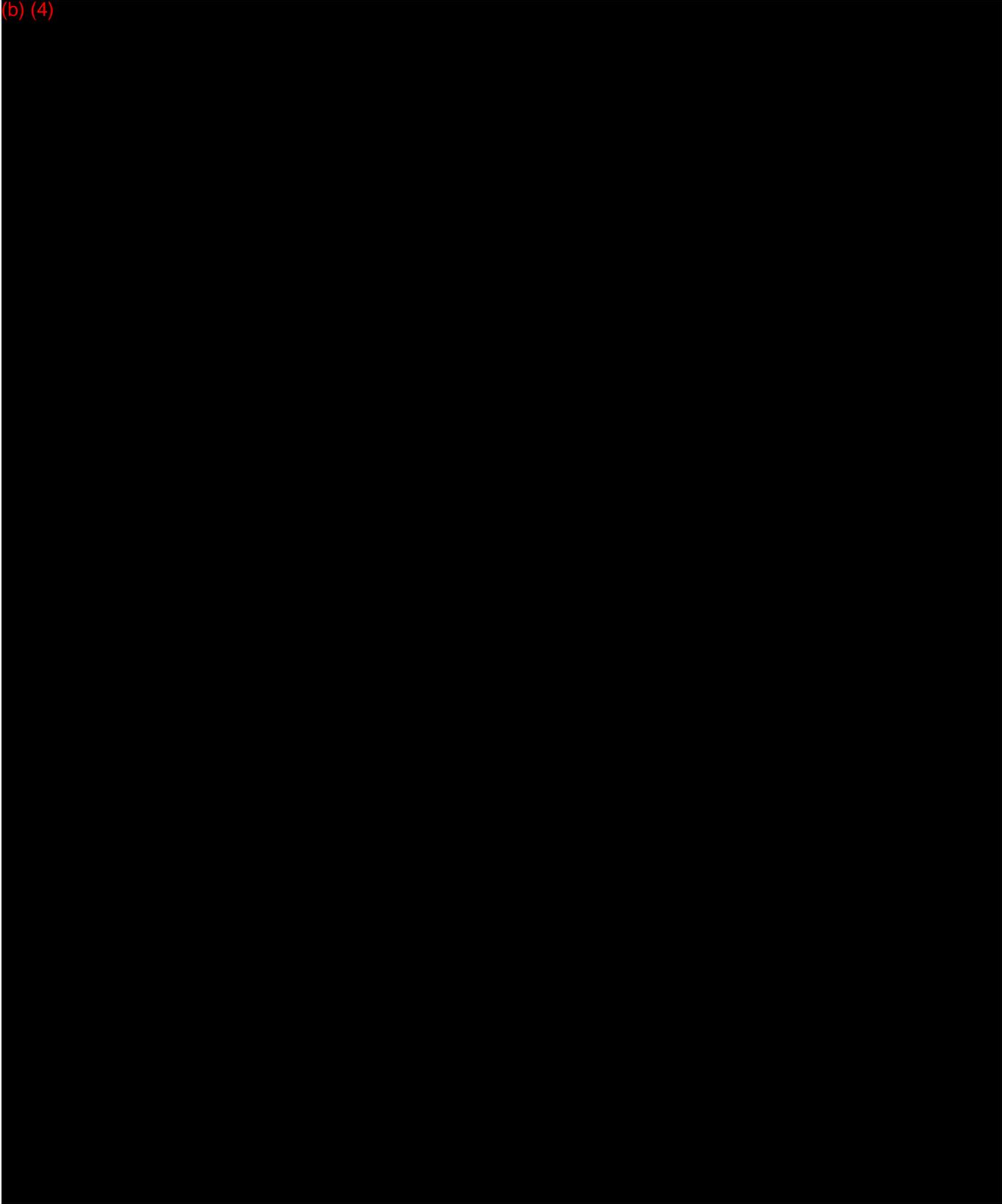
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(b) (4)



(b) (4)



Respectfully submitted,

A handwritten signature in black ink that reads "Mark E. DuVal". The signature is written in a cursive style with a large, stylized "M" and "D".

Mark DuVal, President

DuVal & Associates, P.A.

Cc: Preceptis Medical, Inc.

Appendices

- Appendix 1 Outstanding Drug Issue Letter for K142282
- Appendix 2 Rosenfeld Paper
- Appendix 3 Bibliography, safety of myringotomy procedures
- Appendix 4 SE letter for Hummingbird K133921
- Appendix 5 K142282 principal investigator and study investigator letters
- Appendix 6 ASA guidelines, Continuum of Depth of Sedation: Definition of General Anesthesia and Levels of Sedation/Analgesia.
- Appendix 7 Apdyne phenol kit SE letter, FDA clearance documentation, instructions for use, and phone log with CDER
- Appendix 8 Bibliography, Safety of phenol and local use on the tympanic membrane in children and adults
- Appendix 9 Email from Dr. Mann, FDA, to Preceptis dated November 21, 2014



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Preceptis Medical, Inc.
c/o Mr. Keith Leland
Vice President of Research and Development
505 Highway 169 North, #365
Plymouth, MN 55441

Re: K142282
Trade/Device Name: Hummingbird™ Tympanostomy Tube System (TTS)
Regulation Number: 21 CFR 874.3880
Regulation Name: Tympanostomy Tube
Regulatory Class: Class II
Product Code: ETD
Dated: November 13, 2014
Received: November 14, 2014

Dear Mr. Leland:

(b)(4)



You may resubmit your 510(k) submission after you have received approval by CDER for the drug component as indicated for use with this device (or when a New Drug Application (NDA) for the new drug component is expected to be approved within six months) or you may resubmit your 510(k) with adequate clinical performance data using a different drug component for local

(b) (4)



You may not market this product until you have provided adequate information described above and required by 21 CFR 807.87, and you have received a letter from FDA allowing you to do so. If you market the product without conforming to these requirements, you will be in violation of the Federal Food, Drug, and Cosmetic Act (Act).

If you have any questions concerning the contents of this letter, please contact Dr. Sageev George at (301) 796-6468.

Sincerely yours,

Deborah L. Falls -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

**Proceedings of the 10th International
Symposium on Recent Advances in
Otitis Media**

June 5-9, 2011

New Orleans Marriott

New Orleans, Louisiana, USA



Symposium Director:

**Margaretha L. Casselbrant, MD, PhD
Children's Hospital of Pittsburgh of UPMC
University of Pittsburgh School of Medicine
Pittsburgh, Pennsylvania, USA**

Symposium Co-Directors:

**Lauren O. Bakaletz, PhD
The Research Institute at Nationwide Children's Hospital and
The Ohio State University College of Medicine
Columbus, Ohio, USA**

Richard M. Rosenfeld, MD, MPH

**SUNY Downstate Medical Center and Long Island College Hospital
Brooklyn, New York, USA**

Results

Two remote communities participated. 129 children were screened; 54 were randomized and 45 were seen at six weeks. MOP messaging was acceptable and motivating for the majority of families. Clinic attendance and ear assessments at 6 weeks will be reported.

Conclusion

This is the first randomised controlled trial of mobile phone messaging in an Indigenous language in a population at high risk of CSOM. This novel and culturally appropriate approach offers a new opportunity to enhance the case management of chronic disease in these remote and disadvantaged communities. Greater NextG coverage should be supported.

Office Insertion of Tympanostomy Tubes Without Anesthesia in Young Children

Richard Rosenfeld, MD, Krishna Sury, Christopher Mascarinas, MD
Department of Otolaryngology, SUNY Downstate, Brooklyn, NY

Introduction

Tympanostomy tube insertion is one of the most common surgical procedures in children, with about 12,000 cases performed weekly in the United States. To improve child comfort, general anesthesia is typically used to conduct the procedure. General anesthesia for tube insertion, however, is associated with a 9% incidence of minor complications and 2% incidence of major adverse events. Moreover, early exposure of young children to general anesthesia may predispose to learning disabilities.

The purpose of this study is to report outcomes of office insertion of tympanostomy tubes, without anesthesia, in children age 18 months or younger and to compare those outcomes with a similar cohort of children who had tubes placed in the operating room under general anesthesia.

Methods

This study was conducted at a hospital-based pediatric otolaryngology practice in Brooklyn, New York. A historical cohort was identified by chart review of all children aged 3 to 18 months who had bilateral tympanostomy tubes inserted as a sole surgical procedure by the principal investigator (RMR) as part of routine clinical care for otitis media between January 2006 and March 2009. The goal was to identify approximately 50 children who had tubes placed in the office setting and 50, for comparison, who had tubes placed in the operating room. Children were excluded if they had concurrent surgery other than tubes, tubes were inserted for an indication other than otitis media, the child had a syndrome or craniofacial anomaly, or the caregiver could not speak English. Institutional review board approval was obtained before starting the study.

All procedures were performed as part of routine clinical care using Armstrong beveled fluoroplastic tympanostomy tubes and a binocular microscope. Office insertion was accomplished using a papoose board for restraint and an assistant to steady the child's head. Parents were informed prior to the procedure that the child would likely cry immediately upon being restrained, but would only experience discomfort during the myringotomy and actual tube insertion, which would occupy about 1-2 minutes of the roughly 7-8 minute total procedure time. Tube insertion in the operating room was performed using midazolam premedication followed by mask anesthesia using nitrous oxide and sevoflurane under the supervision of a pediatric anesthesiologist.

The office charts were reviewed to obtain demographic data and information about the child's clinical history, which was recorded on a de-identified data form. The primary outcome was caregiver responses about changes observed after ear tubes using a 5-point Likert scale (agree strongly, agree, neither agree nor disagree, disagree, disagree strongly, don't know). The following questions were administered using a telephone interview by an impartial research assistant:

Getting the ear tubes inserted was pleasant for my child

Having my child get ear tubes was pleasant for me as a parent

My child recovered quickly after the tubes were placed

My child had nightmares or bad memories after the procedure

I am satisfied with the overall experience of getting the ear tubes

Secondary outcomes were obtained from the medical record and included (a) time to obstruction of first tube, (b) time to extrusion of first tube, (c) time to malfunction (obstruction or extrusion) of first tube, and (d) time to extrusion of both tubes. All statistical analyses were performed using SPSS software and comparisons were made with the Mann-Whitney U test, Fisher's exact test, Pearson chi-square, and Kaplan-Meier survival analysis curves. All tests were performed using a two-sided alpha level of 0.05 for statistical significance.

Results

The final sample included 46 children with tubes inserted in the office and 48 children with tubes inserted in the operating room. The two cohorts were comparable with the exception of a slightly younger age and greater prevalence of acute otitis media in the office-insertion group (Table 1). Tubes were inserted for recurrent acute otitis media (25%), otitis media with effusion (20%), or both (55%). Most children had bilateral effusions (82%) and a mild hearing loss (median pure tone average, 35 dB HL).

No differences were found (Tables 2 and 3) for tube insertion in the office vs. operating room for parent perceptions of child recovery ($P=.386$), overall satisfaction ($P=.676$), post-procedure nightmares or bad memories ($P=.113$), pleasantness of procedure for the parents (.848), or pleasantness of procedure for the child ($P=.060$). Similarly, no differences were found (Table 4) for median time to failure (extrusion or obstruction) of one tube ($P=.252$) or both ($P=.445$) No adverse events occurred during tube placement.

Discussion

Our study is the first to compare outcomes of tympanostomy tube insertion in young children without anesthesia in an office setting to traditional placement of tubes under general anesthesia in the operating room. Overall there were no differences in caregiver reports of satisfaction with the procedure, their child's recovery, or the duration of tube patency. In addition, those parents who had experienced the procedure in both settings (office and operating room) with different children universally preferred office placement because the procedure was rapid, their child did not have to fast, and there was immediate recovery with ability to console and feed the child.

The issue of where to perform tympanostomy tube placement in young children involves a process of shared decision-making between the clinician and caregiver, which also takes into account the clinician's experience and comfort level. In addition, caregiver values are an important consideration. For example, some caregivers are very concerned about potential adverse events of anesthesia, the need to keep their child without food prior to the procedure, and the potentially frightening emergence delirium that is typically lasts 5-15 minutes after surgery, but has been associated with agitation and regressive behavior lasting up to 2 days. Other caregivers may be less concerned with general anesthesia, but more worried about having their child be restrained in a papoose board and experience brief pain during the procedure. Most caregivers, however, are comfortable with child restraint if properly counselled.

Limitations of this study include non-randomized allocation, recall bias by caregivers, and allocation bias caused by self-assignment to procedure setting by the caregivers. We conclude, however, that the findings are sufficient to justify office insertion of tubes as a well-tolerated, reasonable alternative to general anesthesia for caregivers and clinicians who are comfortable with this choice.

Table 1.—Characteristics of 94 children under age 19 months receiving tympanostomy tubes

Characteristic	Inserted in office	Inserted in OR	Total	P value	
Total subjects, n(%)	46(49)	48(51)	94(100)	—	
Child age in months, mean (SD)	11.3(3.2)	13.4(3.6)	12.5(3.6)	.021 [†]	
Male gender, n(%)	19(40)	29(60)	48(51)	.098 [§]	
Developmental delay or in therapy, n(%)	9(20)	21(44)	30(32)	.012 [§]	
Otitis media duration in months, median(IQR)	6(5)	6(5)	6(5)	.811 [†]	
Prior AOM episodes, median(IQR)	5(6)	5(5)	5(5)	.730 [†]	
Indication for tubes, n(%):					
AOM or recurrent AOM only	19(41)	4(8)	23(25)	<.001 [§]	
OME only	10(22)	9(19)	19(20)		
Both AOM and OME	17(37)	35(73)	52(55)		
Middle-ear effusion, n(%):					
None	2(4)	4(8)	66)	.695 [§]	
Unilateral	5(11)	6(13)	11(12)		
Bilateral	39(85)	38(79)	77(82)		
Bilateral flat (B) tympanogram, n(%)	23(72)	24(63)	47(67)	.737 [§]	
Valid audiogram, n(%)	38(83)	44(92)	82(87)	.227 [‡]	
Hearing level in decibels, mean(SD):					
Pure tone average (0.5, 1, 2 kHz)	37(15)	36(10)	35(18)	.782 [†]	
Speech reception threshold	30(23)	33(14)	30(15)	.863 [†]	
Years until survey, median(IQR)	1.1(1.7)	1.6(1.7)	1.6(1.7)	.022 [†]	

AOM, acute otitis media; IQR, interquartile range; OME, otitis media with effusion; OR, operating room; SD, standard deviation

[†]Mann-Whitney U test

[‡]Fisher's exact test

[§]Pearson chi-square

Table 2.—Mean caregiver responses regarding the tube insertion experience

Survey item	Response, mean (SD) [†]		
	Inserted in office	Inserted in OR	P value [‡]
Getting the ear tubes inserted was pleasant for my child	3.2(1.5)	2.6(1.2)	.060
Having my child get ear tubes was pleasant for me as a parent	2.6(1.5)	2.6(1.4)	.848
My child recovered quickly after the tubes were placed	1.5(0.8)	1.6(0.7)	.386
My child had nightmares or bad memories after the procedure	4.2(1.0)	4.5(0.6)	.113
I am satisfied with the overall experience of getting the ear tubes	1.4(0.7)	1.3(0.6)	.676

OR, operating room; SD, standard deviation

[†] Range from 1 (agree strongly) to 5 (disagree strongly)

[‡]Mann-Whitney U test

Table 3.—Caregiver agreement with survey items regarding tube insertion experience

Survey item	Agreement, n (%) [†]		Odds ratio (95% CI)	P value
	Inserted in office	Inserted in OR		
Getting the ear tubes inserted was pleasant for my child	21/46(46)	28/45(62)	.51(.22, 1.18)	.113
Having my child get ear tubes was pleasant for me as a parent	25/44(57)	31/48(65)	.72(.31, 1.67)	.446
My child recovered quickly after the tubes were placed	43/46(94)	46/48(96)	.62(.10, 3.91)	.611
My child had nightmares or bad memories after the procedure	4/44(9)	0/42(0)	—	.117
I am satisfied with the overall experience of getting the ear tubes	44/46(96)	47/48(98)	.47(.04, 5.35)	.613

CI, confidence interval

[†]Includes “agree” and “strongly agree” responses

Table 4.—Outcomes of tympanostomy tube insertion

Outcome	Time to outcome (95% CI) [†]		P value
	Inserted in office	Inserted in OR	
Median months until one tube nonfunctional [‡]	12.9(8.3, 17.)	15.6(12.3, 18.8)	.252
Median months until both tubes nonfunctional [‡]	28.2(17.2, 39.2)	24.8(20.4, 29.1)	.445
Median months until repeat tube insertion (if occurred)	30.0(27.9, 33.6)	25.3(22.9, 27.7)	.138

OR, operating room; SD, standard deviation

[†]Kaplan-Meier survival analysis with log rank comparison

[‡]Nonfunctional defined as obstructed or extruded

Prevalence of Otitis Media in Cleft Palate Infants Is Affected by Diagnostic Technique

Allison Tobey, MD¹, Cuneyt M. Alper, MD², Todd Otteson, MD², Joseph E. Losee, MD³, William J. Doyle, PhD²

¹Department of Otolaryngology, University of Pittsburgh School of Medicine, Pittsburgh, PA, ²Department of Otolaryngology, Division of Pediatric Otolaryngology, ³Department of Plastic Surgery, Division of Pediatric Plastic Surgery, Children's Hospital of Pittsburgh of UPMC, University of Pittsburgh School of Medicine, Pittsburgh, PA

Introduction

Nonsyndromic clefts of the lip and/or palate (CL/P) are among the most common birth defects, affecting approximately 1 in 595 newborns in the United States¹. Otitis media (OM) is a known complication of CL/P^{2,3} and early studies reported OM to be a nearly universal condition in young CL/P infants^{2,4,5}. More recent studies demonstrated that OM in CL/P patients persists throughout childhood and into adolescence at a much higher frequency^{6,7} and is associated with greater prevalences of hearing loss⁶, language delays⁸ and cholesteatoma when compared to an age-matched population with CL/P. However, recent studies reported a lesser OM prevalence in CL/P infants when compared to earlier studies and the reasons for this discrepancy has not been clarified.

Because of the increased risk of OM and its complications in CL/P patients, early, prophylactic myringotomy and tympanostomy tube insertion (M&T) has been recommended⁹ and later studies documented lesser OM prevalences and improved hearing in CL/P patients treated with that procedure. However, controversy continues to exist regarding the long term efficacy and potential complications of this treatment strategy³. Other interventions have been evaluated in studies but documented no effects on OM and hearing of the timing of palatal surgery¹⁰ and, with few exceptions, of the type of palatoplasty performed⁷.

Because the data on the prevalence of OM in CL/P infants has not been updated in recent years and the treatment of OM in the CLP population remains controversial, the present study evaluated the prevalence of OM during the first year of life in CL/P

Safety of Myringotomy Procedures

Support of the safe insertion of tubes in pediatric patients without general anesthesia

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Tympanocentesis or Myringotomy under Topical (or less) on pediatric patients

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Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Preceptis Medical
% Mr. Keith Leland
VP of Research and Development
505 Highway 169 North, #365
Plymouth, MN 55441

Re: K133921
Trade/Device Name: Preceptis Tympanostomy Tube System
Regulation Number: 21 CFR 874.3880
Regulation Name: Tympanostomy Tube
Regulatory Class: II
Product Code: ETD
Dated: July 21, 2014
Received: July 22, 2014

Dear Mr. Leland,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

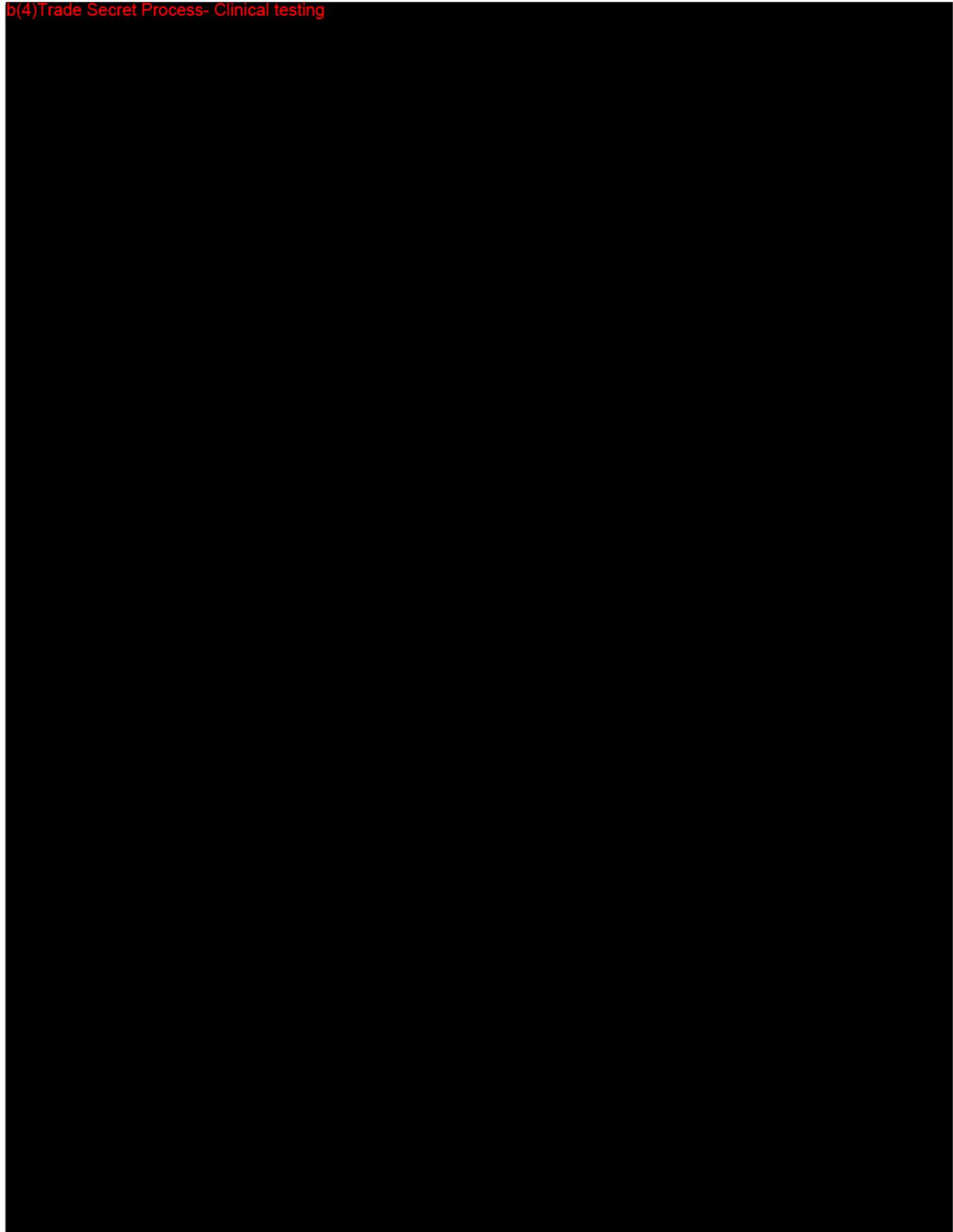
<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

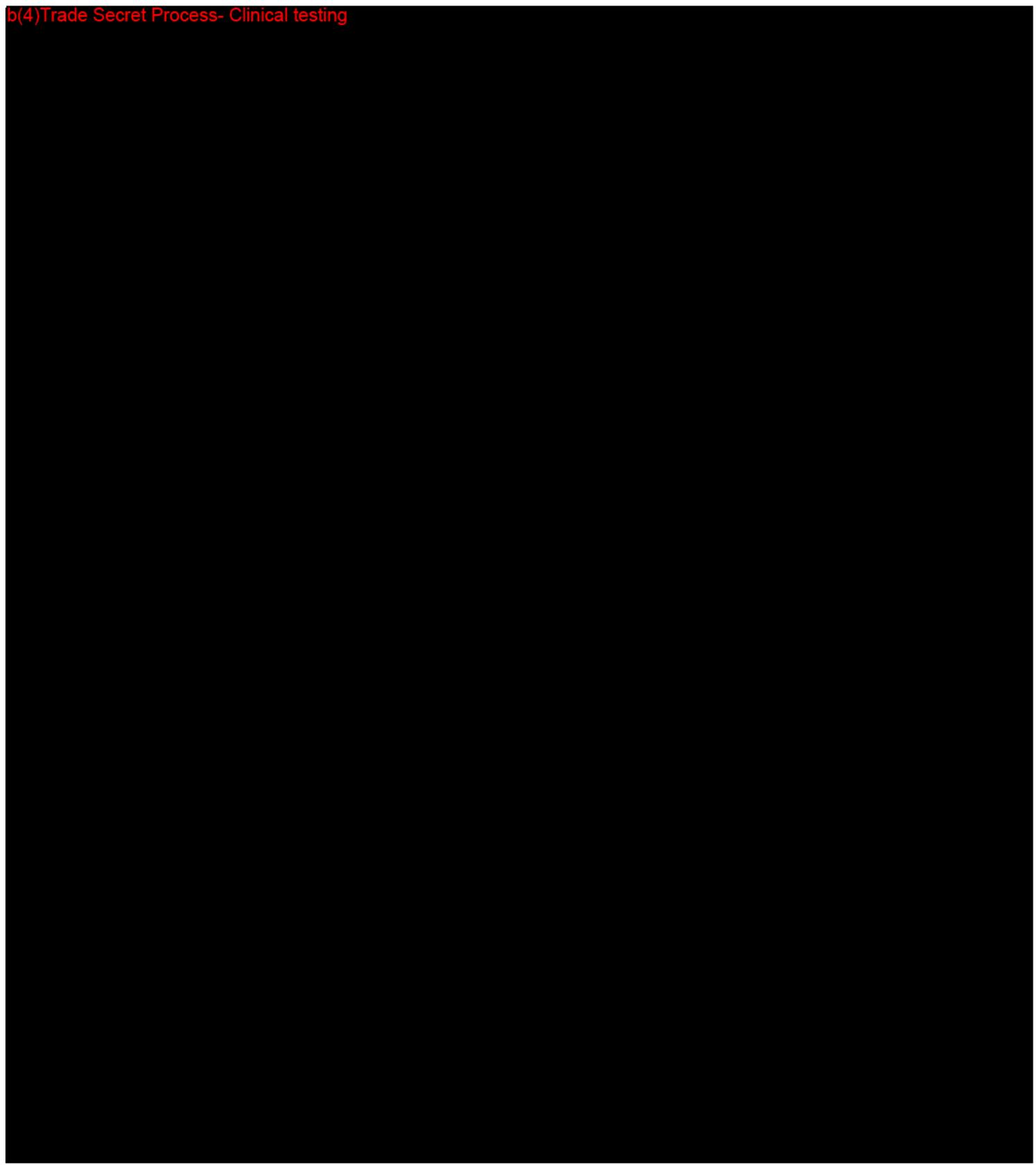
Tina Kiang -S

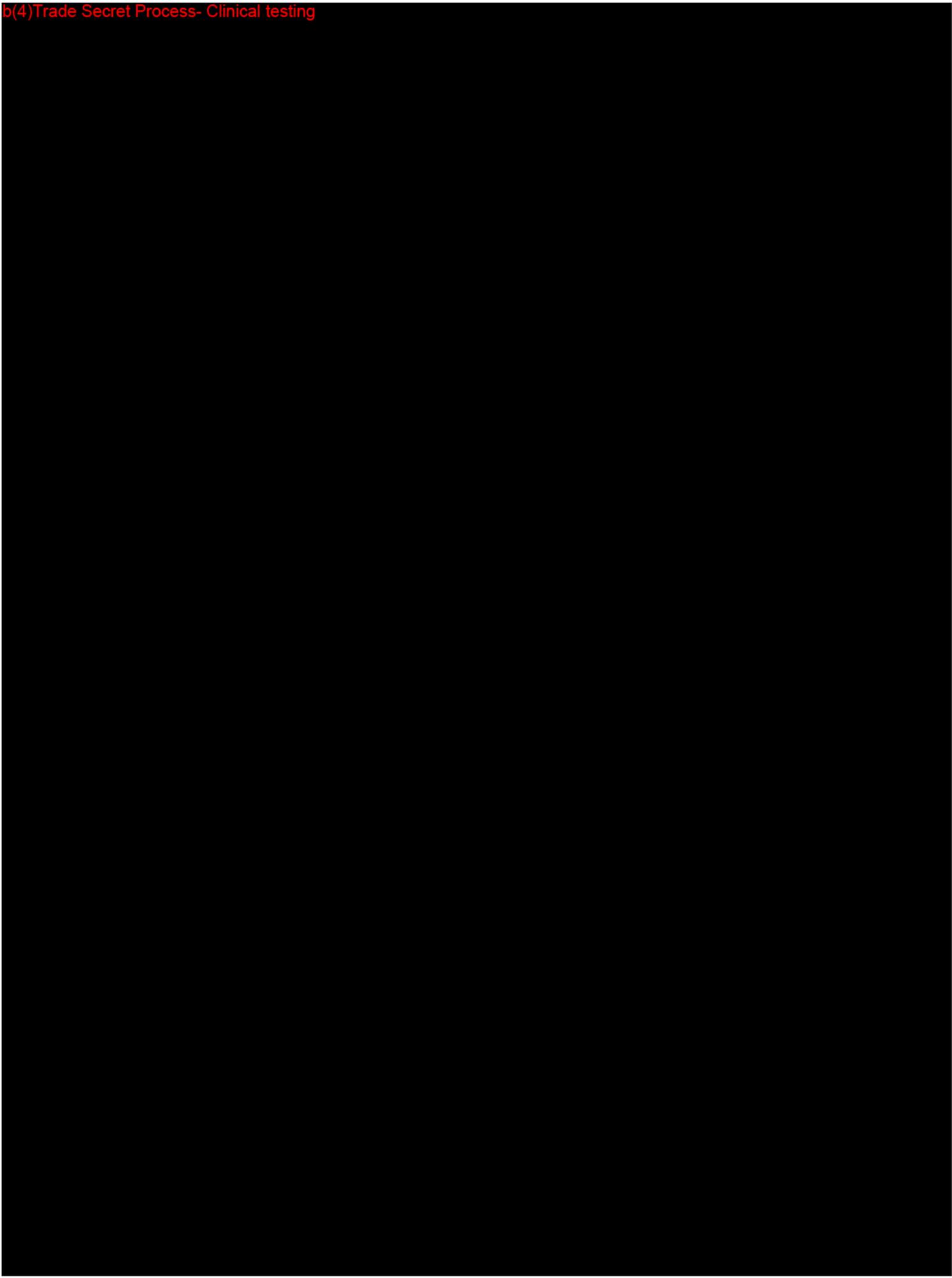
for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

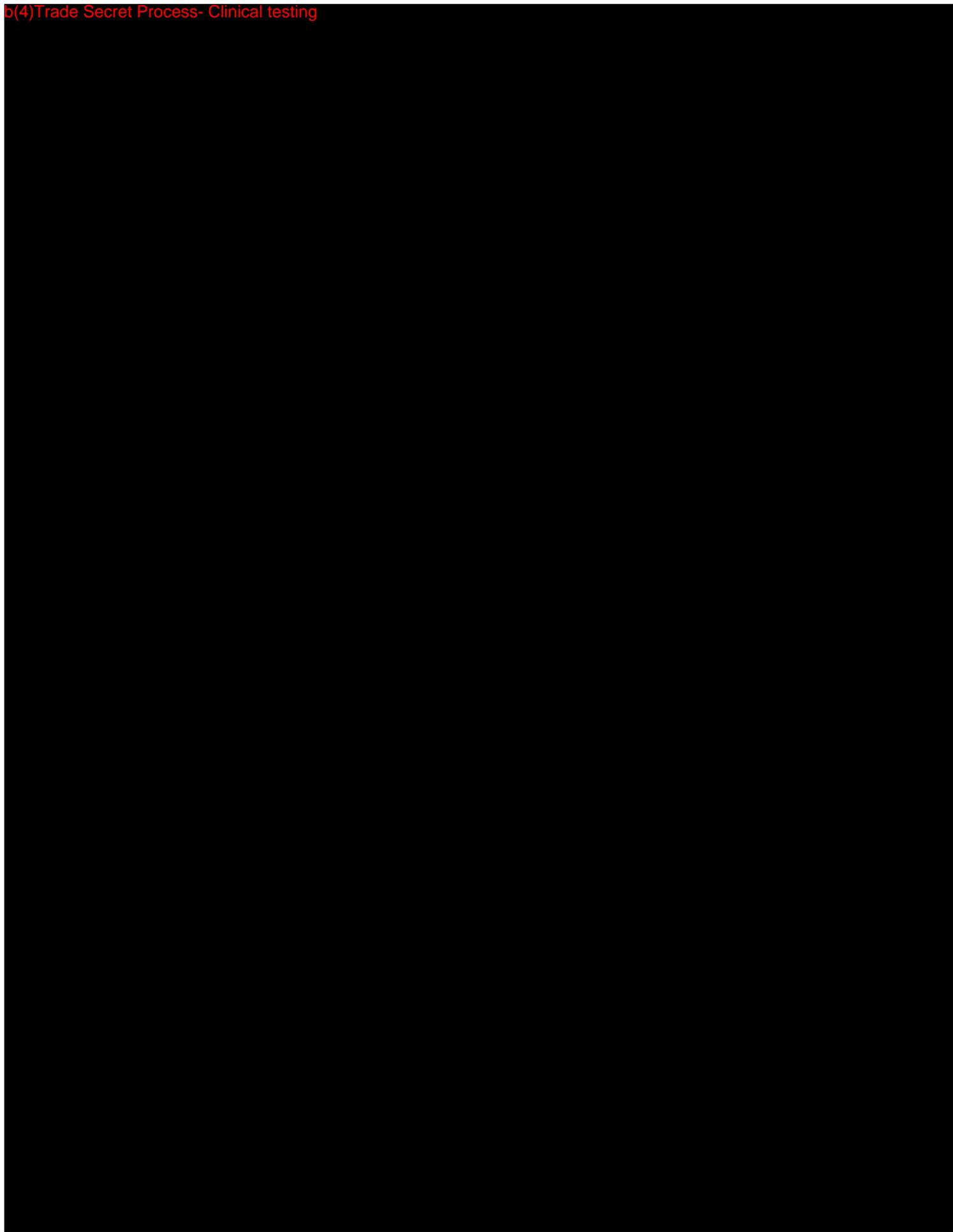


b(4)Trade Secret Process- Clinical testing





b(4)Trade Secret Process- Clinical testing



b(4)Trade Secret Process- Clinical testing



**CONTINUUM OF DEPTH OF SEDATION:
DEFINITION OF GENERAL ANESTHESIA AND LEVELS OF
SEDATION/ANALGESIA***

**Committee of Origin: Quality Management and Departmental Administration
(Approved by the ASA House of Delegates on October 27, 2004, and amended on
October 21, 2009)**

	<i>Minimal Sedation Anxiolysis</i>	<i>Moderate Sedation/ Analgesia</i> <i>(“Conscious Sedation”)</i>	<i>Deep Sedation/ Analgesia</i>	<i>General Anesthesia</i>
<i>Responsiveness</i>	Normal response to verbal stimulation	Purposeful** response to verbal or tactile stimulation	Purposeful** response following repeated or painful stimulation	Unarousable even with painful stimulus
<i>Airway</i>	Unaffected	No intervention required	Intervention may be required	Intervention often required
<i>Spontaneous Ventilation</i>	Unaffected	Adequate	May be inadequate	Frequently inadequate
<i>Cardiovascular Function</i>	Unaffected	Usually maintained	Usually maintained	May be impaired

Minimal Sedation (Anxiolysis) is a drug-induced state during which patients respond normally to verbal commands. Although cognitive function and physical coordination may be impaired, airway reflexes, and ventilatory and cardiovascular functions are unaffected.

Moderate Sedation/Analgesia (“Conscious Sedation”) is a drug-induced depression of consciousness during which patients respond purposefully** to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.

* Monitored Anesthesia Care does not describe the continuum of depth of sedation, rather it describes “a specific anesthesia service in which an anesthesiologist has been requested to participate in the care of a patient undergoing a diagnostic or therapeutic procedure.”

** Reflex withdrawal from a painful stimulus is NOT considered a purposeful response.

**CONTINUUM OF DEPTH OF SEDATION:
DEFINITION OF GENERAL ANESTHESIA AND LEVELS OF
SEDATION/ANALGESIA**

Deep Sedation/Analgesia is a drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully** following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained.

General Anesthesia is a drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired.

Because sedation is a continuum, it is not always possible to predict how an individual patient will respond. Hence, practitioners intending to produce a given level of sedation should be able to rescue*** patients whose level of sedation becomes deeper than initially intended. Individuals administering Moderate Sedation/Analgesia (“Conscious Sedation”) should be able to rescue*** patients who enter a state of Deep Sedation/Analgesia, while those administering Deep Sedation/Analgesia should be able to rescue*** patients who enter a state of General Anesthesia.

** Reflex withdrawal from a painful stimulus is NOT considered a purposeful response.

*** Rescue of a patient from a deeper level of sedation than intended is an intervention by a practitioner proficient in airway management and advanced life support. The qualified practitioner corrects adverse physiologic consequences of the deeper-than-intended level of sedation (such as hypoventilation, hypoxia and hypotension) and returns the patient to the originally intended level of sedation. It is not appropriate to continue the procedure at an unintended level of sedation.



Food and Drug Administration
1390 Piccard Drive
Rockville, MD 20850

OCT 12 1989

Mr. Michael W. Walsh
Apdyne Medical Company
955 West Idaho Avenue
St. Paul, Minnesota 55117

Re: K894369
Apdyne Phenol Applicator Kit
Dated: June 20, 1989
Received: July 14, 1989
Regulatory Class: I
21 CFR 874.5220

Dear Mr. Walsh:

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

If your device is classified (see above) into either class II (Performance Standards) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, the Food and Drug Administration (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 the Radiation Control for Health and Safety Act of 1968, or other Federal Laws or Regulations.

In addition, we have determined that your device contains the following component(s) subject to regulation as a drug(s): Phenol.

Our substantially equivalent determination does not apply to the drug component(s) of your device. For information on applicable Agency requirements for marketing this device, we suggest you contact:

Division of Drug Labeling Compliance (HFD-310)
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857
(301) 295-8063

This letter immediately will allow you to begin marketing your device as described, although we recommend that you first contact the Center for Drug Evaluation and Research before marketing your drug component(s). An FDA finding of substantial equivalence of your device to a pre-Amendments device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in anyway represent your device or its labeling as being approved by FDA. If you desire specific advice on the labeling for your device, please contact the Division of Compliance Operations, Regulatory Guidance Branch (HFZ-323) at (301) 427-8040. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,



David L. West, Ph.D.
Acting Deputy Director
Office of Device Evaluation
Center for Devices and
Radiological Health



Memorandum

July 14, 1989

From Director, Premarket Notification Staff (HFZ-404)
Office of Device Evaluation, CDRH

Subject Temporary Deferment of Activities Relating to Medical Device Submissions

To Premarket Notification (510(k)) Application Applicants

In an effort to consolidate CDRH offices, FDA has moved the Office of Device Evaluation (ODE) and other CDRH offices from their former Silver Spring, Maryland location to Rockville, Maryland. This move occurred in late June through mid July, 1989. Because FDA moved all staff, equipment and files, ODE was unable to start or continue work on new and existing submissions and reports until the relocation was completed. Therefore, ODE has temporarily deferred action on premarket approval applications, premarket notifications and investigational device exemption applications as stated in the Federal Register (54 FR 25705) on June 16, 1989.

This deferment period was from June 26 through July 13, 1989. During this period, ODE continued to accept mail, but we did not officially log it in or commence review. No statutory review period commenced during this time and the statutory review periods on pending submissions were suspended during this relocation. Therefore, the 90-day review period may be exceeded by up to 18 calendar days and you may not market your device without written clearance from FDA.

The Post Office will forward all mail addressed to the Silver Spring facility to our new location for a period of one year after the move. All premarket approval application, premarket notification and investigational device exemption application submissions should be addressed as follows:

Office of Device Evaluation
(PMA, 510(k) or IDE, as appropriate) Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
1390 Piccard Drive
Rockville, Maryland 20850

If you have any questions regarding ODE's move to the Rockville, Maryland area, you may telephone CDRH's Division of Small Manufacturers Assistance at 800-638-2041 or 301-443-6597.

Heather S. Roscrows /for
Robert I. Chissler

OCT 12 1989

~~OCT 11 1989~~

Mr. Michael W. Walsh
Apdyne Medical Company
955 West Idaho Avenue
St. Paul, Minnesota 55117

Re: K894369
Apdyne Phenol Applicator Kit
Dated: June 20, 1989
Received: July 14, 1989
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Division of Drug Labeling Compliance (HFD-310)
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857
(301) 295-3157

AVAILABLE

4

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Page 2 - Mr. Micheal W. Walsh

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Sincerely yours,



David L. West, Ph.D.
Acting Deputy Director
Office of Device Evaluation
Center for Devices and
Radiological Health

cc: HFZ-401
HFZ-470
D.O.

MKJeffries:mkc:10/2/89
MelodyII/#45

BEST COPY AVAILABLE

FILE
COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
2-470	Jeffries	10/3/89	372	Jones	10/11/89			
2-470	Shulman	10/5	404	Chase	10/1/89			
404	Shulman	10/2/89						



Memorandum

ate .

From REVIEWER(S) - NAME(S) Melpomeni K. Jeffries

Subject 510(k) NOTIFICATION K894369

To THE RECORD

It is my recommendation that the subject 510(k) Notification:

- (A) Is substantially equivalent to marketed devices. / *Drug component.*
- (B) Requires premarket approval. NOT substantially equivalent to marketed devices.
- (C) Requires more data.
- (D) Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Additional Comments:

*→ Package with drug component - Pleural.
Special letter, hley
OCT 12 1989 - I telephoned Mr. Walsh. He was not in today. I spoke to Ms. Randy Walsh and informed her of this decision. etc*

The submitter requests under 21 CFR §807.95:

Predicate Product Code w/Panel and class:

- No Confidentiality
- Confidentiality for 90 days
- Continued Confidentiality exceeding 90 days

KCJ / EN / I
CFR: 874.5220
Additional Product Code(s) w/Panel (optional):

REVIEW: David C. Segerson
(BRANCH CHIEF)

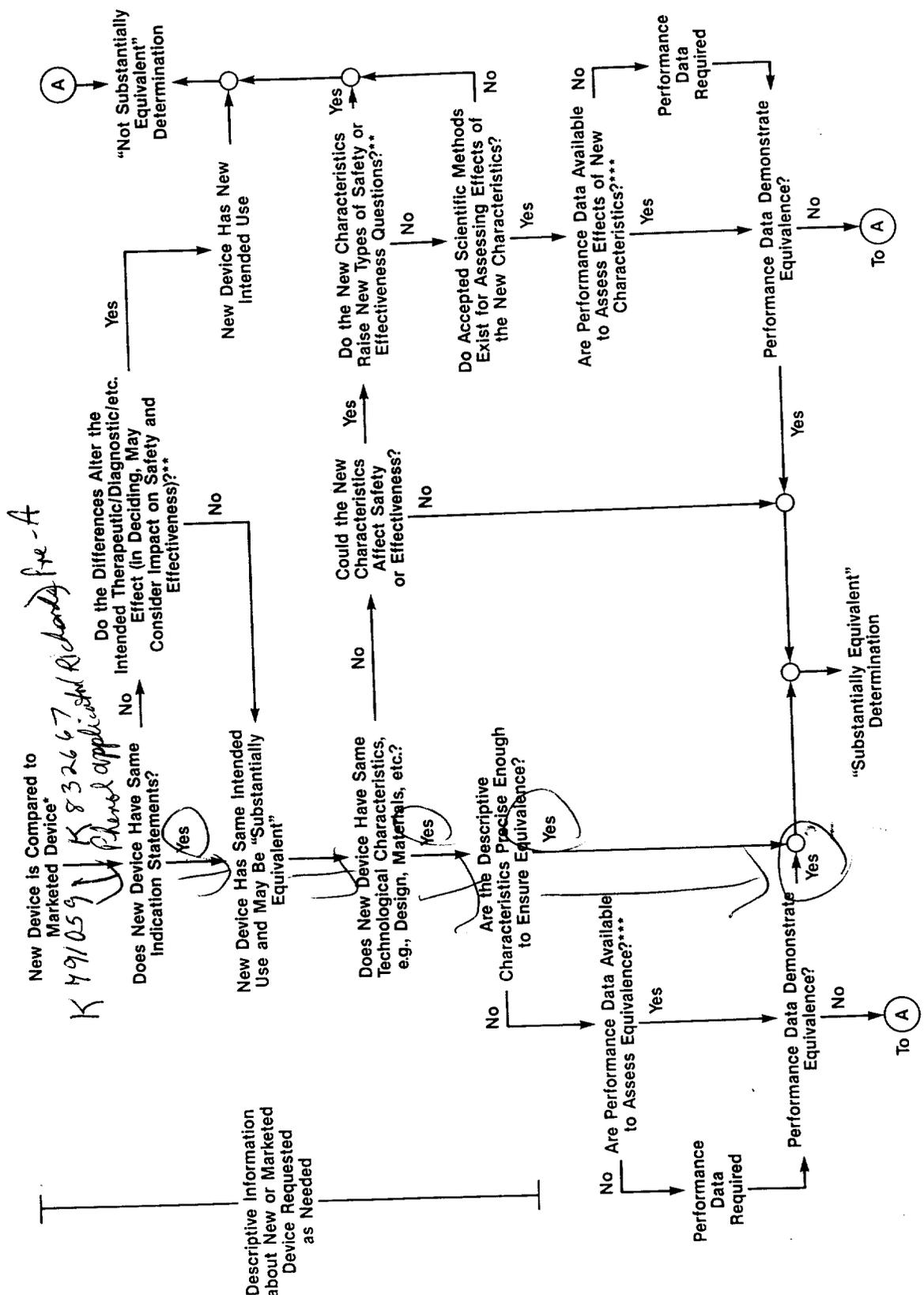
10/3/89
(DATE)

FINAL REVIEW: David C. Segerson
(DIVISION DIRECTOR)

10/5/89
(DATE)

6

510(k) "Substantial Equivalence" Decision-Making Process (Detailed)



** 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.

* 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.

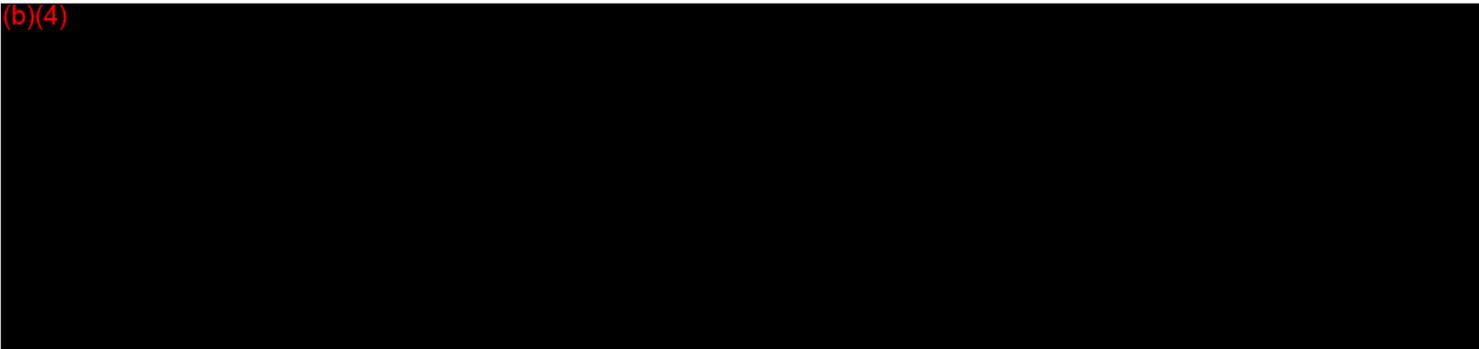
OB/GYN AND ENT & DENTAL REVIEW FORM

DOC#K894369 Date received by reviewer: 8/2/89
510 (k) x IDE PMA
 x original
 amendment
 supplement

Summary:

The ApDyne Medical Company a submitted a 510 (k) notification for the Apdyne Phenol Applicator Kit. The submission includes draft copies of labeling and product enclosure, indication for use, predicate information and specifications. Predicate devices include the Rhichards Pheno|applicator a pre-amendments device, Lucae's Ear applicator, K832667 and the Pope Oto-wick, K791059.

Analysis:



The Apdyne Phenol Applicator Kit is substantially equivalent to the predicate devices. Since the kit contains a drug, Phenol, a special paragraph pertaining to drug compliance with the Act should be inserted into the substantially equivalent letter.

Reviewer: Melpomeni K. Jeffries 9/21/89
Melpomeni K. Jeffries

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
1390 Piccard Drive
Rockville, Maryland 20850

JULY 20, 1989

APDYNE MEDICAL CO.
ATTN: MICHAEL W. WALSH
955 WEST IDAHO AVE.
ST. PAUL, MN 55117

D.C. Number : K894369
Received : 07-14-89
90th Day : 10-12-89
Product : APDYNE PHENOL
APPLICATOR KIT

-- The Premarket Notification you have submitted as required under Section 510(k) of the Federal Food, Drug, and Cosmetic Act for the above referenced device has been received and assigned an unique document control number (D.C. Number above). Please cite this D.C. Number in any future correspondence that relates to this submission.

We will notify you when the processing of this submission has been completed or if any additional information is required. You are required to wait ninety (90) days after the received date shown above or until receipt of a "substantially equivalent" letter before placing the product into commercial distribution. We intend to complete our review expeditiously and within ninety days. Occasionally, however, a submitter will not receive a final decision or a request for additional information until after ninety days has elapsed. Be aware that FDA is able to continue the review of a submission beyond the ninety day period and might conclude that the device is not substantially equivalent. A "not substantially equivalent" device may not be in commercial distribution without an approved premarket approval application or reclassification of the device. We, therefore, recommend that you not market this device before FDA has made a final decision. Thus, if you have not received a decision within ninety days, it would be prudent to check with FDA to determine the status of your submission.

All correspondence concerning your submission MUST be sent to the Document Mail Center at the above address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification application. Telefax material will not be accepted nor considered as part of your official premarket notification application, unless specifically requested of you by an FDA official.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or their toll-free number (800) 638-2041, or contact me at (301) 427-1190.

Sincerely yours,

Robert I. Chissler
Premarket Notification Coordinator
Office of Device Evaluation
Center for Devices and
Radiological Health

Date: October 19, 1989

To: Larry Severeid, M.D.
John Walsh, M.D.
Mike Walsh
cc - Letter to File

From: Richard Erickson

Good news. Mike spoke with our reviewer, Bob Kessler, from the FDA on October 12th. They have completed the review of our 510(k) application and determined it is substantially equivalent (i.e. - we received the 510(k))! He also said we needed to confirm that there would be no additional FDA requirements for the phenol in the kit. Mike spoke with the "Division of Drug Labeling Compliance" and they confirmed that since we will only repackage and relabel U.S.P. grade Phenol no additional approvals are required. This is provided we maintain our FDA registration and follow Good Manufacturing Practices.

I will contact all of you soon to set up a meeting next month to address final issues on the corporation.

Sincerely,



Liquefied Phenol
U.S.P./N.F.
APDYNE MEDICAL COMPANY

DESCRIPTION: Liquefied phenol is a colorless, or faintly colored caustic liquid with characteristic and not tarry odor. It is a solution of 10% water and 90% phenol which is miscible with alcohol, ether, and glycerol and is soluble in water.

CLINICAL PHARMACOLOGY: Liquefied phenol is both an anesthetic and an antiseptic. It penetrates squamous epithelium and may denature protein causing a depolarizing local anesthesia. Liquefied phenol is also bactericidal and fungicidal with some sporicidal and virucidal activity.

Phenol is absorbed through the gastrointestinal tract and directly through the skin and mucous membranes. It is metabolized to phenyl-glucuronide and phenyl sulfate and small amounts are oxidized to catchol and quinol which are mainly conjugated. The metabolites are excreted in the urine and when oxidized to quinones may tint the urine green.

INDICATIONS AND USAGE: Liquefied phenol is a useful topical anesthetic for the tympanic membrane. It simultaneously coagulates, sterilizes and anesthetizes the epithelium of the tympanic membrane prior to myringotomy.

CONTRAINDICATIONS: Liquefied phenol used as a topical anesthetic for the tympanic membrane ~~prior to myringotomy is contraindicated in the~~ presence of pre-existing tympanic membrane perforation, known allergy or hypersensitivity to phenol and in individuals such as young children or the mentally impaired whose ability to remain still during its application is unreliable.

WARNINGS: Local inflammation may occur in individuals with hypersensitivity to phenol. Phenol applied topically to the tympanic membrane has been reported to cause necrosis of the tympanic membrane. ~~Liquefied phenol instilled into the~~ middle ear has caused nerve deafness and may cause facial paralysis with dehiscence of the bone over the fallopian canal. Liquefied phenol is absorbed directly through the skin and prolonged contact may cause chemical burns. Contact over large areas may cause systemic toxicity (see precautions).

PRECAUTIONS: Liquefied phenol should be applied to the tympanic membrane only with ~~applicators designed for this purpose.~~ Prior to myringotomy any excess phenol should be removed from the surface of the tympanic membrane and the ear canal by suction as the excess phenol may be drawn into the middle ear during myringotomy (see warnings). In the presence of an atrophic tympanic membrane phenol may erode through to the middle ear. Incision during myringotomy following topical anesthetic with liquefied phenol should be confined to the blanched area of the tympanic membrane which corresponds to the area anesthetized. During myringotomy following topical anesthesia with liquefied phenol care should be taken to avoid the medial wall of the middle ear as it will not be anesthetized.

Contact of liquefied phenol with the skin should be avoided as it may cause severe irritation with second to third degree burns; areas usually turn white and later yellowish-brown and may be deeply eroded and scarred. Solutions are readily absorbed through the skin and may cause profuse perspiration, intense thirst, nausea and vomiting, diarrhea, cyanosis from methemoglobinemia, hyperactivity, stupor, hypotension, hyperpnea, abdominal pain, hemolysis, convulsions, coma, and pulmonary edema followed by pneumonia. If death from respiratory failure is not immediate, jaundice and oliguria or anuria may occur. Skin sensitization occurs occasionally. A profound fulminating central nervous system depression with coma, hypothermia, loss of vasoconstrictor tone, cardiac depression, cerebral edema and respiratory arrest are common manifestations of systemic poisoning in man. However, stridorous breathing, mucus rales, froth at the mouth and nose eventually occur. Liver, kidney and bladder damage may occur.

ADVERSE REACTIONS: Following application of liquefied phenol to the tympanic membrane nerve deafness has occurred as well as necrosis of the tympanic membrane. Applied to the skin phenol causes blanching and corrosion. A lab technician exposed to an unknown amount developed anorexia, weight loss, weakness, muscle aches and pain, dark urine and tender enlargement of the liver. A case of unconsciousness within five minutes was reported after rubbing a child's head with a solution of phenol. Profound coma has occurred in less than 30 minutes.

OVERDOSAGE: Topically applied liquefied phenol can be absorbed in sufficient amounts to provide systemic effects (see precautions).

For treatment of skin contact remove contaminated clothing and shoes immediately. Wash affected area with soap or mild detergent in large amounts of water until no evidence of chemical remains (at least 15-20 minutes). In case of chemical burns cover area with sterile, dry dressings. Bandage securely, but not too tightly. Seek medical attention immediately.

For eye contact wash eyes immediately with large amounts of water, occasionally lifting upper and lower lids until no evidence of chemical remains (at least 15-20 minutes). In case of burns, apply sterile bandages loosely without medication. Seek medical attention immediately.

In case of ingestion, if the victim is conscious, and if corrosive injury is absent, remove poison by gastric lavage or emesis. Activated charcoal is useful. Follow with 60 ml. of castor oil, which dissolves phenol, retards its absorption and hastens its removal. Follow castor oil by giving 30-60 ml. of Fleet's phospho-soda diluted 1:4 in water. Gastric lavage and emesis are not to be used in the presence of esophageal injury. Gastric lavage or emesis should not be performed on an unconscious person. Gastric lavage should be performed by qualified medical personnel. Medical attention should be sought immediately.

No specific antidote is available. Treat symptomatically and supportively.

DOSAGE AND ADMINISTRATION: Following exposure of the tympanic membrane with an ear speculum the phenol applicator is dipped in the liquefied phenol until it is dripping wet. The tip of the applicator is then touched to the edge of the vial and the excess phenol is allowed to flow back into the vial, leaving the tip soaked but not dripping. Under direct visualization the applicator is swept against the tympanic membrane over the desired site of incision with immediate blanching of the epithelium and profound anesthesia. The applicator is then withdrawn and any excess phenol removed with suction. Myringotomy is performed immediately through the area of blanching. Care should be taken not to touch the medial wall of the middle ear as it is not anesthetized. There is sufficient anesthesia surrounding the myringotomy opening that a small suction tip can be placed directly into the lips of the myringotomy and the middle ear effusions suctioned away.

HOW SUPPLIED: Liquefied phenol is supplied in the single use screw top vials containing 0.20 ml. of liquefied phenol.

Storage: Protect from light and heat.

Caution: Federal (U.S.A.) law prohibits dispensing without prescription.

APDYNE MEDICAL COMPANY
1049 SOUTH VINE STREET
DENVER, CO 80209-4622



**Liquefied Phenol
U.S.P./N.F.**

APDYNE MEDICAL COMPANY

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HOW SUPPLIED: Liquefied phenol is supplied in the single use screw top vials containing 0.20 ml. of liquefied phenol.

Storage: Protect from light and heat.

Caution: Federal (U.S.A.) law prohibits dispensing without prescription.

APDYNE MEDICAL COMPANY
1049 SOUTH VINE STREET
DENVER, CO 80209-4622



Safety of Phenol and Local Use on the Tympanic Membrane in Children and Adults

Support of the safe use of phenol for anesthetizing the tympanic Membrane

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"Is Phenol a Safe Local Anaesthetic for Grommet Insertion?" *The Journal of Laryngology and Otology* 121, no. 12 (December 2007): 1213–14; author reply 1214.

Guidelines

Topical anesthetic, including Phenol, for tympanostomy procedures on children:

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From: Mann, Eric A [<mailto:Eric.Mann@fda.hhs.gov>]
Sent: Friday, November 21, 2014 12:28 PM
To: Steve Anderson
Cc: Keith Leland; Nandkumar, Srinivas; George, Sageev; Bertram, James
Subject: RE: 510(k) K133921 response items

Hello Mr. Anderson,

I have spoken with several individuals in the Office regarding your query, and I reviewed the administrative record for the Apdyne Phenol Applicator Kit (K894369). Please see the attached SE letter for the Apdyne Phenol Applicator Kit. It explicitly indicates that the 510(k) clearance is for the applicator device and not the drug component. The letter instructs the sponsor to contact the Center for Drug Evaluation and Research (CDER) regarding the regulatory requirements for the drug component of the kit, i.e., phenol. (b)(4)

[REDACTED]

[REDACTED]

Regards,

*Eric A. Mann, MD, PhD
CAPT, USPHS
Clinical Deputy Director
DOED/ODE/CDRH/FDA
Phone: 301-796-6460
FAX: 301-847-8126*

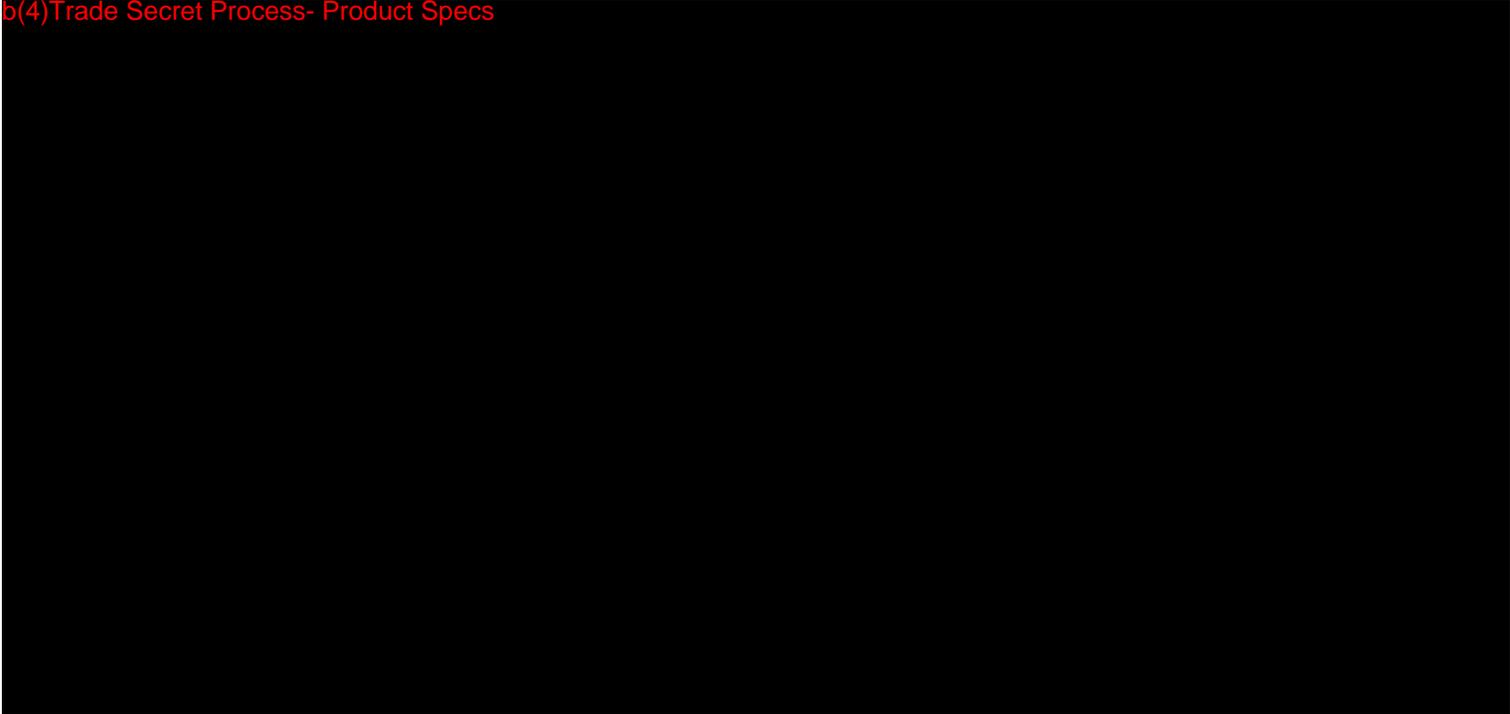
Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:

<https://www.research.net/s/cdrhcustomerservice?O=400&D=450&B=451&E=&S=E>

From: Steve Anderson [<mailto:steve@preceptismedical.com>]
Sent: Monday, November 17, 2014 12:31 PM
To: Mann, Eric A
Cc: Keith Leland
Subject: RE: 510(k) K133921 response items

Dr. Mann,

b(4)Trade Secret Process- Product Specs



Sincerely,

*Steve Anderson | CEO | Preceptis Medical, Inc.
505 Highway 169 N, Suite #365
Plymouth, MN 55441
763-568-7809 Work
612-327-4795 Mobile*



From: Mann, Eric A [<mailto:Eric.Mann@fda.hhs.gov>]
Sent: Friday, October 31, 2014 10:24 AM
To: Keith Leland
Cc: George, Sageev; Nandkumar, Srinivas; Steve Anderson
Subject: RE: 510(k) K133921 response items

Mr. Leland,

(b) (4)



Regards,

*Eric A. Mann, MD, PhD
CAPT, USPHS
Clinical Deputy Director
DOED/ODE/CDRH/FDA
Phone: 301-796-6460
FAX: 301-847-8126*

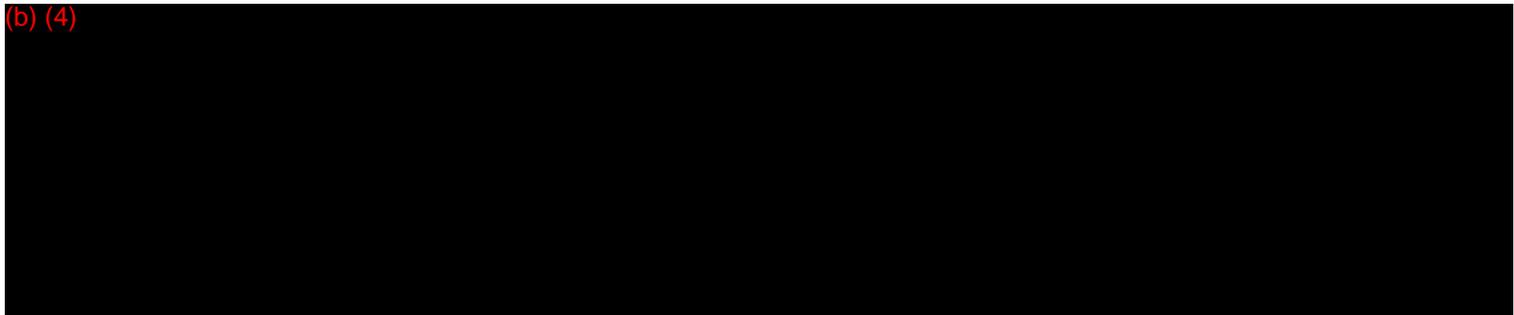
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<https://www.research.net/s/cdrhcustomerservice?O=400&D=450&B=451&E=&S=F>

From: Keith Leland [<mailto:Keith@preceptismedical.com>]
Sent: Friday, October 31, 2014 10:43 AM
To: Mann, Eric A
Cc: George, Sageev; Nandkumar, Srinivas; Steve Anderson
Subject: RE: 510(k) K133921 response items

Dr. Mann,

(b) (4)

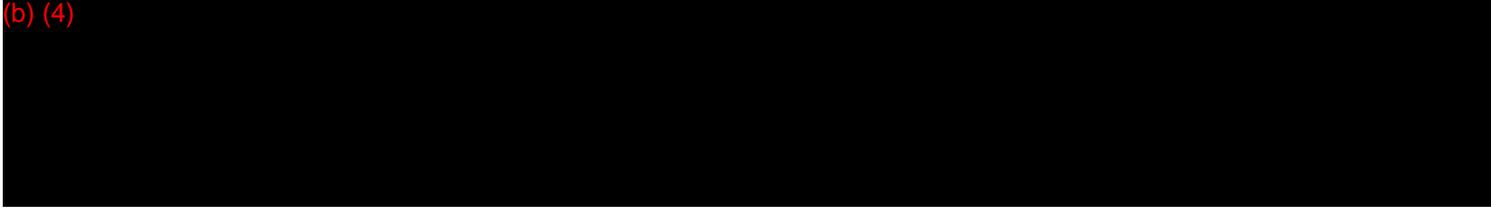


Sincerely,
Keith Leland

From: Mann, Eric A [<mailto:Eric.Mann@fda.hhs.gov>]
Sent: Thursday, October 30, 2014 2:53 PM
To: Keith Leland
Cc: George, Sageev; Nandkumar, Srinivas
Subject: FW: 510(k) K133921 response items

Hello Mr. Leland,

(b) (4)



Regards,

*Eric A. Mann, MD, PhD
CAPT, USPHS
Clinical Deputy Director
DOED/ODE/CDRH/FDA
Phone: 301-796-6460
FAX: 301-847-8126*

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K142282

Section 3
Cover Letter and Acceptance Checklist



14 August 2014

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

FDA CDRH DMC

AUG 15 2014

Received _____

RE: Traditional 510(k) Premarket Notification - 21 CFR 807.90(e)
Preceptis Medical, Inc.

To Whom It May Concern:

The enclosed Traditional 510(k) Pre-Market Notification requests clearance for the clinical use of the Hummingbird™ Tympanostomy Tube System (TTS). This product is preceded by the previous predicates:

1. The Summit Medical ventilation tube (cleared under K830228 **b(4)Trade**)
(b) (4)



2. The Heinz-Kurz Trocar Ventilation Tube – TVT (cleared under K071150).
3. The Preceptis Tympanostomy Tube Inserter (TTI) (i.e., myringotomy tube introducer) is a Class I device as defined in 874.4420(a) of 21 CFR, Ear, nose, and throat manual surgical instrument -- exempt from the premarket notification procedures in Part 807.
4. The Preceptis TTI Convenience Kit consists of the 510k exempt TTI packaged in a convenience kit with the **(b) (4)** ventilation tube. Per the FDA kit guidance, this convenience kit is exempt from 510k requirements since the components consist of an exempt myringotomy tube inserter (the TTI) and an already 510k-cleared ventilation tube.

This 510k submission for the Hummingbird™ Tympanostomy Tube System thereby consists of the four predicates above with the only difference being that the **(b) (4)** **b(4)Trad** ventilation tube is now packaged pre-loaded into the TTI for ease of use for the surgeon. Within this submission, the sponsor will demonstrate that the TTS

Preceptis Medical, Inc • 505 Hwy 169 North, #365 • Plymouth, MN 55441

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2-copy
1-cd

Section 3

Cover Letter and Acceptance Checklist

delivers the (b) (4) ventilation tube as designed, that the TTS safely and effectively inserts tympanostomy tubes into pediatric patients under moderate sedation or general anesthesia provided in a hospital or ASC setting by an anesthesia provider,

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

The abbreviations MTI (Myringotomy Tube Inserter), TTI (Tympanostomy Tube Inserter), TTS (Tympanostomy Tube System), and HTTS (Hummingbird™ Tympanostomy Tube System) used in this submission all refer to the candidate device.

A pending prior submission for this device has been made (K133921), in which the instructions for use specified general anesthesia for pediatric procedures. This new submission is submitted to request clearance for a modified instructions for use, with moderate sedation being specified in addition to general anesthesia for pediatric procedures.

General information for the subject device is provided in the table below.

General Information	
Trade Name	Hummingbird™ Tympanostomy Tube System (TTS)
Common Name	Tympanostomy Tube Inserter with pre-loaded ventilation tube
Predicate 510(k)	<ul style="list-style-type: none">• Micromedics, Inc., Ventilation tube 510(k) #K830228 (Micromedics name has been changed to Summit Medical)• Heinz-Kurz Trocar Ventilation Tube 510(k) K071150• Preceptis TTI (Class I, Exempt)• Preceptis TTI Convenience Kit (TTI packaged in kit with Summit Medical Ventilation Tube)
Product Code	ETD
Classification	Ear Nose & Throat
Review Panel	Ear Nose & Throat
Manufacturer	Preceptis Medical, Inc.
Registration #	3010610937

This premarket notification is organized following the recommendations contained in the CDRH guidance titled *Format for Traditional and Abbreviated 510(k)s* (August 12, 2005). As recommended in the FDA guidance, a table summarizing the device design and use is provided on the following page.

Section 3
Cover Letter and Acceptance Checklist

Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?	X	
Is the device intended for single use?	X	
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?		NA
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?		X
Does the submission include clinical information?	X	
Is the device implanted?	X	

Contact Information	
Primary contact person	Alternate contact person
Keith Leland VP of R&D Tel: 763.568.7819; Fax: 763.568.7820 Email: keith@preceptismedical.com	Steve Anderson President and CEO Tel: 763.568.7809; Fax: 763.568.7820 Email: steve@preceptismedical.com

This 510(k) submission, and the information it contains, is considered confidential; Preceptis Medical, Inc. respectfully requests that the FDA give it the maximum protection provided by law per 21 CFR 807.95.

In accordance with Section 510(k) of the Federal Food, Drug and Cosmetic Act and in conformance with 21 CFR 807, one (1) complete original paper submission and one (1) eCopy on CD-ROM, which is a complete and exact copy of the paper submission, are provided. If you require further information, please contact me.

Sincerely,

Keith Leland



VP of R&D
 Preceptis Medical, Inc.
 505 Highway 169 N, #365
 Plymouth, Minnesota 55441



Preceptis
MEDICAL

14 August 2014

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – W066-G609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

FDA CDRH DMC
AUG 15 2014
Received

**RE: Traditional 510(k) Premarket Notification – 21 CFR 807.90(e)
Preceptis Medical, Inc.**

To Whom It May Concern:

Please find included an eCopy of the traditional 510(k) being submitted by
Preceptis Medical, Inc.

The eCopy is an exact duplicate of the paper copy.

Sincerely,

Keith Leland

105
1-CD
1-COPY

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Section 1 MDUFMA

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION MEDICAL DEVICE USER FEE COVER SHEET	PAYMENT IDENTIFICATION NUMBER: (b) (4) Write the Payment Identification number on your check.
A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/cover sheet.html	
1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code) PRECEPTIS MEDICAL INC 505 HIGHWAY 169 N STE 365 PLYMOUTH MN US 554416434 US 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) *****8728	2. CONTACT NAME Keith Leland 2.1 E-MAIL ADDRESS keith@preceptismedical.com 2.2 TELEPHONE NUMBER (include Area code) 612-353 7011 2.3 FACSIMILE (FAX) NUMBER (Include Area code)
3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm) <u>Select an application type:</u>	
<input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party <input type="checkbox"/> 513(g) Request for Information <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR) <input type="checkbox"/> 30-Day Notice	3.1 Select a center <input checked="" type="checkbox"/> CDRH <input type="checkbox"/> CBER 3.2 <u>Select one of the types below</u> <input checked="" type="checkbox"/> Original Application <u>Supplement Types:</u> <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP)
4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status) <input checked="" type="checkbox"/> YES, I meet the small business criteria and have submitted the required qualifying documents to FDA NO, I am not a small business 4.1 If Yes, please enter your Small Business Decision Number: SBD148195	

Section 1
MDUFMA

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?

YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.)

NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see <http://www.fda.gov/cdrh/mdufma> for additional information)

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

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

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

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

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

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).)

YES NO

PAPERWORK REDUCTION ACT STATEMENT

Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 8455 Colesville Road, COLE-14-14253 Silver Spring, MD 20993-0002
[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

(b) (4)

14-Aug-2014

Section 2

CDRH Premarket Review Submission Cover Sheet

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION CDRH PREMARKET REVIEW SUBMISSION COVER SHEET			Form Approval OMB No. 0910-0120 Expiration Date: December 31, 2013 See PRA Statement on page 5.		
Date of Submission		User Fee Payment ID Number		FDA Submission Document Number (if known)	
SECTION A TYPE OF SUBMISSION					
PMA <input type="checkbox"/> Original Submission <input type="checkbox"/> Premarket Report <input type="checkbox"/> Modular Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment <input type="checkbox"/> Licensing Agreement	PMA & HDE Supplement <input type="checkbox"/> Regular (180 day) <input type="checkbox"/> Special <input type="checkbox"/> Panel Track (PMA Only) <input type="checkbox"/> 30-day Supplement <input type="checkbox"/> 30-day Notice <input type="checkbox"/> 135-day Supplement <input type="checkbox"/> Real-time Review <input type="checkbox"/> Amendment to PMA & HDE Supplement <input type="checkbox"/> Other	PDP <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP	510(k) <input checked="" type="checkbox"/> Original Submission: <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated (Complete section I, Page 5) <input type="checkbox"/> Additional Information <input type="checkbox"/> Third Party	Request for Feedback <input type="checkbox"/> Pre-Submission <input type="checkbox"/> Informational Meeting <input type="checkbox"/> Submission Issue Meeting <input type="checkbox"/> Day 100 Meeting <input type="checkbox"/> Agreement Meeting <input type="checkbox"/> Determination Meeting <input type="checkbox"/> Study Risk Determination <input type="checkbox"/> Other (specify):	
IDE <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	Humanitarian Device Exemption (HDE) <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	Class II Exemption Petition <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Evaluation of Automatic Class III Designation (De Novo) <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Other Submission <input type="checkbox"/> 513(g) <input type="checkbox"/> Other (describe submission):	
Have you used or cited Standards in your submission? <input type="checkbox"/> Yes <input type="checkbox"/> No (If Yes, please complete Section I, Page 5)					
SECTION B SUBMITTER, APPLICANT OR SPONSOR					
Company / Institution Name			Establishment Registration Number (if known)		
Preceptis Medical, Inc.			3010610937		
Division Name (if applicable)			Phone Number (including area code)		
			763-568-7819		
Street Address			FAX Number (including area code)		
505 Highway 169 North, #365			763-568-7820		
City		State / Province	ZIP/Postal Code	Country	
Plymouth		MN	55441	USA	
Contact Name					
Keith Leland					
Contact Title			Contact E-mail Address		
Vice President of Research and Development			keith@preceptismedical.com		
SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)					
Company / Institution Name					
Division Name (if applicable)			Phone Number (including area code)		
Street Address			FAX Number (including area code)		
City		State / Province	ZIP Code	Country	
Contact Name					
Contact Title			Contact E-mail Address		

Section 2

CDRH Premarket Review Submission Cover Sheet

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

Section 2

CDRH Premarket Review Submission Cover Sheet

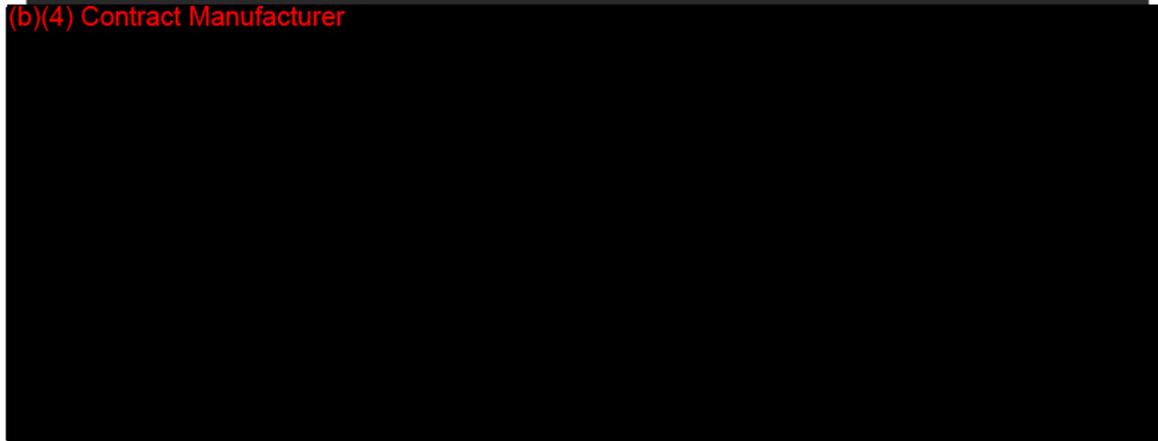
SECTION E								ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS							
Product codes of devices to which substantial equivalence is claimed								Summary of, or statement concerning, safety and effectiveness information <input checked="" type="checkbox"/> 510 (k) summary attached <input type="checkbox"/> 510 (k) statement							
1	ETD	2	ETD	3	ETD	4	JYM								
5		6		7		8									
Information on devices to which substantial equivalence is claimed (if known)															
510(k) Number				Trade or Proprietary or Model Name				Manufacturer							
1	K830228	1	OTOLOGIC VENTILATION TUBES - VARIOUS	1	SUMMIT MEDICAL, INC. formerly MicroMedics, Inc.										
2	K071150	2	Trocar Ventilation Tube with Trocar Tip / Trocar Handle	2	Heinz Kurz GMBH Medizintechnik Amsterdam, NL D-72144										
3	N/A	3	Preceptis Tympanostomy Tube Inserter Convenience Kit (PN 05-1001-005)	3	Preceptis Medical, Inc. Plymouth MN 55340										
4	N/A	4	Preceptis Tympanostomy Tube Inserter (PN 05-1001-006)	4	Preceptis Medical, Inc. Plymouth MN 55340										
5		5		5											
6		6		6											
SECTION F								PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS							
Common or usual name or classification name Tympanostomy Tube and Tympanostomy Tube Inserter															
Trade or Proprietary or Model Name for This Device								Model Number							
1	Hummingbird(TM) Tympanostomy Tube System (TTS)							1	05-1001-50X						
2								2							
3								3							
4								4							
5								5							
FDA document numbers of all prior related submissions (regardless of outcome)															
1	2	3	4	5	6	7	8	9	10	11	12				
Data Included in Submission <input checked="" type="checkbox"/> Laboratory Testing <input type="checkbox"/> Animal Trials <input checked="" type="checkbox"/> Human Trials															
SECTION G								PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS							
Product Code ETD				C.F.R. Section (if applicable) 21 CFR 874.3880				Device Class <input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified							
Classification Panel Ear, Nose and Throat Devices															
Indications (from labeling) The Tympanostomy Tube Inserter (TTI) is intended to deliver a tympanostomy tube in tympanostomy procedures in which the patient is receiving a tympanostomy tube.															

Section 2

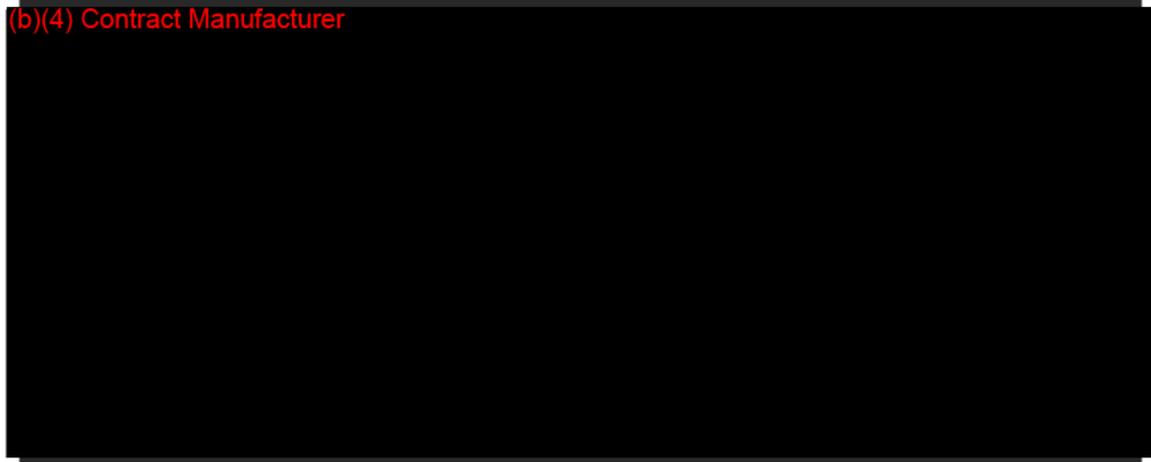
CDRH Premarket Review Submission Cover Sheet

Note: Submission of the information entered in Section H does not affect the need to submit device establishment registration.		FDA Document Number <i>(if known)</i>	
SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION			
<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	Facility Establishment Identifier (FEI) Number		<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler
Company / Institution Name Preceptis Medical		Establishment Registration Number	
Division Name <i>(if applicable)</i>		Phone Number <i>(including area code)</i> 763-568-7819	
Street Address 505 Highway 169 North, #365		FAX Number <i>(including area code)</i> 763-568-7820	
City Plymouth		State / Province MN	ZIP Code 55441
Contact Name Keith Leland		Contact Title VP of Research and Development	Contact E-mail Address keith@preceptismedical.com

(b)(4) Contract Manufacturer



(b)(4) Contract Manufacturer

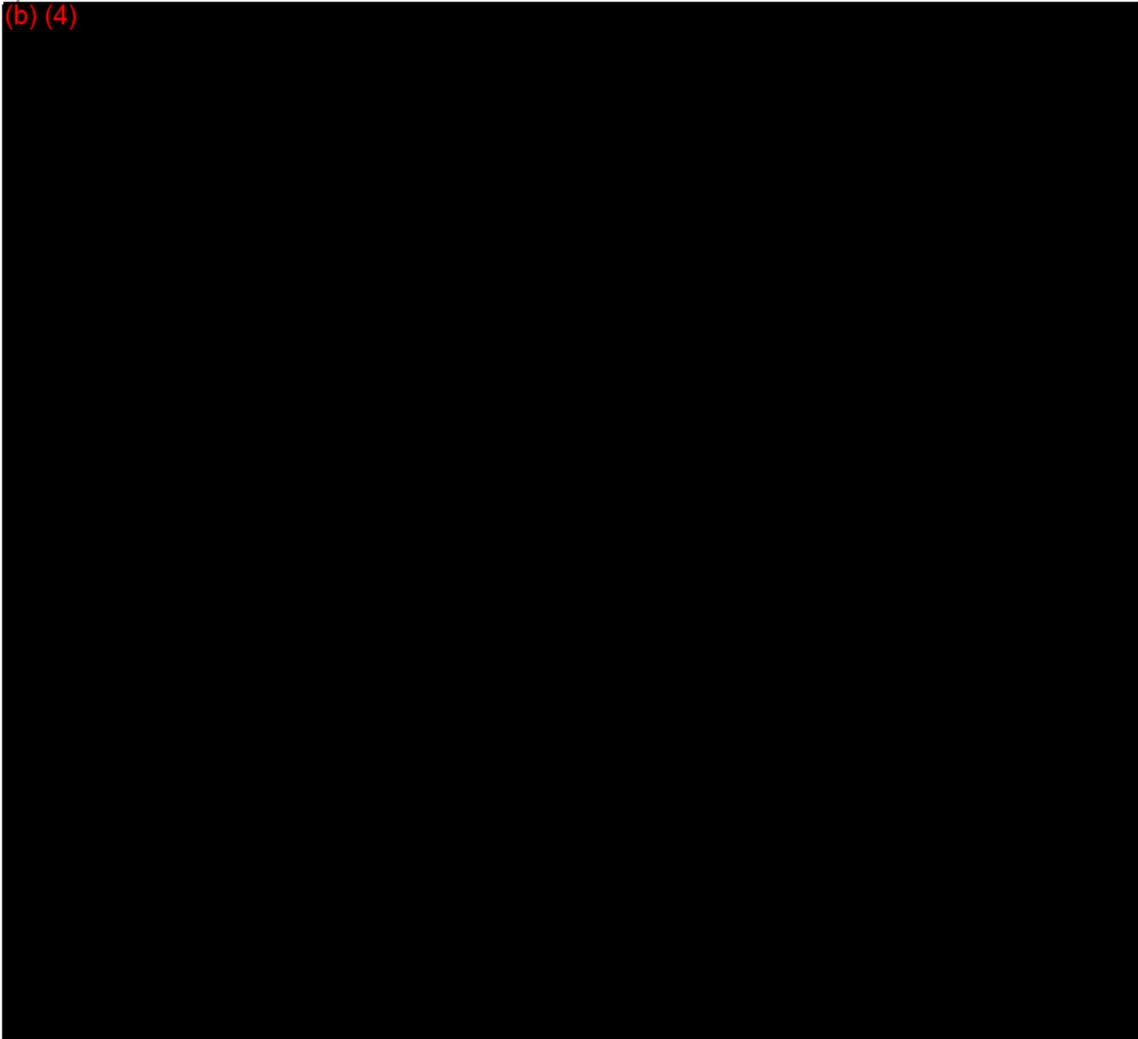


Section 2

CDRH Premarket Review Submission Cover Sheet

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



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

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF ADDRESS BELOW.

The burden time for this collection of information is estimated to average 0.5 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
1350 Piccard Drive, Room 400
Rockville, MD 20850

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

Section 2
CDRH Premarket Review Submission Cover Sheet

Additional standards cited (beyond those listed in FORM FDA 3514)

Standards No.	Standards	Standards Title	Version	Date
(b) (4)				

Section 3

Cover Letter and Acceptance Checklist

delivers the (b) (4) ventilation tube as designed, that the TTS safely and effectively inserts tympanostomy tubes into pediatric patients under moderate sedation or general anesthesia provided in a hospital or ASC setting by an anesthesia provider,

(b) (4)

The abbreviations MTI (Myringotomy Tube Inserter), TTI (Tympanostomy Tube Inserter), TTS (Tympanostomy Tube System), and HTTS (Hummingbird™ Tympanostomy Tube System) used in this submission all refer to the candidate device.

A pending prior submission for this device has been made (K133921), in which the instructions for use specified general anesthesia for pediatric procedures. This new submission is submitted to request clearance for a modified instructions for use, with moderate sedation being specified in addition to general anesthesia for pediatric procedures.

General information for the subject device is provided in the table below.

General Information	
Trade Name	Hummingbird™ Tympanostomy Tube System (TTS)
Common Name	Tympanostomy Tube Inserter with pre-loaded ventilation tube
Predicate 510(k)	<ul style="list-style-type: none">• Micromedics, Inc., Ventilation tube 510(k) #K830228 (Micromedics name has been changed to Summit Medical)• Heinz-Kurz Trocar Ventilation Tube 510(k) K071150• Preceptis TTI (Class I, Exempt)• Preceptis TTI Convenience Kit (TTI packaged in kit with Summit Medical Ventilation Tube)
Product Code	ETD
Classification	Ear Nose & Throat
Review Panel	Ear Nose & Throat
Manufacturer	Preceptis Medical, Inc.
Registration #	3010610937

This premarket notification is organized following the recommendations contained in the CDRH guidance titled *Format for Traditional and Abbreviated 510(k)s* (August 12, 2005). As recommended in the FDA guidance, a table summarizing the device design and use is provided on the following page.

Section 3

Cover Letter and Acceptance Checklist

Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?	X	
Is the device intended for single use?	X	
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?		NA
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?		X
Does the submission include clinical information?	X	
Is the device implanted?	X	

Contact Information	
Primary contact person	Alternate contact person
Keith Leland VP of R&D Tel: 763.568.7819; Fax: 763.568.7820 Email: keith@preceptismedical.com	Steve Anderson President and CEO Tel: 763.568.7809; Fax: 763.568.7820 Email: steve@preceptismedical.com

This 510(k) submission, and the information it contains, is considered confidential; Preceptis Medical, Inc. respectfully requests that the FDA give it the maximum protection provided by law per 21 CFR 807.95.

In accordance with Section 510(k) of the Federal Food, Drug and Cosmetic Act and in conformance with 21 CFR 807, one (1) complete original paper submission and one (1) eCopy on CD-ROM, which is a complete and exact copy of the paper submission, are provided. If you require further information, please contact me.

Sincerely,

Keith Leland



VP of R&D
 Preceptis Medical, Inc.
 505 Highway 169 N, #365
 Plymouth, Minnesota 55441

Section 3 Cover Letter and Acceptance Checklist

Appendix - Acceptable Checklists

Contains Nonbinding Recommendations

Acceptance Checklist for Traditional 510(k)s

(should be completed within 15 days of DCC receipt)

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

510(k) Number: _____ **Date Received by DCC:** _____

Lead Reviewer Name: _____ **Branch:** _____ **Division:** _____ **Office:** _____

Note: If an element is left blank on the checklist, it does not mean the checklist is incomplete; it means the reviewer did not assess the element during RTA and that element will be assessed during substantive review.

Preliminary Questions		
Answers in the shaded blocks indicate consultation with Center advisor is needed.	Yes	No
<p>1. Is the product a device (per section 201(h) of the FD&C Act) or a combination product (per 21 CFR 3.2(e)) with a device constituent part subject to review in a 510(k)?</p> <p>If it appears not to be a device (per section 201(h) of the FD&C Act) or such a combination product, or you are unsure, consult with the CDRH Jurisdictional Officer or the CBER Office Jurisdiction Liaison to determine the appropriate action, and inform division management. <i>Provide a summary of the Jurisdictional Officer's/Liaison's determination.</i> If the product does not appear to be a device or such a combination product, mark "No."</p>	X	
Comments:		
<p>2. Is the application with the appropriate Center?</p> <p>If the product is a device or a combination product with a device constituent part, is it subject to review by the Center in which the submission was received? If you believe the application is not with the appropriate Center or you are unsure, consult with the CDRH Jurisdictional Officer or CBER Office Jurisdiction Liaison to determine the appropriate action and inform your division management. <i>Provide a summary of the Jurisdictional Officer's/Liaison's determination.</i> If application should not be reviewed by your Center mark "No."</p>	X	
Comments:		
<p>3. If a Request for Designation (RFD) was submitted for the device or combination product with a device constituent part and assigned to your center, identify the RFD # and confirm the following:</p>	NA	

Acceptance Checklist for Traditional 510(k)

Section 3 Cover Letter and Acceptance Checklist

Contains Nonbinding Recommendations

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

If the answer to 1 or 2 appears to be "No," then stop review of the 510(k) and issue the "Original Jurisdictional Product" letter.
 If the answer to 3a or 3b appears to be "No," then stop the review and contact the CDRH Jurisdictional Officer or CBER Office of Jurisdiction Liaison.
 If the answer to 4 is "No", the lead reviewer should consult division management and other Center resources to determine the appropriate action.
 If the answer to 5 is "Yes," then stop review of the 510(k), contact the CDRH 510(k) Staff and PMA Staff, or appropriate CBER staff.

Acceptance Checklist for Traditional 510(k)

Section 3 Cover Letter and Acceptance Checklist

Contains Nonbinding Recommendations

If the answer to 6 is “Yes,” then contact CDRH/OC/DBM – BIMO or CBER/OCBQ/DIS/BMB, provide a summary of the discussion with the BIMO Staff, and indicate BIMO’s recommendation/action.

<u>Organizational Elements</u>		
<i>Failure to include these items alone generally should not result in an RTA designation</i>		
	Yes	No
a. Submission contains Table of Contents	<input checked="" type="checkbox"/>	<input type="checkbox"/>
b. Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)	<input checked="" type="checkbox"/>	<input type="checkbox"/>
c. All pages of the submission are numbered <i>All pages should be numbered in such a manner that information can be referenced by page number. This may be done either by consecutively numbering the entire submission, or numbering the pages within a section (e.g., 12-1, 12-2...).</i>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
d. Type of 510(k) is identified– traditional, abbreviated, or special <i>If type of 510(k) is not designated, review as a traditional</i>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Comments:		

<u>Elements of a Complete Submission (RTA Items)</u> <u>(21 CFR 807.87 unless otherwise indicated)</u>				
Submission should be designated RTA if not addressed				
Check “Yes” if item is present, “N/A” if it is not needed and “No” if it is not included but needed.				
		Yes	N/A	No
	<ul style="list-style-type: none"> Any “No” answer will result in a “Refuse to Accept” decision. Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission. 			
A.	Administrative			
	1. All content used to support the submission is written in English (including translations of test reports, literature articles, etc.)	<input checked="" type="checkbox"/>		<input type="checkbox"/>
	Comments:			
	2. Submission identifies the following (such as in CDRH Premarket Review Submission Cover Sheet (Form 3514) or 510(k) cover letter):	<input checked="" type="checkbox"/>		<input type="checkbox"/>
	a. Device trade name or proprietary name	<input checked="" type="checkbox"/>		<input type="checkbox"/>
	b. Device common name	<input checked="" type="checkbox"/>		<input type="checkbox"/>

Acceptance Checklist for Traditional 510(k)

Section 3 Cover Letter and Acceptance Checklist

Contains Nonbinding Recommendations

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated)				
Submission should be designated RTA if not addressed				
Check “Yes” if item is present, “N/A” if it is not needed and “No” if it is not included but needed.				
		<ul style="list-style-type: none"> Any “No” answer will result in a “Refuse to Accept” decision. Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission. 	Yes	N/A
	c.	Device class and panel or Classification regulation or Statement that device has not been classified with rationale for that conclusion	<input checked="" type="checkbox"/>	<input type="checkbox"/>
		Comments:		
	3.	Submission contains Indications for Use Statement with Rx and/or OTC designated (see also 21 CFR 801.109) <i>Submitter should use format appropriate for the reviewing Center/Office (CDRH/ODE, CDRH/OIVD, CBER/OBRR, CBER/OCTGT). If not provided in correct format, request the correct format during substantive review.</i>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
		Comments:		
	4.	Submission contains 510(k) Summary or 510(k) Statement <i>Either a) or b) must be answered “Yes” to be considered complete. Identify any missing element(s) in Comments.</i>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
	a.	Summary contains all elements per 21 CFR 807.92 <i>See also 510(k) Summary Checklist</i>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
	b.	Statement contains all elements per 21 CFR 807.93	<input type="checkbox"/>	<input checked="" type="checkbox"/>
		Comments:		
	5.	Submission contains Truthful and Accuracy Statement per 21 CFR 807.87(k) <i>See recommended format. Select “Yes” if statement is present and includes the text in the recommended format, and is signed by a responsible person of the firm (not consultant).</i>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
		Comments:		

Acceptance Checklist for Traditional 510(k)

Section 3 Cover Letter and Acceptance Checklist

Contains Nonbinding Recommendations

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated)				
Submission should be designated RTA if not addressed				
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.				
		Yes	N/A	No
	<ul style="list-style-type: none"> • Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission. 			
6.	Submission contains Class III Summary and Certification <i>See recommended content. Form should be signed by a responsible person of the firm, not a consultant. Select "N/A" only if submission is not a Class III 510(k).</i>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
	Comments:			
7.	Submission contains clinical data <i>Select "N/A" if the submission does not contain clinical data. If "N/A" is selected, parts a and b below are omitted from the checklist.</i>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
	a. Submission includes completed Financial Certification (FDA Form 3454) or Disclosure (FDA Form 3455) information for each covered clinical study included in the submission. <i>Select "N/A" if the submitted clinical data is not a "covered clinical study" as defined in the Guidance for Industry- Financial Disclosures by Clinical Investigators</i>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	b. Submission includes completed Certification of Compliance with requirements of ClinicalTrials.gov Data Bank (FDA Form 3674) (42 U.S.C. 282(j)(5)(B)) for each applicable device clinical trial included in the submission. <i>Select "N/A" if the submitted clinical data is not an "applicable device clinical trial" as defined in Title VIII of FDAAA, Sec. 801(j)</i>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Comments:			
8.	If submission references use of a national or international standard as part of demonstration of substantial equivalence, submission contains complete Standards Data Report for 510(k)s (FDA Form 3654) <i>There should be a completed form for each referenced national or international standard. Select "N/A" only if submission does not reference any standards.</i>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Acceptance Checklist for Traditional 510(k)

Section 3 Cover Letter and Acceptance Checklist

Contains Nonbinding Recommendations

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated)				
Submission should be designated RTA if not addressed				
Check “Yes” if item is present, “N/A” if it is not needed and “No” if it is not included but needed.				
		Yes	N/A	No
	<ul style="list-style-type: none"> • Any “No” answer will result in a “Refuse to Accept” decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission. 			
	Comments:			
9.	<p>The submission identifies prior submissions for the same device for which FDA provided feedback related to the data or information needed to support substantial equivalence (e.g., submission numbers for Pre-Submission, IDE, prior not substantially equivalent (NSE) determination, prior 510(k) that was deleted or withdrawn) or states that there were no prior submissions for the subject device.</p> <p><i>This information may be included in the Cover Letter (i.e., as a statement that there were no prior submissions for the device or a listing of the number(s) of the prior submissions). Alternatively, a list of submission numbers may be found in Section F (prior related submissions section) of the CDRH Coversheet form (Form 3514) to address this criterion. Please be advised that if this section of the form is left blank, it should not be considered a statement that there were no prior submissions.</i></p>	<input type="checkbox"/>		<input checked="" type="checkbox"/>
	<p>a. If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence outlined in prior communications are addressed.</p> <p><i>To address this criterion, the submission may include a separate section with the prior submission number(s), a copy of the FDA feedback (e.g., letter, meeting minutes), and a statement of how or where in the submission this prior feedback was addressed. Note that the adequacy of how the feedback was addressed should be assessed during the substantive review. For additional information regarding the Pre-Submission process, please refer to the Draft Guidance “Medical Devices: The Pre-Submission Program and Meetings with FDA Staff.” (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm310375.htm). Once finalized, this guidance will represent the</i></p>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>

Acceptance Checklist for Traditional 510(k)

Section 3 Cover Letter and Acceptance Checklist

Contains Nonbinding Recommendations

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated)								
Submission should be designated RTA if not addressed								
Check “Yes” if item is present, “N/A” if it is not needed and “No” if it is not included but needed.								
<ul style="list-style-type: none"> • Any “No” answer will result in a “Refuse to Accept” decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission. 					Yes	N/A	No	
			Agency’s current thinking on this topic. <i>Select “N/A” if the submitter states there were no prior submissions in criterion above.</i>					
			Comments:					
B.		Device Description						
10.	a.	If there are requirements regarding the device description, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes device description information to establish that the submitter has followed the device-specific requirement. <i>Select “N/A” if there are no applicable requirements in a device-specific regulation. Select “No” if the submission does not include a rationale for any omitted information. Note that the adequacy of how such requirements have been addressed should be assessed during the substantive review.</i>			<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
	b.	If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes device description information to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach. <i>Select “N/A” if there is no applicable device-specific guidance. Select “No” if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance, etc., have been addressed should be assessed during the substantive review.</i>			<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
			Comments:					

Acceptance Checklist for Traditional 510(k)

Section 3 Cover Letter and Acceptance Checklist

Contains Nonbinding Recommendations

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated)				
Submission should be designated RTA if not addressed				
Check “Yes” if item is present, “N/A” if it is not needed and “No” if it is not included but needed.				
		Yes	N/A	No
	<ul style="list-style-type: none"> • Any “No” answer will result in a “Refuse to Accept” decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission. 			
	11. Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling), including:			
	a. A description of the principle of operation and mechanism of action for achieving the intended effect.	<input checked="" type="checkbox"/>		<input type="checkbox"/>
	b. A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.	<input checked="" type="checkbox"/>		<input type="checkbox"/>
	c. A list and description of each device for which clearance is requested. <i>Select “N/A” if there is only one device or model. “Device” may refer to models, part numbers, or various sizes, etc.</i>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Comments:			
	12. Submission contains representative engineering drawing(s), schematics, illustrations and/or figures of the device that are clear, legible, labeled, and include dimensions. <i>In lieu of drawings, schematics, etc. of each device to be marketed, “representative” drawings, etc. may be provided, where “representative” is intended to mean that the drawings, etc. provided capture the differences in design, size, and other important characteristics of the various models, sizes, or versions of the device(s) to be marketed.</i> <i>Select “N/A” if the submitter provided a rationale for why the submission does not contain engineering drawings, schematics, etc. (e.g., device is a reagent and figures are not pertinent to describe the device).</i>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Comments:			

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Check “Yes” if item is present, “N/A” if it is not needed and “No” if it is not included but needed.				
		Yes	N/A	No
	<ul style="list-style-type: none"> • Any “No” answer will result in a “Refuse to Accept” decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission. 			
	13. If device is intended to be marketed with multiple components, accessories, and/or as part of a system, <i>Select “N/A” if the device is not intended to be marketed with multiple components, accessories, and/or as part of a system.</i>		<input type="checkbox"/>	
	a. Submission includes a list of all components and accessories to be marketed with the subject device.	<input checked="" type="checkbox"/>		<input type="checkbox"/>
	b. Submission includes a description (as detailed in item 11.a. and b. and 12 above) of each component or accessory. <i>Select “N/A” if the component(s)/accessory(ies) has been previously cleared, or is exempt, and the proposed indications for use are consistent with the cleared indications.</i>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	c. A 510(k) number is provided for each component or accessory that received a prior 510(k) clearance. <i>Select “N/A” if the submission states that the component(s)/accessory(ies) does not have a prior 510(k) clearance or the component(s)/accessory(ies) is 510(k) exempt.</i>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Comments:			
C.	Substantial Equivalence Discussion			
	14. Submitter has identified a predicate(s) device	<input checked="" type="checkbox"/>		<input type="checkbox"/>
	a. Predicate’s 510(k) number, trade name, and model number (if applicable) provided. For predicates that are preamendments devices, information is provided to document preamendments status. <i>Information regarding documenting preamendment status is available online</i> <i>(http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidan)</i>	<input checked="" type="checkbox"/>		<input type="checkbox"/>

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		<ul style="list-style-type: none"> • Any “No” answer will result in a “Refuse to Accept” decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission. 	Yes	N/A
		ce/ComplianceActivities/ucm072746.htm		
	b.	The identified predicate(s) is consistent throughout the submission (i.e., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing.	<input checked="" type="checkbox"/>	<input type="checkbox"/>
		Comments:		
15.		Submission includes a comparison of the following for the predicate(s) and subject device		
	a.	Indications for use	<input checked="" type="checkbox"/>	<input type="checkbox"/>
	b.	Technology, including features, materials, and principles of operation	<input checked="" type="checkbox"/>	<input type="checkbox"/>
		Comments:		
	16.	Submission includes an analysis of why any differences between the subject device and predicate(s) do not render the device NSE (e.g., does not constitute a new intended use; and any differences in technological characteristics are accompanied by information that demonstrates the device is as safe and effective as the predicate and do not raise different questions of safety and effectiveness than the predicate), affect safety or effectiveness, or raise different questions of safety and effectiveness (see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f)) <i>If there is no difference between the subject and predicate(s) with respect to indications for use or technology, this should be explicitly stated, in which case “N/A” should be selected. Select “No” only if the submission does not include an analysis of differences as described above or a statement that there are no differences. Note that the adequacy of the analysis should be assessed during the substantive review; only the presence of such an analysis is required for acceptance. In addition, note that due to potential differences in</i>	<input checked="" type="checkbox"/>	<input type="checkbox"/>

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	<ul style="list-style-type: none"> • Any “No” answer will result in a “Refuse to Accept” decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission. 	Yes	N/A	No
	<i>manufacturing that may not be known to the submitter, the fact that no differences are identified does not necessarily mean that no performance testing is needed.</i>			
	Comments:			
D.	Proposed Labeling (see also 21 CFR part 801) <i>If in vitro diagnostic (IVD) device, criteria 17, 18, and 19 may be omitted. These criteria will be omitted from the checklist if “N/A” is selected. IVD labeling is addressed in section 21 below.</i>		<input type="checkbox"/>	
	17. Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator’s manual) that include a description of the device, its intended use, and the directions for use	<input checked="" type="checkbox"/>		<input type="checkbox"/>
	a. Indications for use are stated in labeling and are identical to Indications for Use form and 510(k) Summary (if 510(k) Summary provided)	<input checked="" type="checkbox"/>		<input type="checkbox"/>
	b. Submission includes directions for use that <ul style="list-style-type: none"> - include statements of all conditions, purposes or uses for which the device is intended (e.g., hazards, warnings, precautions, contraindications) (21 CFR 801.5) AND - Includes directions for layperson (see 21 CFR 801.5) OR submission states that device qualifies for exemption per 21 CFR 801 Subpart D 	<input checked="" type="checkbox"/>		<input type="checkbox"/>
	Comments:			
	18. If indicated for prescription use, labeling includes the prescription use statement (see 21 CFR 801.109(b)(1)) or “Rx only” symbol [See also Alternative to Certain Prescription Device Labeling Requirements] <i>Select “N/A” if not indicated for prescription use.</i>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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		Yes	N/A	No
	<ul style="list-style-type: none"> • Any “No” answer will result in a “Refuse to Accept” decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission. 			
	Comments:			
	19. General labeling provisions			
	a. Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1)	<input checked="" type="checkbox"/>		<input type="checkbox"/>
	b. Labeling includes device common or usual name (21 CFR 801.61) <i>Select “N/A” if device is for prescription use only.</i>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
	Comments:			
	20. a. If there are requirements regarding labeling, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes labeling to establish that the submitter has followed the device-specific requirement. <i>Select “N/A” if there are no applicable requirements in a device-specific regulation. Select “No” if the submission does not include a rationale for any omitted information. Note that the adequacy of how such requirements have been addressed should be assessed during the substantive review.</i>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
	b. If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes labeling to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach. <i>Select “N/A” if there is no applicable device-specific guidance. Select “No” if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance have been addressed should be assessed during the substantive review.</i>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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		Yes	N/A	No
	<ul style="list-style-type: none"> • Any “No” answer will result in a “Refuse to Accept” decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission. 			
	<p>c. If there is a special controls document applicable to the device, the submission includes labeling to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness. <i>Select “N/A” if there is no applicable special controls document. Select “No” if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how mitigation measures in a special controls document have been addressed should be assessed during the substantive review.</i></p>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
	Comments:			
	<p>21. If the device is an in vitro diagnostic device, provided labeling includes all applicable information required per 21 CFR 809.10. <i>Select “N/A” if not an in vitro diagnostic device.</i></p>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
E.	<p>Sterilization <i>If in vitro diagnostic (IVD) device and sterilization is not applicable, select “N/A.” The criteria in this section will be omitted from the checklist if “N/A” is selected.</i></p>		<input type="checkbox"/>	
	<p>Submission states that the device and/or accessories are: <i>(one of the below must be checked)</i></p> <p><input checked="" type="checkbox"/> provided sterile</p> <p><input type="checkbox"/> provided non-sterile but sterilized by the end user</p> <p><input type="checkbox"/> non-sterile when used</p> <p>This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. <i>If “non-sterile when used” is selected, the sterility-related criteria below are omitted from</i></p>			<input type="checkbox"/>

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		Yes	N/A	No
	<ul style="list-style-type: none"> • Any “No” answer will result in a “Refuse to Accept” decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission. 			
	<i>the checklist. If information regarding the sterility status of the device is not provided, select “No.”</i>			
	Comments:			
	22. Assessment of the need for sterilization information			
	a. Identification of device, and/or accessories, and/or components that are provided sterile.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	b. Identification of device, and/or accessories, and/or components that are end user sterilized	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
	c. Identification of device, and/or accessories, and/or components that are reusable and cleaning/disinfection instructions are provided.	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
	Comments:			
	23. If the device, and/or accessory, and/or a component is provided sterile: <i>Select “N/A” if no part of the device, accessories, or components is provided sterile, otherwise complete a-e below.</i>		<input type="checkbox"/>	
	a. Sterilization method is stated for each component (including parameters such as dry time for steam sterilization, radiation dose, etc.)	<input checked="" type="checkbox"/>		<input type="checkbox"/>
	b. A description of method to validate the sterilization parameters (e.g., half-cycle method and full citation of FDA-recognized standard, including date) is provided for each proposed sterilization method. <i>Note, the sterilization validation report is not required.</i>	<input checked="" type="checkbox"/>		<input type="checkbox"/>
	c. For devices sterilized using chemical sterilants such as ethylene oxide (EO) and hydrogen peroxide, submission states maximum	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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			Yes	N/A	No
		<ul style="list-style-type: none"> • Any “No” answer will result in a “Refuse to Accept” decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission. 			
		levels of sterilant residuals remaining on the device and sterilant residual limits. <i>Select “N/A” if not sterilized using chemical sterilants.</i>			
	d.	Submission includes description of packaging and packaging contents (e.g., if multiple devices are included within the same package, Tyvek packaging, etc.)	<input checked="" type="checkbox"/>		<input type="checkbox"/>
	e.	Sterility Assurance Level (SAL) stated	<input checked="" type="checkbox"/>		<input type="checkbox"/>
		Comments:			
	24.	If the device, and/or accessory, and/or a component is end user sterilized: <i>Select “N/A” if no part of the device, accessories, or components are end user sterilized, otherwise complete a-d below.</i>		<input checked="" type="checkbox"/>	
	a.	Sterilization method is stated for each component (including parameters such as dry time for steam sterilization, radiation dose, etc.)	<input type="checkbox"/>		<input type="checkbox"/>
	b.	A description of method to validate the sterilization parameters (e.g., half-cycle method and full citation of FDA-recognized standard, including date) is provided for each proposed sterilization method. <i>Note, the sterilization validation is not required.</i>	<input type="checkbox"/>		<input type="checkbox"/>
	c.	Submission includes description of packaging and packaging contents (e.g., if multiple devices are included within the same package, Tyvek packaging, etc.)	<input type="checkbox"/>		<input type="checkbox"/>
	d.	Submission includes sterilization instructions for end user	<input type="checkbox"/>		<input type="checkbox"/>
		Comments:			
	25. a.	If there are requirements regarding sterility, such as special	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>

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			Yes	N/A	No
	<ul style="list-style-type: none"> • Any “No” answer will result in a “Refuse to Accept” decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission. 				
		controls, in a device-specific regulation that are applicable to the device, the submission includes sterility information to establish that the submitter has followed the device-specific requirement. <i>Select “N/A” if there are no applicable requirements in a device-specific regulation. Select “No” if the submission does not include a rationale for any omitted information. Note that the adequacy of how such requirements have been addressed should be assessed during the substantive review.</i>			
	b.	If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes sterility information to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach. <i>Select “N/A” if there is no applicable device-specific guidance. Select “No” if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance have been addressed should be assessed during the substantive review.</i>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	c.	If there is a special controls document applicable to the device, the submission includes sterility information to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness. <i>Select “N/A” if there is no applicable special controls document. Select “No” if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how mitigation measures in a</i>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>

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	<ul style="list-style-type: none"> Any “No” answer will result in a “Refuse to Accept” decision. Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission. 	Yes	N/A	No
	<i>special controls document have been addressed should be assessed during the substantive review.</i>			
	Comments:			
F.	Shelf Life			
	26. Proposed shelf life/ expiration date stated <i>Select “N/A” if the device is not provided sterile and the submitter states that storage conditions could not affect device safety or effectiveness.</i>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Comments:			
	27. For sterile device, submission includes summary of methods used to establish that device sterility will remain substantially equivalent to that of the predicate through the proposed shelf life, or a rationale for why testing to establish shelf life is not applicable. <i>Select “N/A” if the device is not provided sterile.</i>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Comments:			
	28. Submission includes summary of methods used to establish that device performance is not adversely affected by aging and therefore device performance will remain substantially equivalent to that of the predicate, or includes a rationale for why the storage conditions are not expected to affect device safety or effectiveness.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Comments:			
G.	Biocompatibility <i>If in vitro diagnostic (IVD) device, select “N/A.” The criteria in this section will be omitted from the checklist if “N/A” is selected.</i>		<input type="checkbox"/>	
	Submission states that there: <i>(one of the below must be checked)</i> <input checked="" type="checkbox"/> are			<input type="checkbox"/>

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		Yes	N/A	No
	<ul style="list-style-type: none"> Any “No” answer will result in a “Refuse to Accept” decision. Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission. 			
	<input type="checkbox"/> are not direct or indirect (e.g., through fluid infusion) patient-contacting components. This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. <i>If “are not” is selected, the biocompatibility-related criteria below are omitted from the checklist. If information regarding whether the device is patient-contacting is not provided, select “No.”</i>			
	Comments:			
29.	Submission includes list of patient-contacting device components and associated materials of construction, including identification of color additives, if present	<input checked="" type="checkbox"/>		<input type="checkbox"/>
	Comments:			
30.	Submission identifies contact classification (e.g., surface-contacting, less than 24 hour duration)	<input checked="" type="checkbox"/>		<input type="checkbox"/>
	Comments:			
31.	Biocompatibility assessment of patient-contacting components Submission includes: Test protocol (including identification and description of test article), methods, pass/fail criteria, and results provided for each completed test, OR a statement that biocompatibility testing is not needed with a rationale (e.g., materials and manufacturing/processing are identical to the predicate).	<input checked="" type="checkbox"/>		<input type="checkbox"/>
	Comments:			
H.	Software			

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		Yes	N/A	No
	<ul style="list-style-type: none"> Any “No” answer will result in a “Refuse to Accept” decision. Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission. 			
	Submission states that the device: <i>(one of the below must be checked)</i> <input type="checkbox"/> does <input checked="" type="checkbox"/> does not contain software/firmware. This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. <i>If “does not” is selected, the software-related criterion is omitted from the checklist. If information regarding whether the device contains software is not provided, select “No.”</i>			<input type="checkbox"/>
	Comments:			
32.	Submission includes a statement of software level of concern and rationale for the software level of concern	<input type="checkbox"/>		<input type="checkbox"/>
	Comments:			
33.	All applicable software documentation provided based on level of concern identified by the submitter, as described in Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices , or the submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through an alternative approach (i.e., the submitter has identified an alternate approach with a rationale).	<input type="checkbox"/>		<input type="checkbox"/>
	Comments:			
I.	EMC and Electrical Safety			
	Submission states that the device: <i>(one of the below must be checked)</i> <input type="checkbox"/> does <input checked="" type="checkbox"/> does not require EMC and Electrical Safety evaluation.			<input type="checkbox"/>

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		Yes	N/A	No
	<ul style="list-style-type: none"> • Any “No” answer will result in a “Refuse to Accept” decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission. 			
	<p>This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. <i>If “does not” is selected, the EMC-related and Electrical Safety-related criteria below are omitted from the checklist. If information regarding whether the device requires EMC and Electrical Safety evaluation is not provided, select “No.”</i></p>			
	Comments:			
34.	Submission includes evaluation of electrical safety (e.g., per IEC 60601-1, or equivalent FDA-recognized standard, and if applicable, the device-specific standard), OR submission includes electrical safety evaluation using methods or standards that are not FDA-recognized and submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternate methods or standards with a rationale).	<input type="checkbox"/>		<input type="checkbox"/>
	Comments:			
35.	Submission includes evaluation of electromagnetic compatibility (e.g., per IEC 60601-1-2 or equivalent FDA-recognized standard and if applicable, the device-specific standard) OR submission includes electromagnetic compatibility evaluation using methods or standards that are not FDA-recognized and submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternate methods or standards with a rationale).	<input type="checkbox"/>		<input type="checkbox"/>
	Comments:			

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		Yes	N/A	No
	<ul style="list-style-type: none"> • Any “No” answer will result in a “Refuse to Accept” decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission. 			
J.	Performance Data – General <i>If in vitro diagnostic (IVD) device, select “N/A.” The criteria in this section will be omitted from the checklist if “N/A” is selected. Performance data criteria relating to IVD devices will be addressed in Section K.</i>		<input type="checkbox"/>	
	Comments:			
	36. Full test report is provided for each completed test. A full test report includes: objective of the test, description of the test methods and procedures, study endpoint(s), pre- defined pass/fail criteria, results summary, conclusions, and an explanation of how the data generated from the test supports a finding of substantial equivalence. <i>Full test reports provided for all completed tests/evaluations (e.g., bench evaluations, comparative performance tests, etc.). Select “N/A” if the submission does not include performance data.</i>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Comments:			
	37. a. If there are requirements regarding performance data, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes performance data to establish that the submitter has followed the device-specific requirement. <i>Select “N/A” if there are no applicable requirements in a device-specific regulation. Select “No” if the submission does not include a rationale for any omitted information. Note that the adequacy of how such requirements have been addressed should be assessed during the substantive review.</i>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
	b. If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes performance data to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Acceptance Checklist for Traditional 510(k)

Section 3 Cover Letter and Acceptance Checklist

Contains Nonbinding Recommendations

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated)					
Submission should be designated RTA if not addressed					
Check “Yes” if item is present, “N/A” if it is not needed and “No” if it is not included but needed.					
			Yes	N/A	No
	<ul style="list-style-type: none"> • Any “No” answer will result in a “Refuse to Accept” decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission. 				
	<p>approach. <i>Select “N/A” if there is no applicable device-specific guidance. Select “No” if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance have been addressed should be assessed during the substantive review.</i></p>				
	c.	<p>If there is a special controls document applicable to the device, the submission includes performance data to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness. <i>Select “N/A” if there is no applicable special controls document. Select “No” if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how mitigation measures in a special controls document have been addressed should be assessed during the substantive review.</i></p>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
	Comments:				
	38.	<p>If literature is referenced in the submission, submission includes: <i>Select “N/A” if the submission does not reference literature. Note that the applicability of the referenced article to support a substantial equivalence finding should be assessed during the substantive review; only the presence of a discussion is required to support acceptance.</i></p>		<input checked="" type="checkbox"/>	
	a.	Legible reprints or a summary of each article	<input type="checkbox"/>		<input type="checkbox"/>
	b.	Discussion of how each article is applicable to support the	<input type="checkbox"/>		<input type="checkbox"/>

Acceptance Checklist for Traditional 510(k)

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Submission should be designated RTA if not addressed				
Check “Yes” if item is present, “N/A” if it is not needed and “No” if it is not included but needed.				
		Yes	N/A	No
	<ul style="list-style-type: none"> • Any “No” answer will result in a “Refuse to Accept” decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission. 			
	substantial equivalence of the subject device to the predicate.			
	Comments:			
	39. For each completed nonclinical (i.e., animal) study conducted, <i>Select “N/A” if no animal study was conducted. Note that this section does not address biocompatibility evaluations, which are assessed in Section G of the checklist,</i>		<input checked="" type="checkbox"/>	
	a. Submission includes a study protocol which includes all elements as outlined in 21 CFR 58.120	<input type="checkbox"/>		<input type="checkbox"/>
	b. Submission includes final study report which includes all elements outlined in 21 CFR 58.185	<input type="checkbox"/>		<input type="checkbox"/>
	c. Submission contains a statement that the study was conducted in compliance with applicable requirements in the GLP regulation (21 CFR Part 58), or, if the study was not conducted in compliance with the GLP regulation, the submission explains why the noncompliance would not impact the validity of the study data provided to support a substantial equivalence determination.	<input type="checkbox"/>		<input type="checkbox"/>
	Comments:			
K.	Performance Characteristics – In Vitro Diagnostic Devices Only (see also 21 CFR 809.10(b)(12))			
	Submission indicates that device: <i>(one of the below must be checked)</i> <input type="checkbox"/> is <input checked="" type="checkbox"/> is not an in vitro diagnostic device (IVD). <i>If “is not” is selected, the performance data-related criteria below are omitted from the checklist.</i>			
	Comments:			

Acceptance Checklist for Traditional 510(k)

Section 3 Cover Letter and Acceptance Checklist

Contains Nonbinding Recommendations

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated)					
Submission should be designated RTA if not addressed					
Check “Yes” if item is present, “N/A” if it is not needed and “No” if it is not included but needed.					
			Yes	N/A	No
<ul style="list-style-type: none"> • Any “No” answer will result in a “Refuse to Accept” decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission. 					
40.	Submission includes the following studies, as appropriate for the device type, including associated protocol descriptions, study results and line data:				
	a.	Precision/reproducibility	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
	b.	Accuracy (includes as appropriate linearity; calibrator or assay traceability; calibrator and/or assay stability protocol and acceptance criteria; assay cut-off; method comparison or comparison to clinical outcome; matrix comparison; and clinical reference range or cutoff.	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
	c.	Sensitivity (detection limits, LoB, LoD, LoQ where relevant for the device type).	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
	d.	Analytical specificity	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Comments:					
41.	a.	If there are requirements regarding performance data, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes performance data to establish that the submitter has followed the device-specific requirement. <i>Select “N/A” if there are no applicable requirements in a device-specific regulation. Select “No” if the submission does not include a rationale for any omitted information. Note that the adequacy of how such requirements have been addressed should be assessed during the substantive review.</i>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
	b.	If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes performance data to establish that the submitter has addressed the recommendations or otherwise has met the	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>

Acceptance Checklist for Traditional 510(k)

Section 3 Cover Letter and Acceptance Checklist

Contains Nonbinding Recommendations

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated)				
Submission should be designated RTA if not addressed				
Check “Yes” if item is present, “N/A” if it is not needed and “No” if it is not included but needed.				
		Yes	N/A	No
	<ul style="list-style-type: none"> • Any “No” answer will result in a “Refuse to Accept” decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission. 			
	<p>applicable statutory or regulatory criteria through an alternative approach. <i>Select “N/A” if there is no applicable device-specific guidance. Select “No” if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance have been addressed should be assessed during the substantive review.</i></p>			
	<p>c. If there is a special controls document applicable to the device, the submission includes performance data to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness. <i>Select “N/A” if there is no applicable special controls document. Select “No” if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how mitigation measures in a special controls document have been addressed should be assessed during the substantive review.</i></p>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
	Comments:			

Acceptance Checklist for Traditional 510(k)

Standards Data Report (FDA Form 3654)

Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services Food and Drug Administration STANDARDS DATA REPORT FOR 510(k)s (To be filled in by applicant)	
This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).	
TYPE OF 510(K) SUBMISSION <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated	
STANDARD TITLE ¹ (b) (4)	
Please answer the following questions	
	Yes No
Is this standard recognized by FDA ² ?	<input checked="" type="checkbox"/> <input type="checkbox"/>
FDA Recognition number ³	(b)(4)Tr
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	<input checked="" type="checkbox"/> <input type="checkbox"/>
Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?	<input type="checkbox"/> <input checked="" type="checkbox"/>
If no, complete a summary report table.	
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	<input checked="" type="checkbox"/> <input type="checkbox"/>
Does this standard include acceptance criteria?	<input checked="" type="checkbox"/> <input type="checkbox"/>
If no, include the results of testing in the 510(k).	
Does this standard include more than one option or selection of tests?	<input type="checkbox"/> <input checked="" type="checkbox"/>
If yes, report options selected in the summary report table.	
Were there any deviations or adaptations made in the use of the standard?.....	<input type="checkbox"/> <input checked="" type="checkbox"/>
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵ ?	<input type="checkbox"/> <input type="checkbox"/>
Were deviations or adaptations made beyond what is specified in the FDA SIS?.....	<input type="checkbox"/> <input checked="" type="checkbox"/>
If yes, report these deviations or adaptations in the summary report table.	
Were there any exclusions from the standard?	<input type="checkbox"/> <input checked="" type="checkbox"/>
If yes, report these exclusions in the summary report table.	
Is there an FDA guidance ⁶ that is associated with this standard?.....	<input checked="" type="checkbox"/> <input type="checkbox"/>
If yes, was the guidance document followed in preparation of this 510k?	<input checked="" type="checkbox"/> <input type="checkbox"/>
Title of guidance (b) (4)	
<small> ¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication] ² Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html ³ http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm ⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device. ⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm ⁶ The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html </small>	

Standards Data Report (FDA Form 3654)

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE (b) (4)		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER b(4)Trade	SECTION TITLE (b) (4)	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		

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

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

Paperwork Reduction Act Statement

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

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

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

Section 4
Indications For Use Statement

Indications for Use

510(k) Number (if known):

Device Name: Hummingbird™ Tympanostomy Tube System

Indications For Use:

The Hummingbird™ Tympanostomy Tube System (TTS) is intended to deliver a tympanostomy tube in tympanostomy procedures in which the patient is receiving a tympanostomy tube.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

**Section 5
510k Summary**

Submitter Information:	Preceptis Medical, Inc. 505 Highway 169 North, #365 Plymouth, MN 55441 763.568.7819
Contact:	Keith Leland, VP of R&D
Date Prepared:	12 August 2014
Trade Name	Hummingbird™ Tympanostomy Tube System (TTS)
Product Code	ETD (21 CFR Part 874.3880)
Common Name	Tympanostomy Tube Inserter with pre-loaded ventilation tube
Predicate Devices	<ul style="list-style-type: none">• Summit Medical Ventilation Tube Model 05-1026-001, 510(k) #K830228• Heinz Kurz Trocar Ventilation Tube, 510(k) K071150• Preceptis Tympanostomy Tube Inserter, 510(k) Exempt• Preceptis Tympanostomy Tube Convenience Kit, 510(k) Exempt

Section 5 510k Summary

<p>Device Description</p>	<p>The Hummingbird™ Tympanostomy Tube System (TTS) is a single-use, sterile manual surgical instrument which is used to create a myringotomy in the tympanic membrane and place a ventilation tube. The device comprises a handle with one or more tip assemblies which contain a sterile tympanostomy tube.</p> <p>Each tip assembly can be removably attached to the handle and includes a positioning rod and a ventilation tube pre-loaded inside the distal end of a sharpened sheath. Attaching the tip assembly to the handle also connects the sheath and actuator, allowing the user to retract the sheath by manually scrolling an actuator located on the handle.</p> <p>The user manually advances the sharpened sheath to create a myringotomy and simultaneously positions the ventilation tube within the myringotomy, always under direct visualization. The user then manually retracts the sharpened sheath away from the myringotomy using the manual actuator located on the handle. The retraction of the sheath releases the tube within the myringotomy.</p> <p>A first tip assembly can then be removed from the handle and replaced with a second preloaded tip assembly for bilateral procedures.</p>
<p>Indications For Use</p>	<p>The Hummingbird™ Tympanostomy Tube System (TTS) is intended to deliver a tympanostomy tube in tympanostomy procedures in which the patient is receiving a tympanostomy tube.</p>
<p>Technological Characteristics</p>	<p>The TTS is intended to deliver a tympanostomy tube (also referred to as a ventilation tube) through the tympanic membrane (TM) of the patient. It combines the separate functions of creating a myringotomy, positioning and placing a ventilation tube across the TM, and suctioning.</p> <p>The TTS is a manual surgical instrument. The actions of creating the myringotomy, positioning the ventilation tube, and retracting the sheath surrounding the ventilation tube are all performed manually by the user.</p> <p>A comparison between the TTS and predicate device shows that the technological characteristics as confirmed through dimensional attributes and the indications for use are substantially equivalent</p>

Section 5 510k Summary

Performance Data	<p>In two non-significant risk studies, a total of 69 children (mean age of 2.4 years, ranging from 8 months to 8.9 years) underwent tympanostomy procedures under moderate sedation using the Preceptis TTS to reduce surgical trauma for the patients. Results:</p> <ul style="list-style-type: none">• The IRBs at each institution designated the studies as Non-Significant Risk due to the low risk profile of the TTS and the fact that anesthetic regimen is determined and delivered by an anesthesia professional within the hospital.• This approach is presented as an additional option to the current standard of care under general anesthesia.. It is also an extension of current tympanostomy medical practice in which children 12 and above are treated in the office with only topical anesthetic.• 100% of the children received ventilation tubes as planned.• There were <u>no intra-operative adverse events</u>, no unanticipated adverse events, and adverse event rates were well within normal reported rates.• There is no additional risk in converting cases from moderate sedation to general since the conversion process simply involves turning off the nitrous oxide and turning on the flow of sevoflurane to the mask already in place over a child's nose and mouth. <p>Performing tympanostomy procedures in young children under moderate sedation in a hospital setting with anesthesia delivered by an anesthesia professional is safe and a well-reasoned alternative to the use of general anesthesia for caregivers and clinicians who are comfortable with this choice.</p>
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Section 6
Truthful and Accurate Statement

[As Required by 21 CFR 807.87(k)]

I certify that, in my capacity as Chief Executive Officer of Preceptis Medical, Inc., I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.



(Signature)

Steve Anderson, CEO

14 Aug 2014

(Date)

(Premarket Notification [510(k)] Number)

*For a new submission, leave the 510(k) number blank.

Section 7
Class III Summary and Certification

This section does not apply as the device has been classified as class II under 21 CFR 874.3880

[Code of Federal Regulations]
[Title 21, Volume 8]
[Revised as of April 1, 2013]
[CITE: 21CFR874.3880]

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER H--MEDICAL DEVICES

PART 874 -- EAR, NOSE, AND THROAT DEVICES

Subpart D--Prosthetic Devices

Sec. 874.3880 Tympanostomy tube.

(a) *Identification.* A tympanostomy tube is a device that is intended to be implanted for ventilation or drainage of the middle ear. The device is inserted through the tympanic membrane to permit a free exchange of air between the outer ear and middle ear. A type of tympanostomy tube known as the malleous clip tube attaches to the malleous to provide middle ear ventilation. The device is made of materials such as polytetrafluoroethylene, polyethylene, silicon elastomer, or porous polyethylene.

(b) *Classification.* Class II.

Section 8 Financial Certification and Disclosure Statement

DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration	Form Approved: OMB No. 0910-0396 Expiration Date: December 31, 2015
CERTIFICATION: FINANCIAL INTERESTS AND ARRANGEMENTS OF CLINICAL INVESTIGATORS	
<i>TO BE COMPLETED BY APPLICANT</i>	
<p>With respect to all covered clinical studies (or specific clinical studies listed below (if appropriate)) submitted in support of this application, I certify to one of the statements below as appropriate. I understand that this certification is made in compliance with 21 CFR part 54 and that for the purposes of this statement, a clinical investigator includes the spouse and each dependent child of the investigator as defined in 21 CFR 54.2(d).</p> <p style="text-align: center;">Please mark the applicable check box.</p> <p><input checked="" type="checkbox"/> (1) As the sponsor of the submitted studies, I certify that I have not entered into any financial arrangement with the listed clinical investigators (enter names of clinical investigators below or attach list of names to this form) whereby the value of compensation to the investigator could be affected by the outcome of the study as defined in 21 CFR 54.2(a). I also certify that each listed clinical investigator required to disclose to the sponsor whether the investigator had a proprietary interest in this product or a significant equity in the sponsor as defined in 21 CFR 54.2(b) did not disclose any such interests. I further certify that no listed investigator was the recipient of significant payments of other sorts as defined in 21 CFR 54.2(f).</p> <p>(b) (6)</p> <p><input type="checkbox"/> (2) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that based on information obtained from the sponsor or from participating clinical investigators, the listed clinical investigators (attach list of names to this form) did not participate in any financial arrangement with the sponsor of a covered study whereby the value of compensation to the investigator for conducting the study could be affected by the outcome of the study (as defined in 21 CFR 54.2(a)); had no proprietary interest in this product or significant equity interest in the sponsor of the covered study (as defined in 21 CFR 54.2(b)); and was not the recipient of significant payments of other sorts (as defined in 21 CFR 54.2(f)).</p> <p><input type="checkbox"/> (3) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that I have acted with due diligence to obtain from the listed clinical investigators (attach list of names) or from the sponsor the information required under 54.4 and it was not possible to do so. The reason why this information could not be obtained is attached.</p> <p>(b) (6)</p>	
<p>This section applies only to the requirements of the Paperwork Reduction Act of 1995. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Public reporting burden for this collection of information is estimated to average 1 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the necessary data, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information to the address to the right:</p> <p><i>*An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.*</i></p>	<p>Do NOT send your completed form to the PRA Staff email address below. Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer PRASStaff@fda.hhs.gov</p>

Section 9
Declaration of Conformity

Declaration of Conformity

Standards cited in this submission are listed in Section I of the CDRH Premarket Review Submission Cover Sheet (section 2 of this submission).

Keith J. Leland



V.P. of Research and Development
Preceptis Medical, Inc.
505 Highway 169 North, #365
Plymouth, Minnesota 55441
Phone: (763) 568-7819

Section 10 Executive Summary

Executive Summary

Overview of Device

The Hummingbird™ Tympanostomy Tube System (TTS) is a manual surgical instrument that places a standard ventilation tube across the tympanic membrane of a patient. It combines the separate functions of creating a myringotomy, positioning and placing the ventilation tube, and suctioning.

The TTS is intended to place a ventilation tube to provide ventilation to the middle ear space through the tympanic membrane.

(b)(4) Contract Manufacturer

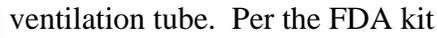


The TTI w/ tube is preceded by the previous predicates:

1. The Summit Medical ventilation tube (cleared under K830228, model # 05-1026-001). (b) (4) 





2. The Heinz-Kurz Trocar Ventilation Tube – TVT (cleared under K071150).
3. The Preceptis Tympanostomy Tube Inserter - TTI (i.e., myringotomy tube introducer) is a Class I device as defined in 874.4420(a) of 21 CFR, Ear, nose, and throat manual surgical instrument -- exempt from the premarket notification procedures in Part 807.
4. The Preceptis TTI Convenience Kit consists of the 510k exempt TTI packaged in a convenience kit with the (b) (4)  ventilation tube. Per the FDA kit guidance, this convenience kit is exempt from 510k requirements since the

Section 10 Executive Summary

components consist of an exempt myringotomy tube inserter (the TTI) and an already 510k-cleared ventilation tube.

This 510k submission for the Hummingbird™ TTS with pre-loaded ventilation tube thereby consists of the four predicates above with the only difference being that the (b) (4) ventilation tube is now packaged pre-loaded into the TTS for ease of use for the ENT surgeon. Within this submission, the sponsor will demonstrate that the TTI delivers the (b) (4) ventilation tube as designed, that the TTS safely and effectively inserts tympanostomy tubes into pediatric patients under moderate sedation or general anesthesia provided in a hospital or ASC setting by an anesthesia provider, (b) (4)

Bench Testing

(b)(4) Testing

Clinical Testing

In two non-significant risk studies, a total of 69 children (mean age of 2.4 years, ranging from 8 months to 8.9 years) underwent tympanostomy procedures under moderate sedation using the Preceptis TTS to reduce surgical trauma for the patients. Results:

- The IRBs at each institution designated the studies as Non-Significant Risk due to the low risk profile of the TTS and the fact that anesthetic regimen is determined and delivered by an anesthesia professional within the hospital.
- This approach is presented as an additional option to the current standard of care under general anesthesia.. It is also an extension of current tympanostomy medical practice in which children 12 and above are treated in the office with only topical anesthetic.
- 100% of the children received ventilation tubes as planned.
- There were no intra-operative adverse events, no unanticipated adverse events, and adverse event rates were well within normal reported rates.
- There is no additional risk in converting cases from moderate sedation to general since the conversion process simply involves turning off the nitrous oxide and

Section 10

Executive Summary

turning on the flow of sevoflurane to the mask already in place over a child's nose and mouth.

Performing tympanostomy procedures in young children under moderate sedation in a hospital setting with anesthesia delivered by an anesthesia professional is safe and a well-reasoned alternative to the use of general anesthesia for caregivers and clinicians who are comfortable with this choice.

Substantial Equivalence Analysis

The key performance, safety and design characteristics of the devices that are used to establish equivalence are identified and are listed in the substantial equivalence table.

The device comparison tables show the similarities and differences between the Hummingbird™ Tympanostomy Tube System and the predicate device. The indications for use for the devices are the same. The Hummingbird TTS is identical with respect to function and materials as the TTI predicates and Summit Medical ventilation tube. The Hummingbird TTS is comparable dimensionally to the Heinz Kurz TVT.

An analysis of the differences between the devices showed that the only differences are: 1) the ventilation tube is pre-loaded in the proposed device as compared to the TTI predicates and 2) the TTS uses a silicone vent tube as opposed to the titanium tube used by the Heinz Kurz TVT. The devices are substantially equivalent.

Section 11 Device Description

Device Description

The Hummingbird™ Tympanostomy Tube System is comprised of the following components:

Component/ Model	Description
(b) (4)	

Section 11
Device Description

b(4)Trade Secret Process- Design Specs

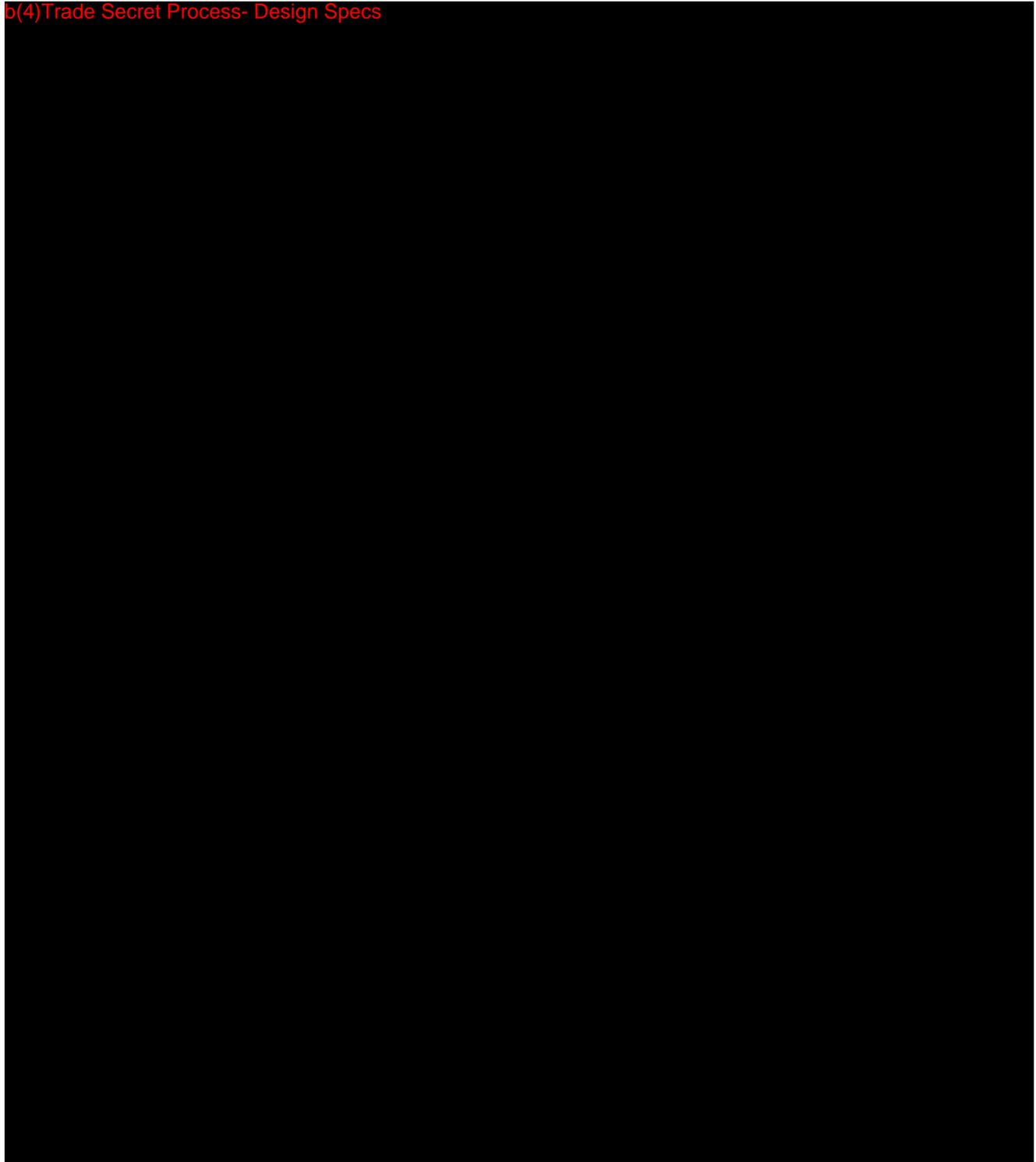


Diagram 2

Section 11 Device Description

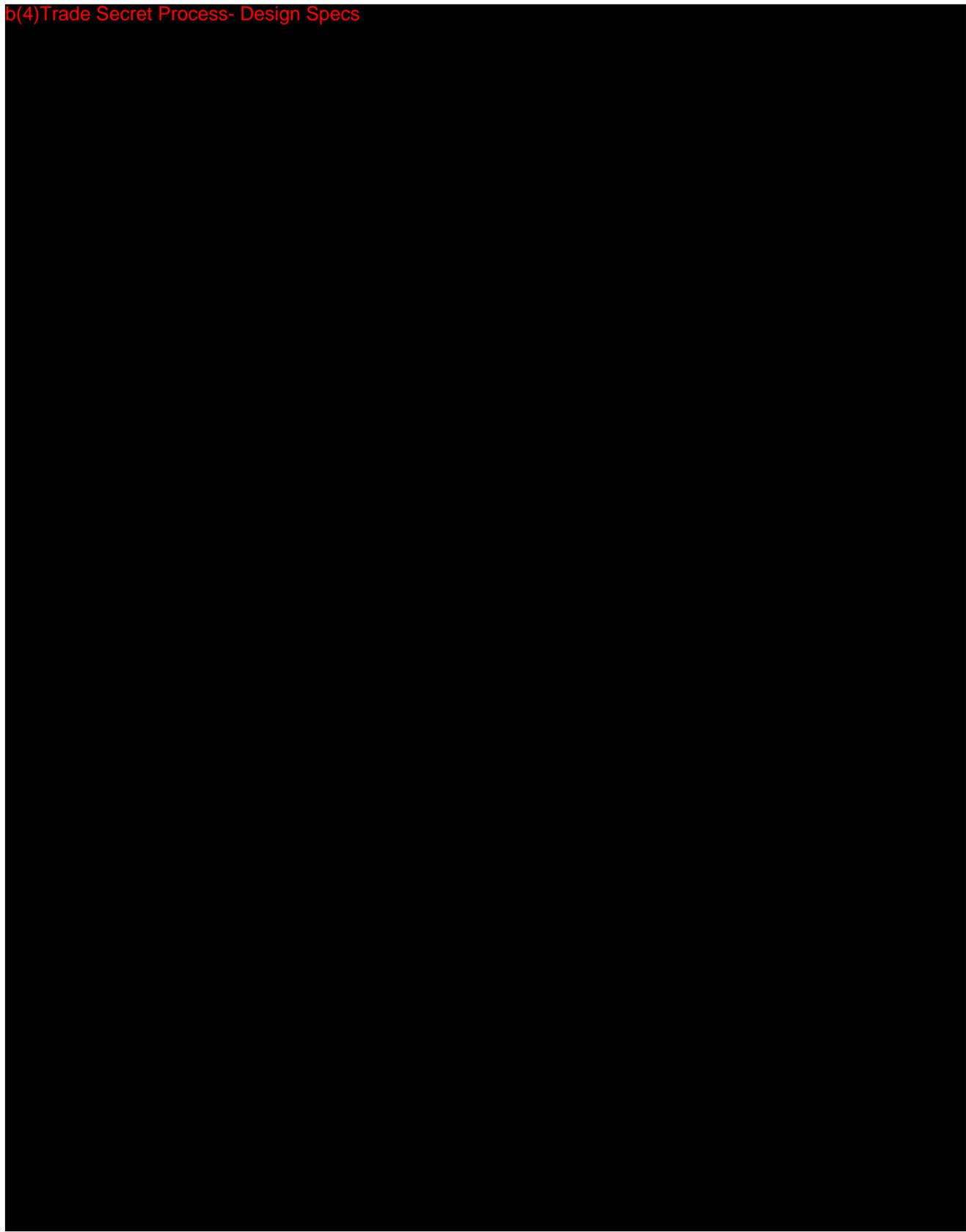
The ventilation tube is contained within the distal end of cutting sheath, and is manually deployed across the tympanic membrane as shown in diagram 3.

b(4)Trade Secret Process- Design Specs



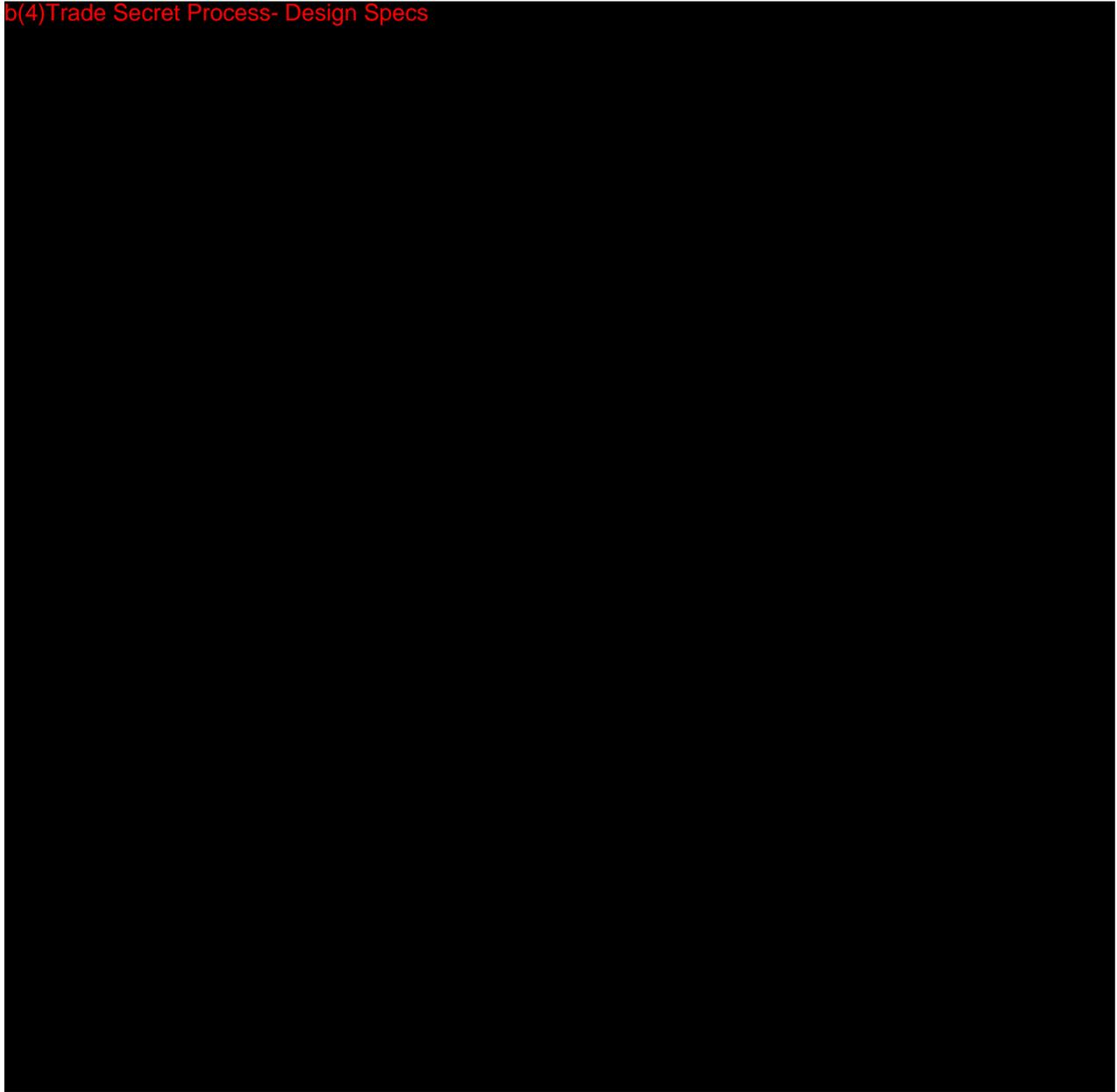
Section 11
Device Description

b(4)Trade Secret Process- Design Specs



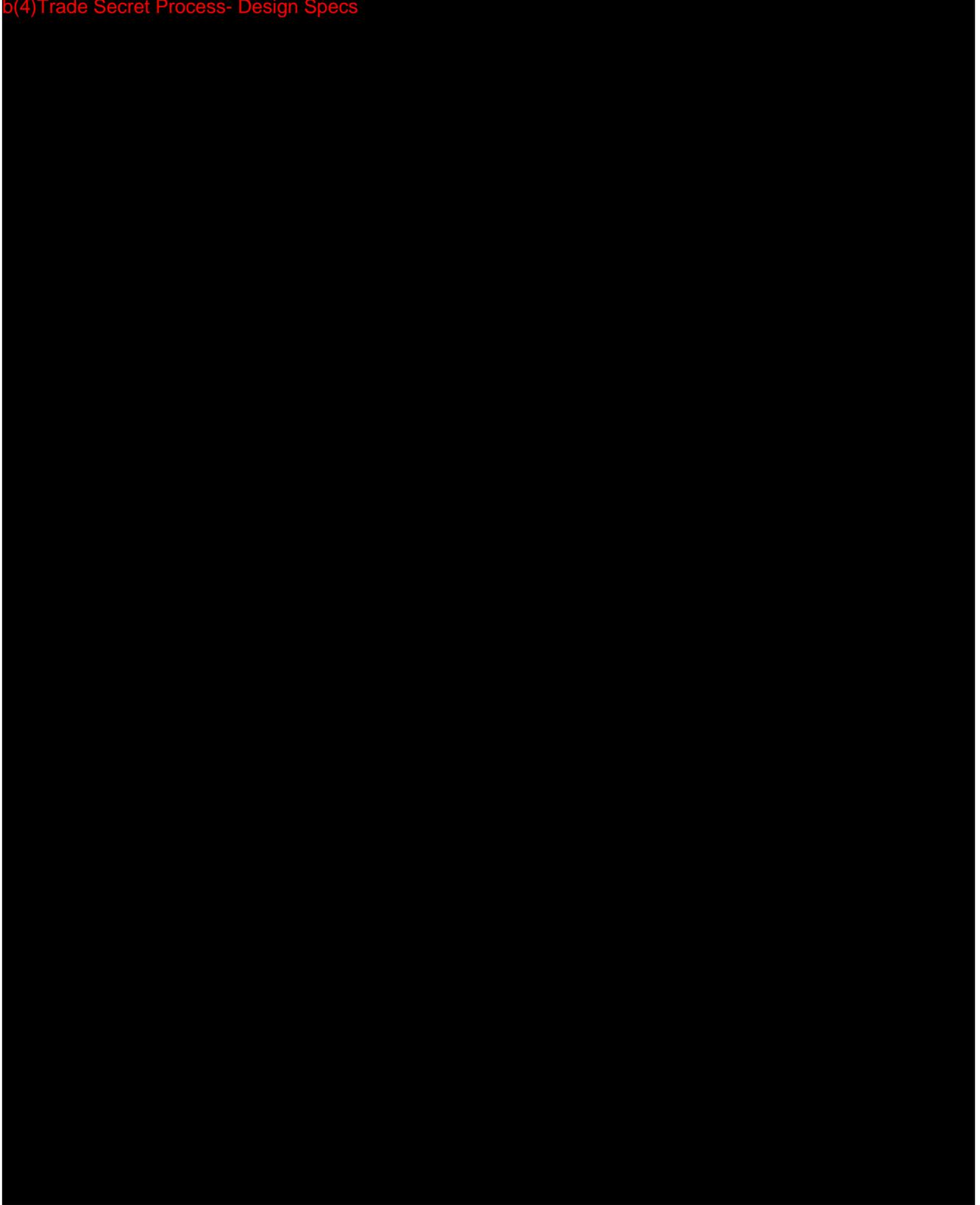
Section 11
Device Description

b(4)Trade Secret Process- Design Specs



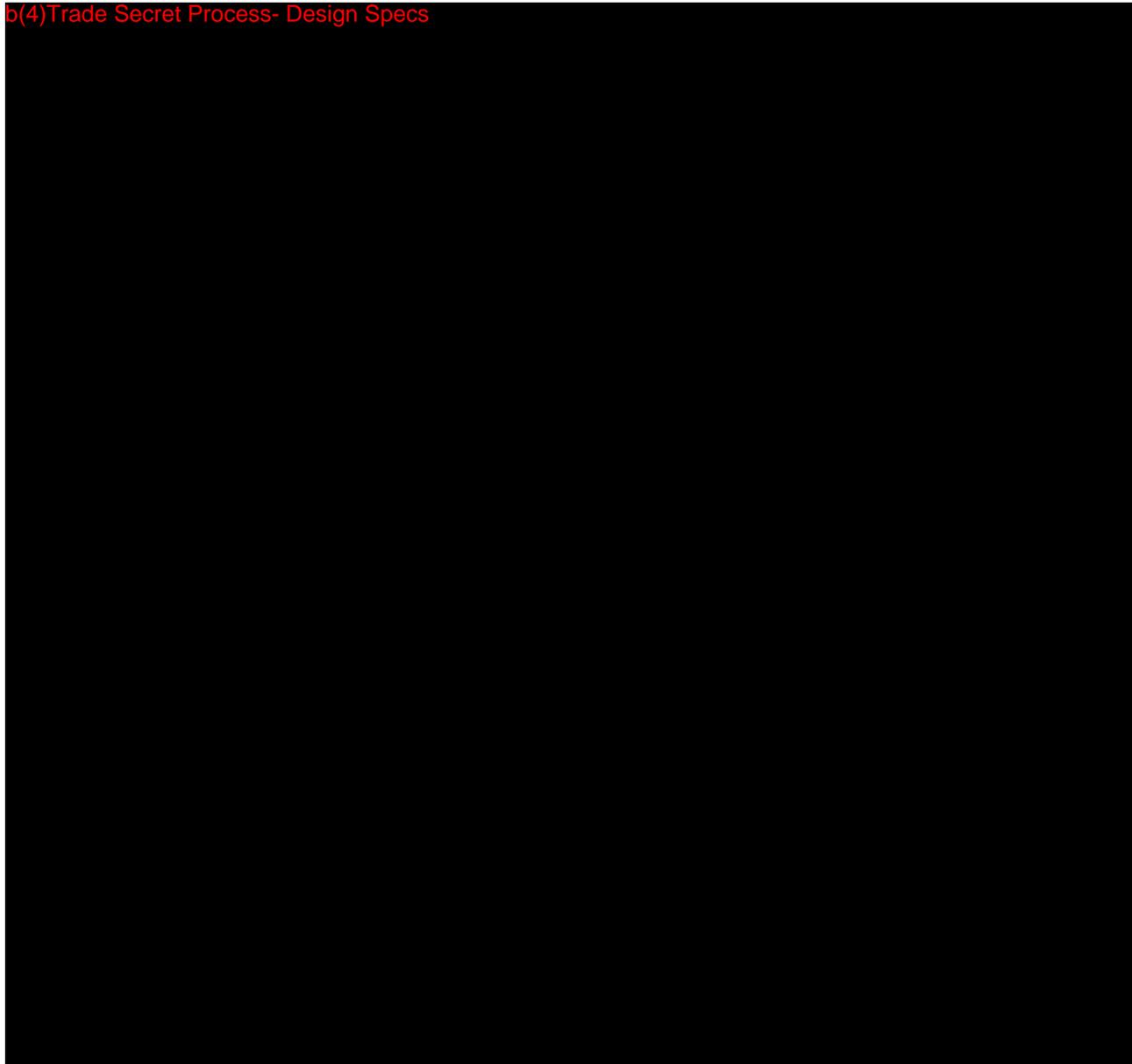
Section 11
Device Description

b(4)Trade Secret Process- Design Specs



Section 11
Device Description

b(4)Trade Secret Process- Design Specs



Section 11 Device Description

The ventilation tube is a standard, medical grade silicone otologic ventilation tube with a 1 mm inside lumen diameter as illustrated in diagram 4 (note all dimensions shown are in millimeters.) **b(4)Trade Secret Process- Design Specs**



b(4)Trade Secret Process- Design Specs

Diagram 4

Detailed schematics are included in Appendices F1 – F4. Appendix F1 is a schematic of the packaged device, Appendix F2 includes drawings of the TTS Handle assemblies, and Appendix F3 includes schematics of the tip assemblies. Appendix F4 is a schematic of the ventilation tube.

Section 12 Substantial Equivalence Discussion

Substantial Equivalence

The Hummingbird™ TTS with preloaded tube is substantially equivalent with respect to the Heinz Kurz TVT as confirmed through dimensional attributes, which are shown in Figure 7. For additional clarity, a photograph of the Heinz Kurz TVT next to a Preceptis TTI is shown in Figure 8 Photograph of a Heinz Kurz TVT with preloaded ventilation tube (right) next to a Hummingbird™ TTS with preloaded ventilation tube. (left). (b)(4)

[REDACTED]

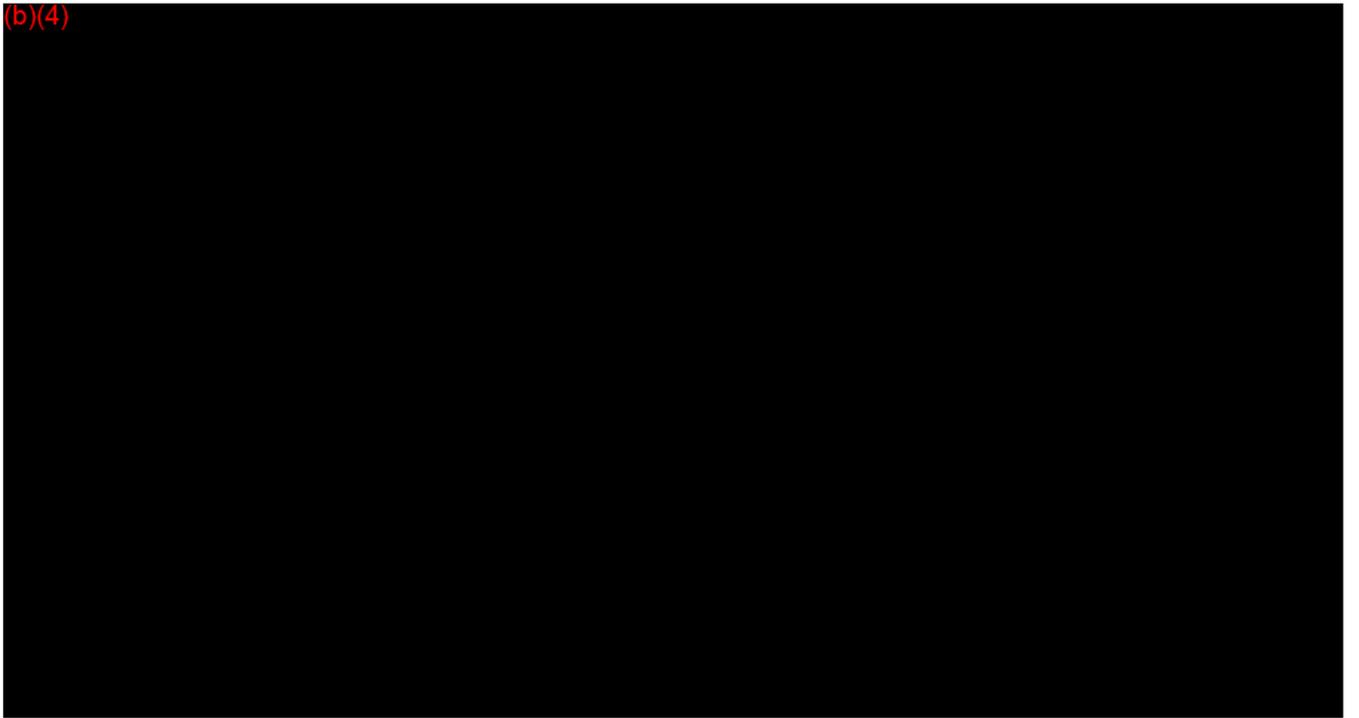
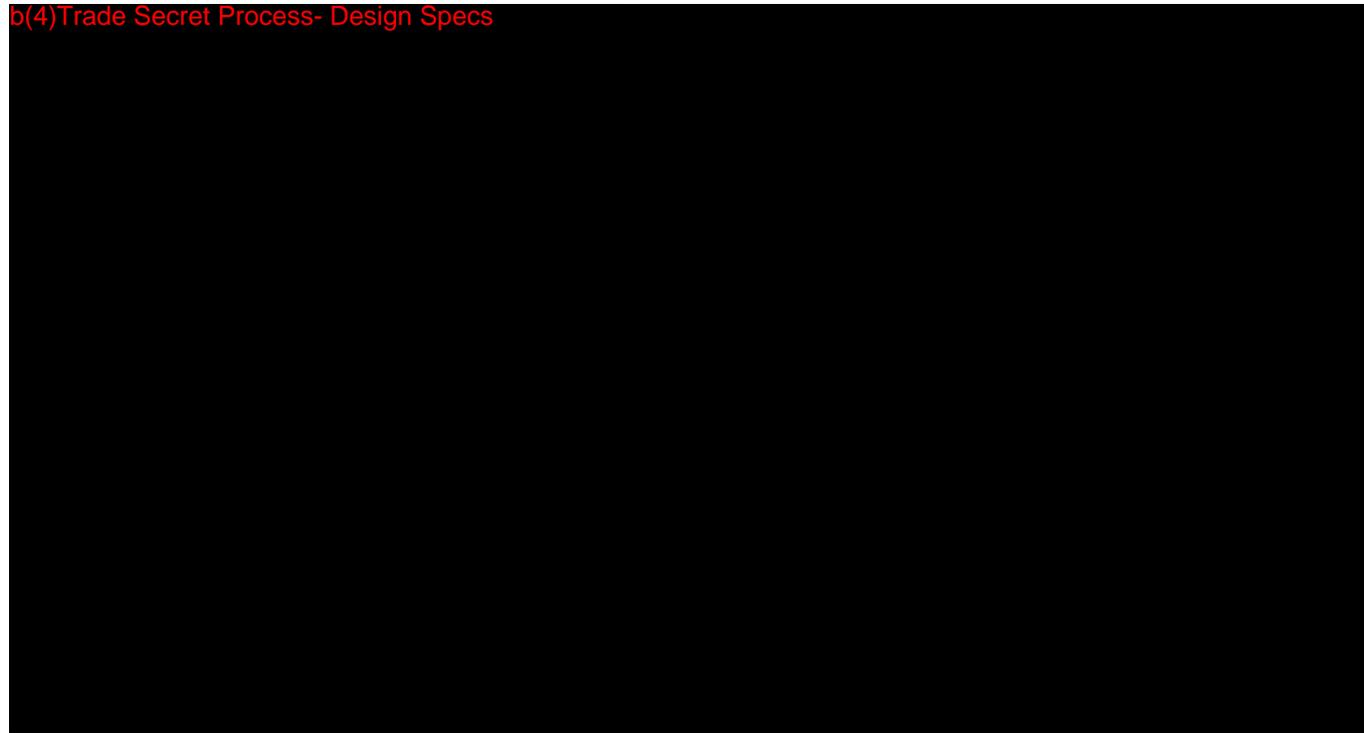


Figure 7 Dimensional attribute comparison between the Heinz Kurz Trocar Ventilation Tube and the Hummingbird™ TTS with preloaded ventilation tube.

Section 12
Substantial Equivalence Discussion

b(4)Trade Secret Process- Design Specs



Section 12 Substantial Equivalence Discussion

The device comparison table shows the similarities and differences between the Hummingbird™ Tympanostomy Tube System and the predicate devices. The indications for use, physical characteristics, materials, and safety testing requirements are all the same.

Device Comparison Table

Parameter	Hummingbird™ Tympanostomy Tube System w/ pre-loaded ventilation tube (TTS - PN 05-1001-50X)	Heinz-Kurz Trocar Ventilation Tube (TVT) -Predicate	Tympanostomy Tube Inserter Convenience Kit (PN 05-1001-005) - Tympanostomy Tube Inserter (TTI - PN 05-1001-006) -Predicates	Summit Medical Otologic Ventilation Tubes - Predicate	Comparison
General Description	Sterile Tube Inserter Pre-loaded with Sterile Vent Tubes	Sterile Tube Inserter Packaged with Sterile Vent Tubes	Sterile Tube Inserter Packaged with Sterile Vent Tubes - Sterile Tube Inserter	Ventilation Tube	
Indications for Use	The Hummingbird Tympanostomy Tube System (TTS) is intended to deliver a tympanostomy tube in tympanostomy procedures in which the patient is receiving a tympanostomy tube.	Temporary implant for ventilation and drainage of middle ear subsequent to acute otitis media.	The Tympanostomy Tube Inserter (TTI) is intended to deliver a tympanostomy tube in tympanostomy procedures in which the patient is receiving a tympanostomy tube.	Indicated where chronic Eustachian tube dysfunction does not respond to conventional therapy.	Same
Intended use	The TTS is intended to deliver a tympanostomy tube through the tympanic membrane (TM) of the patient. It combines the separate functions of creating a myringotomy, positioning and placing a ventilation tube across the TM, and suctioning.	Temporary implant for ventilation and drainage of middle ear.	The TTI is intended to deliver a tympanostomy tube through the tympanic membrane (TM) of the patient. It combines the separate functions of creating a myringotomy, positioning and placing a ventilation tube across the TM, and suctioning.	Temporary implant for ventilation and drainage of middle ear.	Same

Section 12 Substantial Equivalence Discussion

Parameter	Hummingbird™ Tympanostomy Tube System w/ pre-loaded ventilation tube (TTS - PN 05-1001-50X)	Heinz-Kurz Trocar Ventilation Tube (TVT) -Predicate	Tympanostomy Tube Inserter Convenience Kit (PN 05-1001-005) - Tympanostomy Tube Inserter (TTI - PN 05-1001-006) -Predicates	Summit Medical Otolgic Ventilation Tubes - Predicate	Comparison
Design	<u>Manual Surgical Instrument</u> 1. Vent tube provided pre-loaded inside of a cutting sheath (hollow trocar). 2. Incision of the tympanic membrane using the cutting sheath, and insertion of the tube is performed manually by user. 3. Hollow cutting sheath manually retracted from around vent tube after placement by sliding actuation wheel.	<u>Manual Surgical Instrument</u> 1. Vent tube provided pre-loaded on outside of a trocar. 2. Incision of the tympanic membrane/insertion of the tube is performed manually by user. 3. Trocar manually retracted after vent tube placement.	<u>Manual Surgical Instrument</u> 1. Vent tube provided pre-loaded inside of a cutting sheath (hollow trocar). 2. Incision of the tympanic membrane using the cutting sheath, and insertion of the tube is performed manually by user. 3. Hollow cutting sheath manually retracted from around vent tube after placement by sliding actuation wheel.	N/A	Same/Similar
Technological Characteristics	<u>Manual operation</u> 1. Manual myringotomy creation controlled by surgeon. 2. Depth of penetration controlled manually by surgeon. 3. Vent tube positioned manually in myringotomy under direct visualization. 4. Manual retraction of cutting element by surgeon.	<u>Manual operation</u> 1. Manual myringotomy creation controlled by surgeon. 2. Depth of penetration controlled manually by surgeon. 3. Vent tube positioned manually in myringotomy under direct visualization. 4. Manual retraction of cutting element by surgeon.	<u>Manual operation</u> 1. Manual myringotomy creation controlled by surgeon. 2. Depth of penetration controlled manually by surgeon. 3. Vent tube positioned manually in myringotomy under direct visualization. 4. Manual retraction of cutting element by surgeon.	N/A	Same
Dimensions (vent tube)	1 mm lumen diameter	1.25 mm lumen diameter	1 mm lumen diameter - NA	0.89-1.14 mm lumen diameter	Same/ Similar
Materials	Medical Grade Silicone, Stainless Steel, Plastic	Ventilation Tube: Titanium Insertion Accessory: Stainless Steel	Medical Grade Silicone, Stainless Steel, Plastic - Stainless Steel, Plastic	Medical Grade Silicone	Same/ Similar

Section 12 Substantial Equivalence Discussion

Parameter	Hummingbird™ Tympanostomy Tube System w/ pre-loaded ventilation tube (TTS - PN 05-1001-50X)	Heinz-Kurz Trocar Ventilation Tube (TVT) -Predicate	Tympanostomy Tube Inserter Convenience Kit (PN 05-1001-005) - Tympanostomy Tube Inserter (TTI - PN 05-1001-006) -Predicates	Summit Medical Otologic Ventilation Tubes - Predicate	Comparison
Sterile	Sterile (EO)	Trocar and Tube: Sterile (Radiation) Insertion Accessory: Non-sterile, provided with sterilization recommendations.	Sterile (EO)	Sterile (EO)	Same

Summary of Similarities

- Indications for use are the same or similar.
- Design and Technological Characteristics are the same or similar.
- Materials are the same.
- Method of sterilization is the same or similar.

Summary of Differences

- No differences exist between the Hummingbird™ TTS and the predicate devices.
- The (b) (4) ventilation tube comes pre-loaded inside the TTS in the new device, as compared to being loaded by a clinician at the point of use in the predicate Preceptis convenience kit (TTI with (b) (4) ventilation tube.)
- The Hummingbird TTS places a silicone vent tube and the Heinz-Kurz TVT places a titanium vent tube.

An analysis of the differences between the devices showed that the loading of the tube into the inserter prior to sterilization is the only difference. This difference does not raise a question of safety or efficacy. The devices are substantially equivalent.

Section 13

Proposed Labeling

Predicate labeling is included in Appendices A1 thru A3.

- Appendix A1 includes instructions for use for the predicate ventilation tube.
- Appendix A2 includes instructions for use for the predicate TTI (w/out pre-loaded ventilation tube)
- Appendix A3 includes instructions for use for Heinz-Kurz TVT

Proposed labeling is included in Appendix B.

- Ventilation Tube Instructions for Use
- Ventilation Tube Packaging Labeling
- Hummingbird™ TTS Instructions for Use
- Hummingbird™ TTS Packaging Labeling

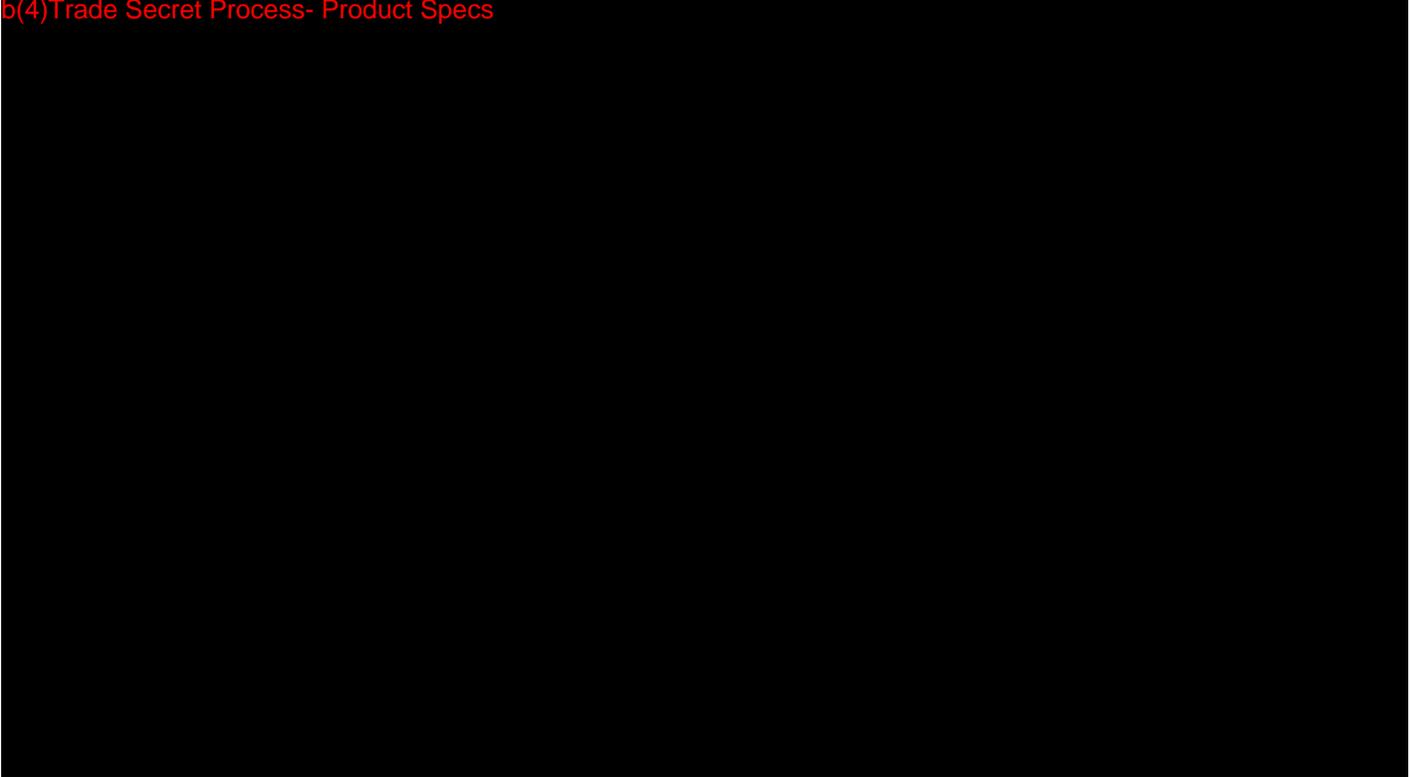
Section 14 Sterilization and Shelf Life

The (b) (4)



Sterilization

b(4)Trade Secret Process- Product Specs



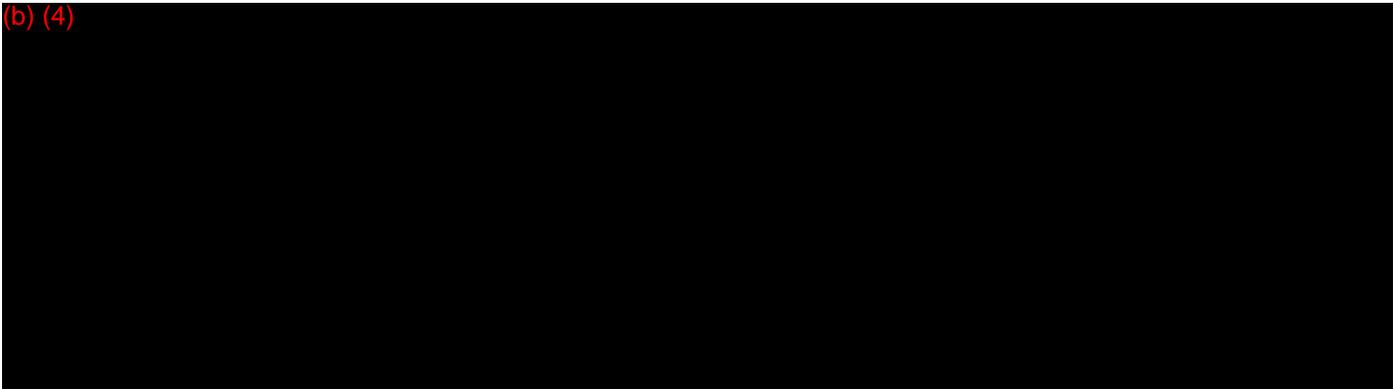
**Section 14
Sterilization and Shelf Life**

(b) (4)



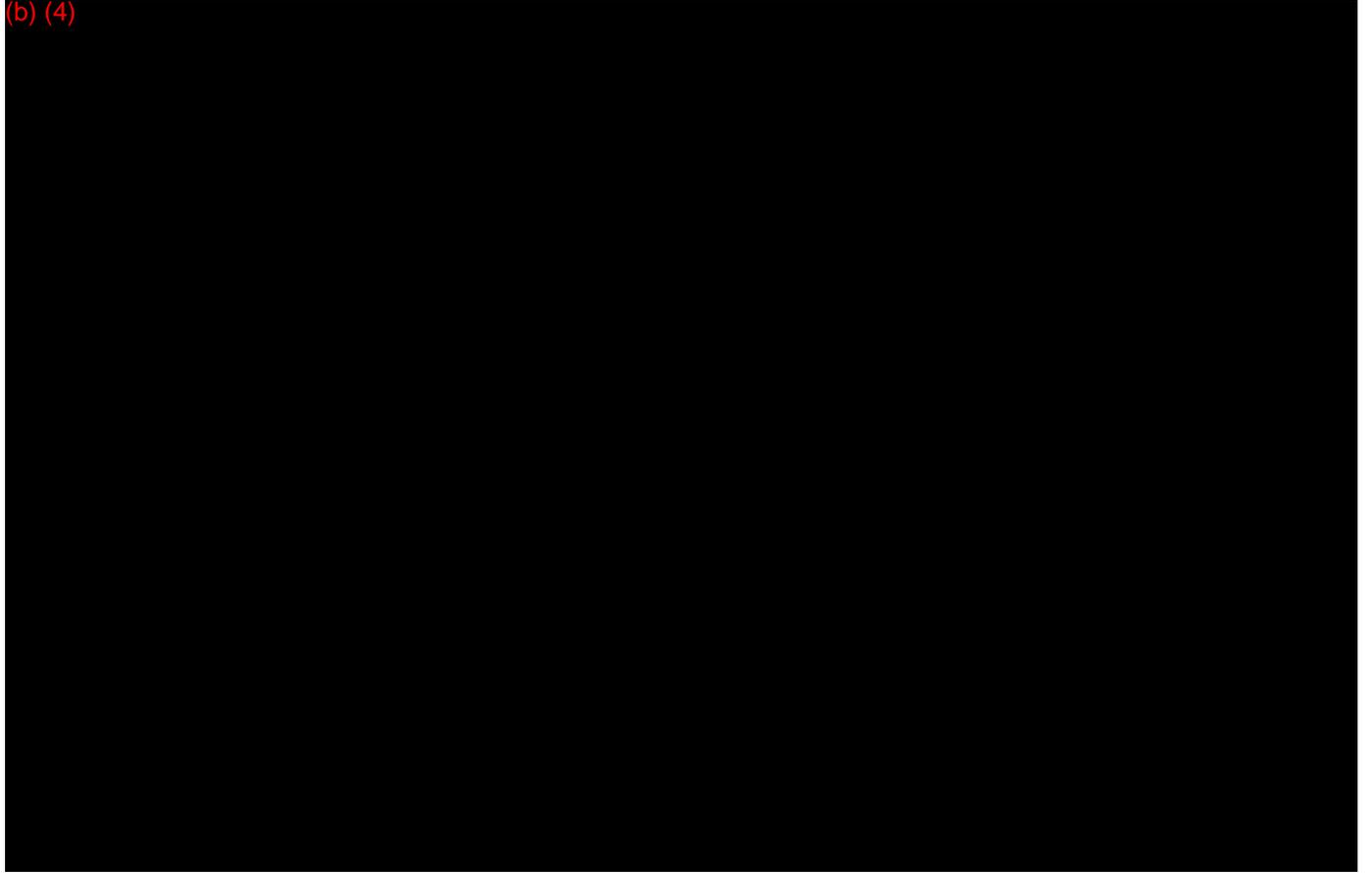
Shelf Life

(b) (4)



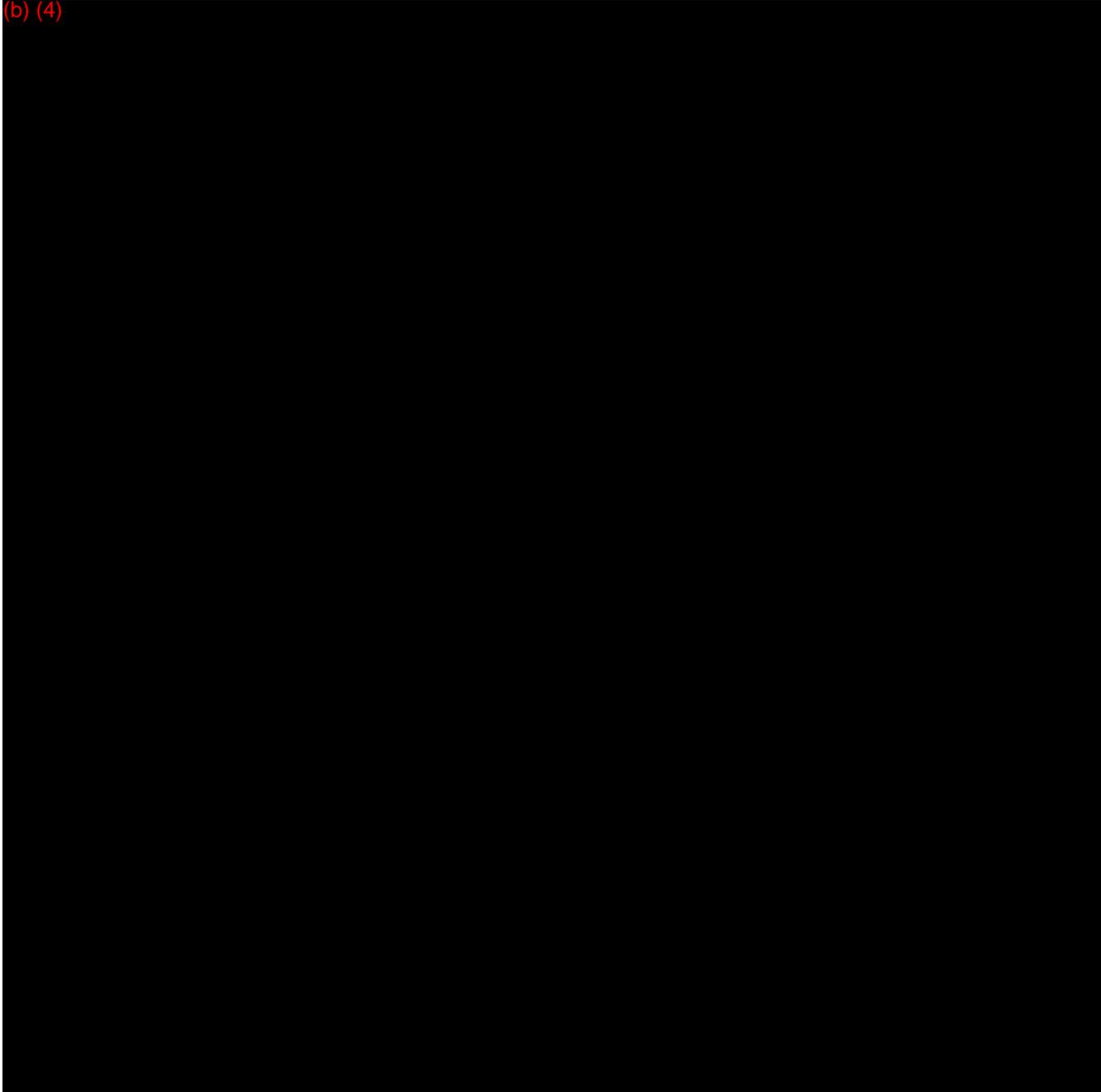
Section 14
Sterilization and Shelf Life

(b) (4)



Section 15
Biocompatibility

(b) (4)



Section 15
Biocompatibility

(b) (4)



Section 16 Software

This section does not apply as the device does not use software.

Section 17

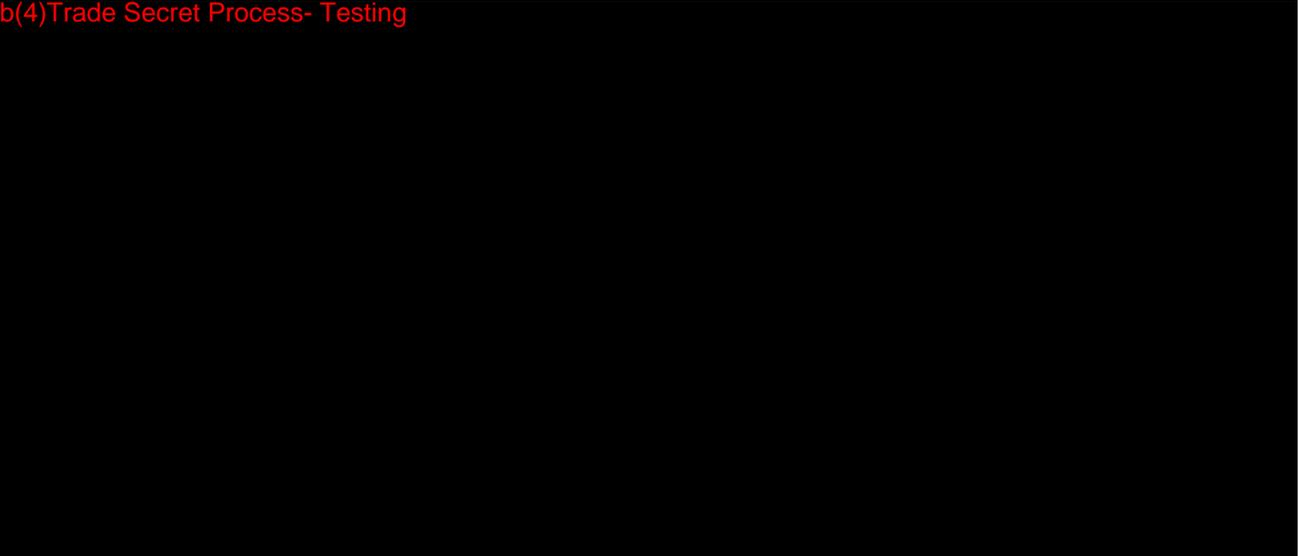
Electromagnetic Compatibility and Electrical Safety

This section does not apply as the device is a manual surgical instrument.

Section 18
Performance Testing - Bench

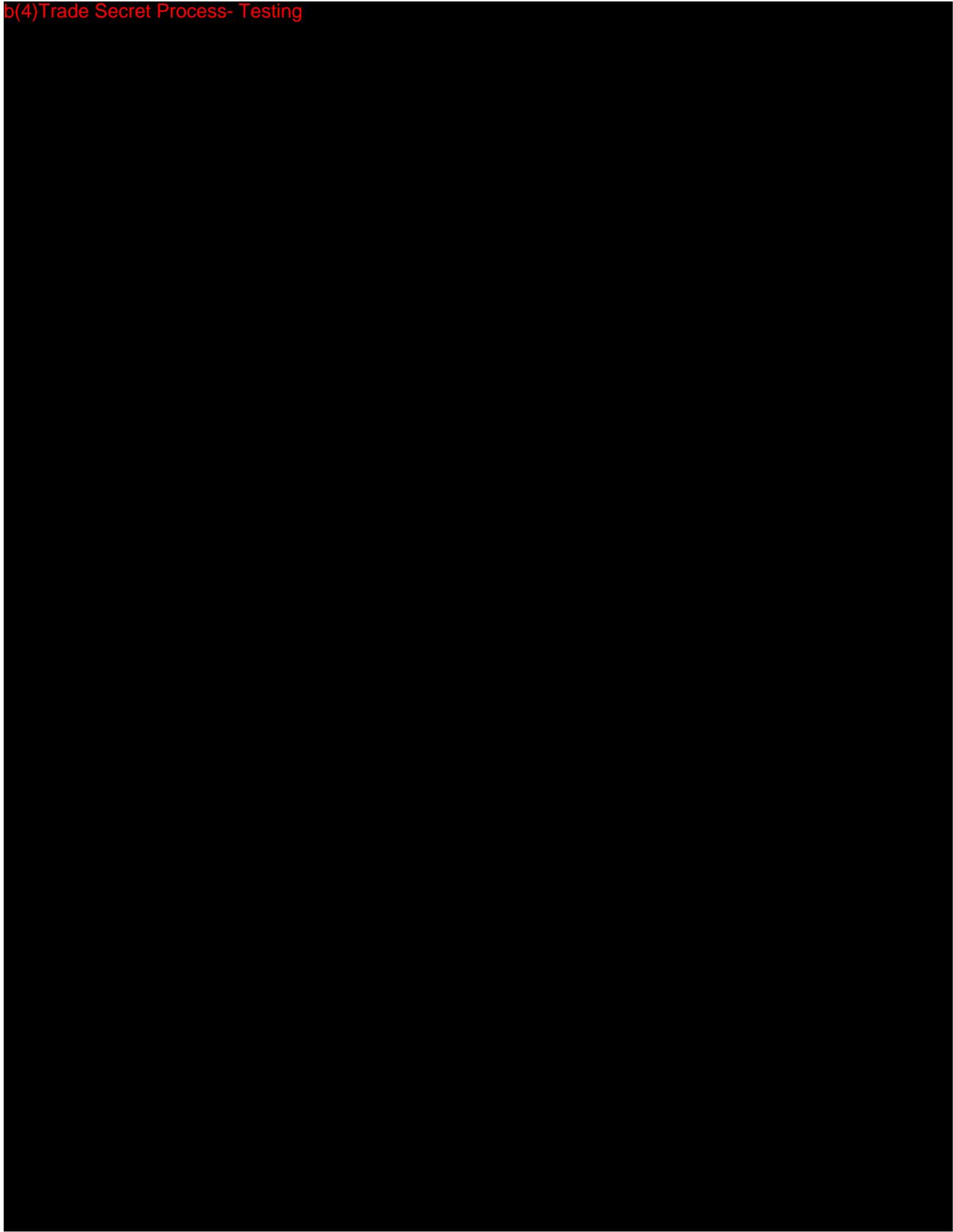
Bench Testing

b(4)Trade Secret Process- Testing



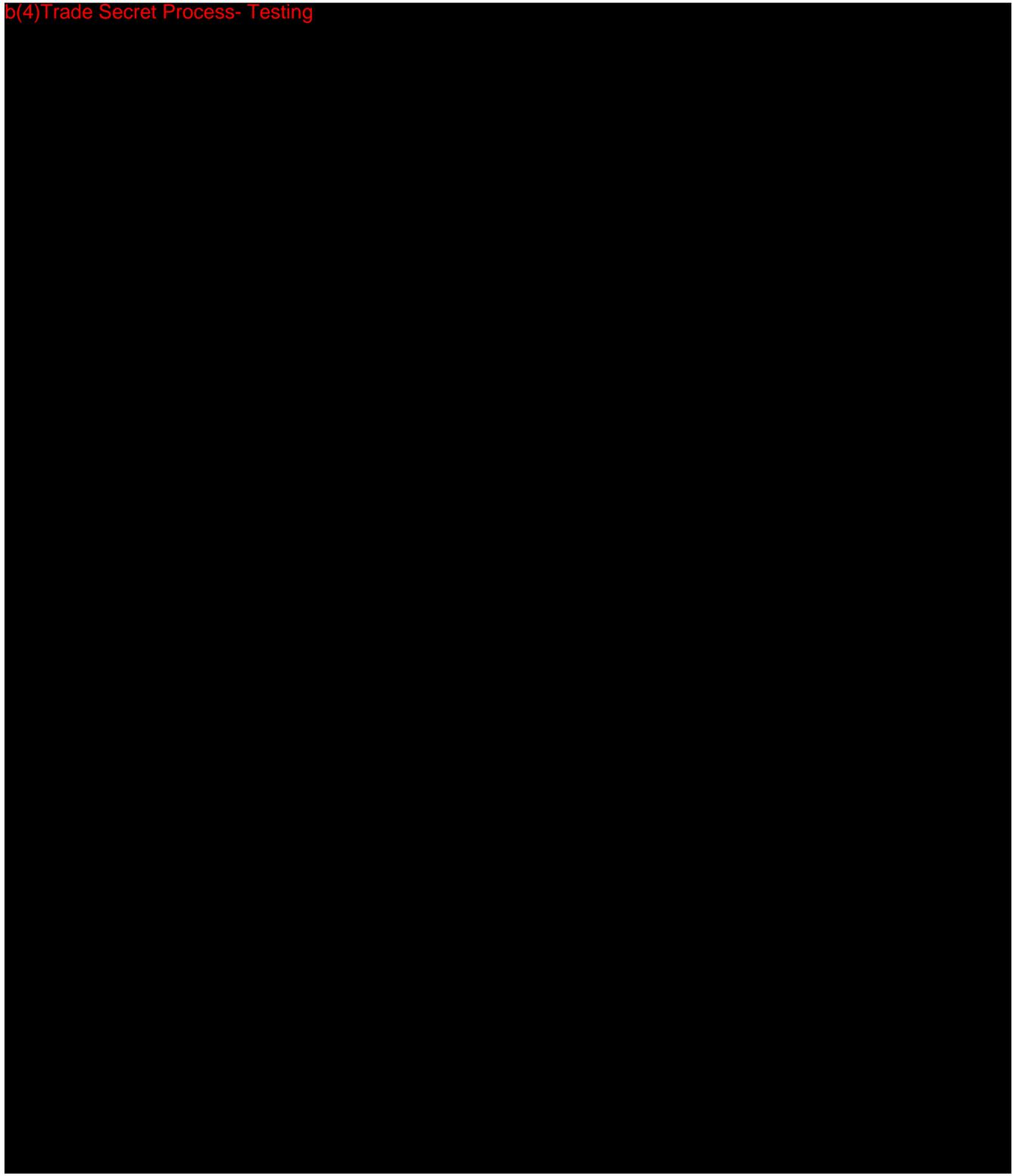
Section 18
Performance Testing - Bench

b(4)Trade Secret Process- Testing



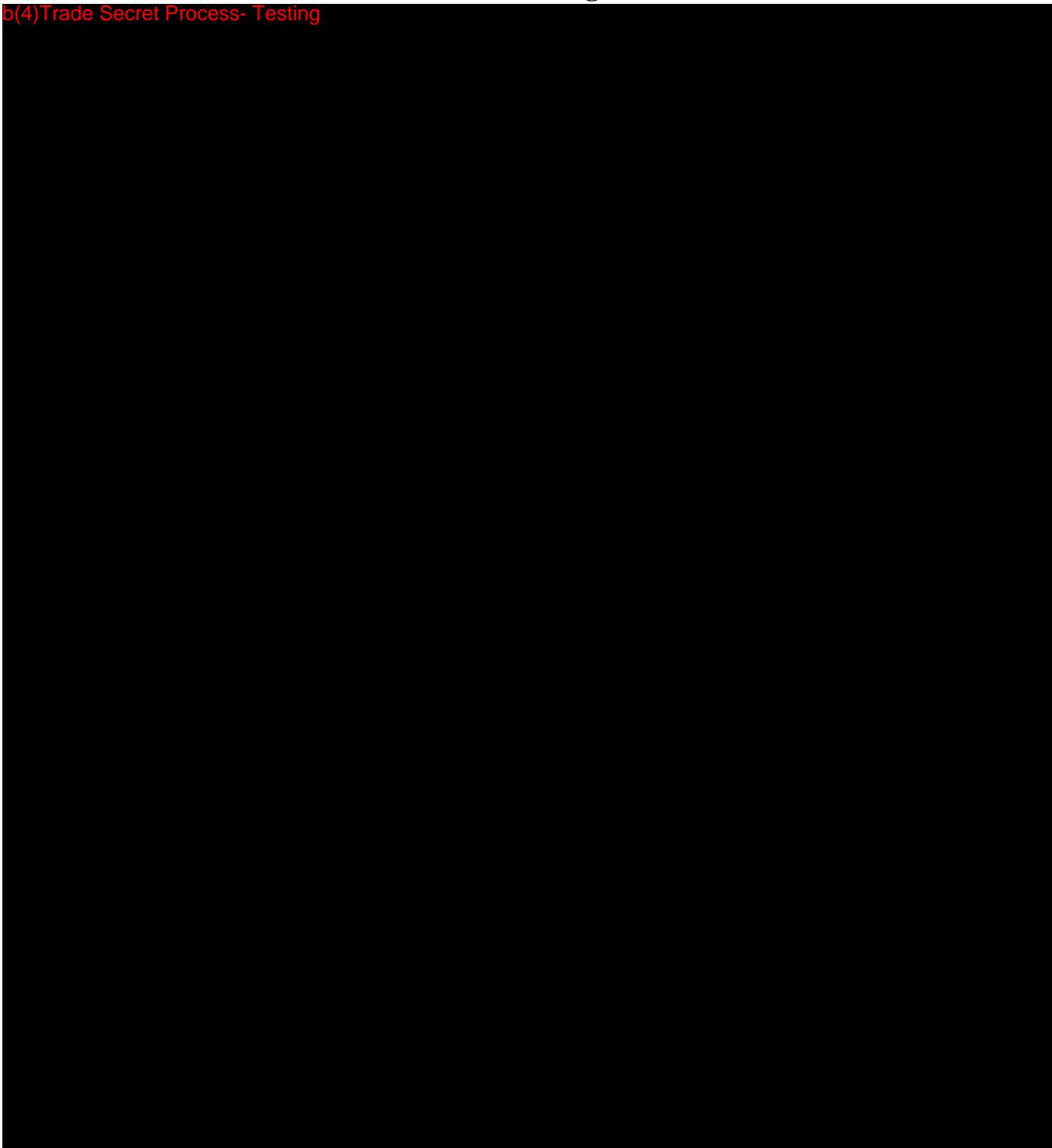
Section 18
Performance Testing - Bench

b(4)Trade Secret Process- Testing



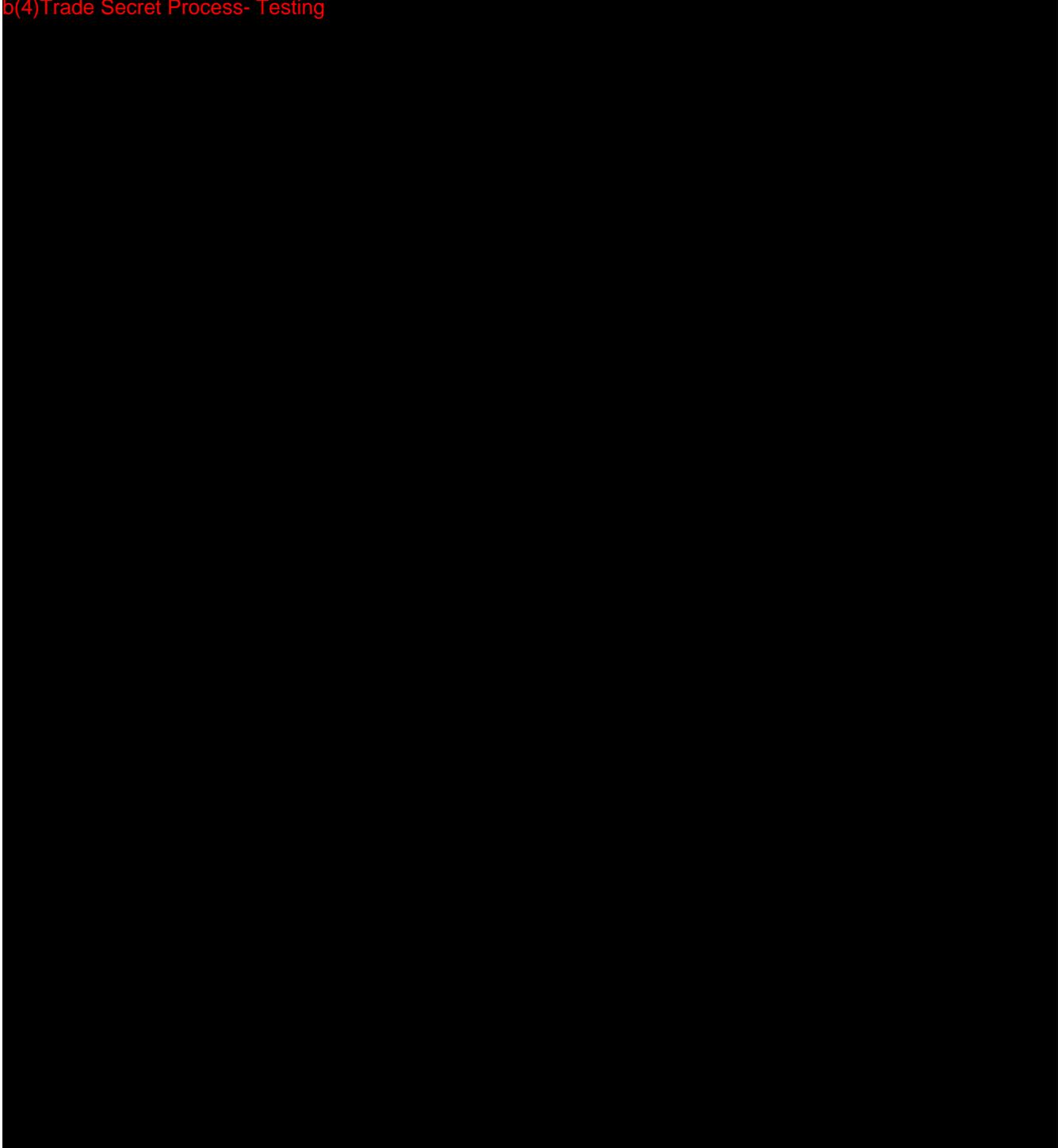
Section 18
Performance Testing - Bench

b(4)Trade Secret Process- Testing



Section 18
Performance Testing - Bench

b(4)Trade Secret Process- Testing



Section 19
Performance Testing - Animal

No performance data from animal testing is being submitted with this application.

Section 20 Performance Testing - Clinical

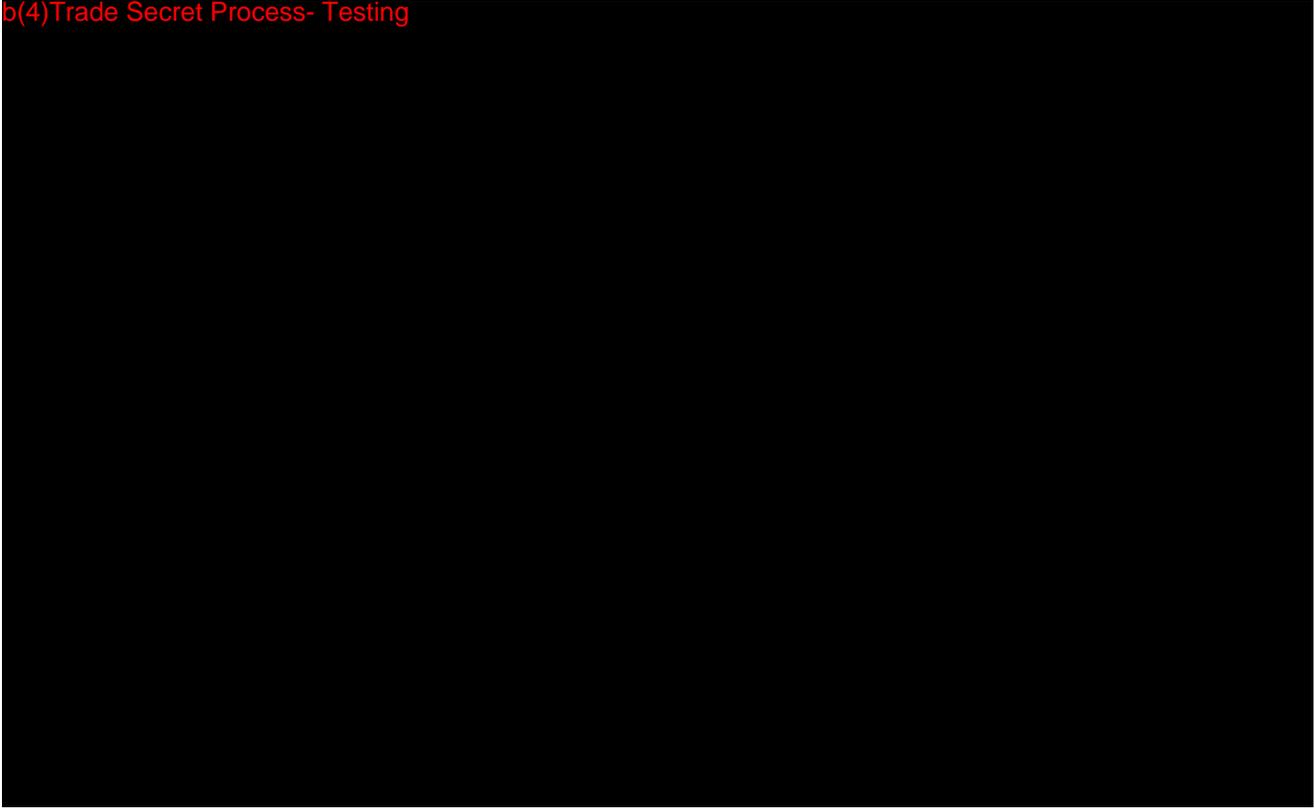
Clinical Summary of the Hummingbird™ Tympanostomy Tube System (HTTS) for Use in Children with Moderate Sedation

Background

More than 1,000,000 tympanostomy procedures are performed annually in the US, making it one of the most common surgical procedures performed in children^{1, 2}. Most ventilation tubes (VT) are inserted by otolaryngologists in cooperative patients under local anesthesia (usually ages 12 and above) and in young children under general anesthesia (usually below age 12)³.

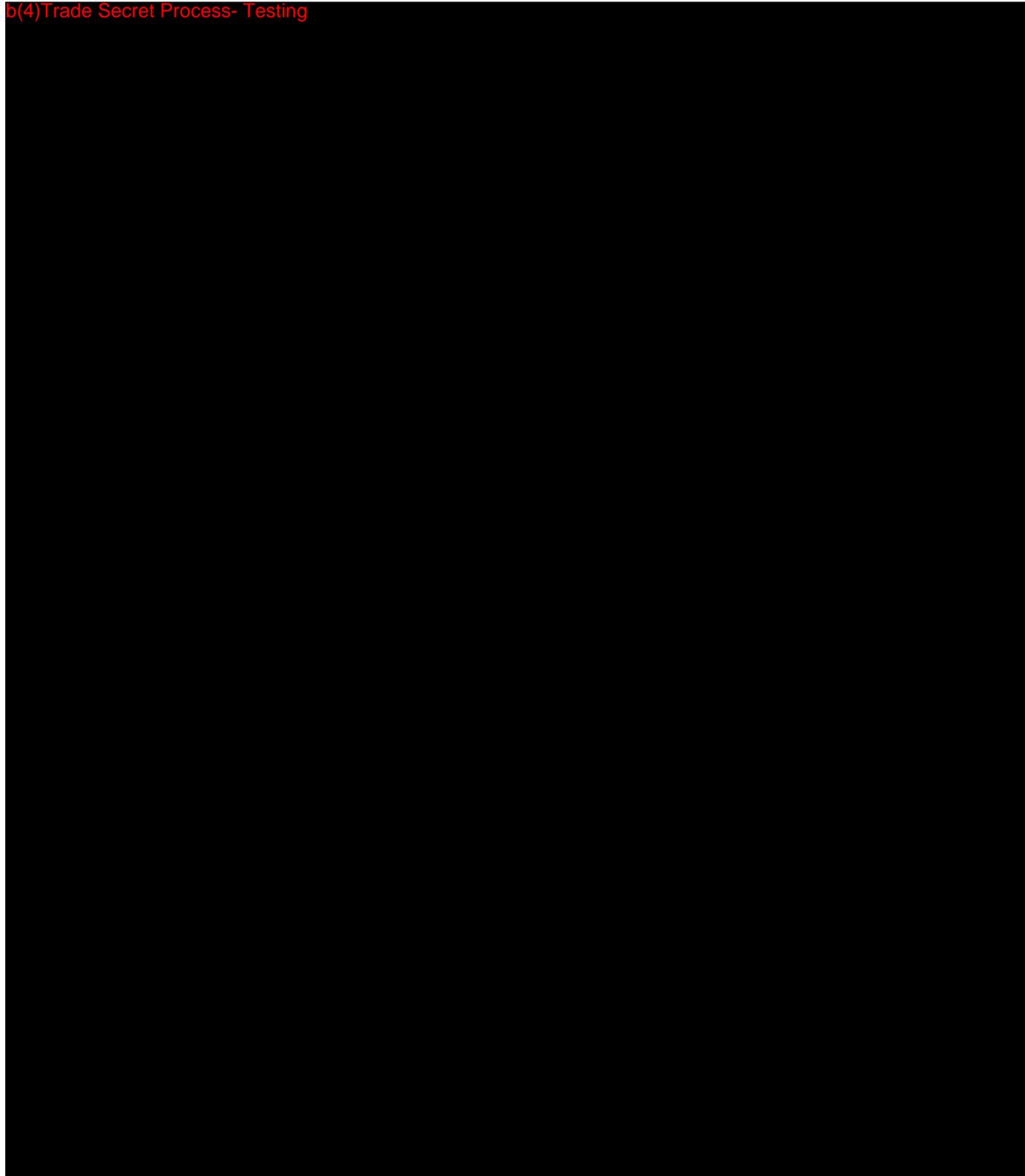
However, general anesthesia for VT insertion is associated with a 9% incidence of minor complications and a 2% incidence of major adverse events⁴. Additionally, the rate of emergence agitation in children who received general anesthesia for VT procedures is reported at 56%⁵. Most concerning of all, early exposure of young children to general anesthesia may predispose to learning disabilities^{6, 7, 8}. Since the HTTS is designed to significantly reduce surgical trauma for the patient, otolaryngologists associated with the design of the HTTS hypothesized that it could potentially allow VT placement in children to be performed with less anesthesia, mitigating the risk of general anesthesia and emergence agitation. This approach would provide an important option for otolaryngologists and anesthesiologists in a hospital setting or an ASC setting.

b(4)Trade Secret Process- Testing



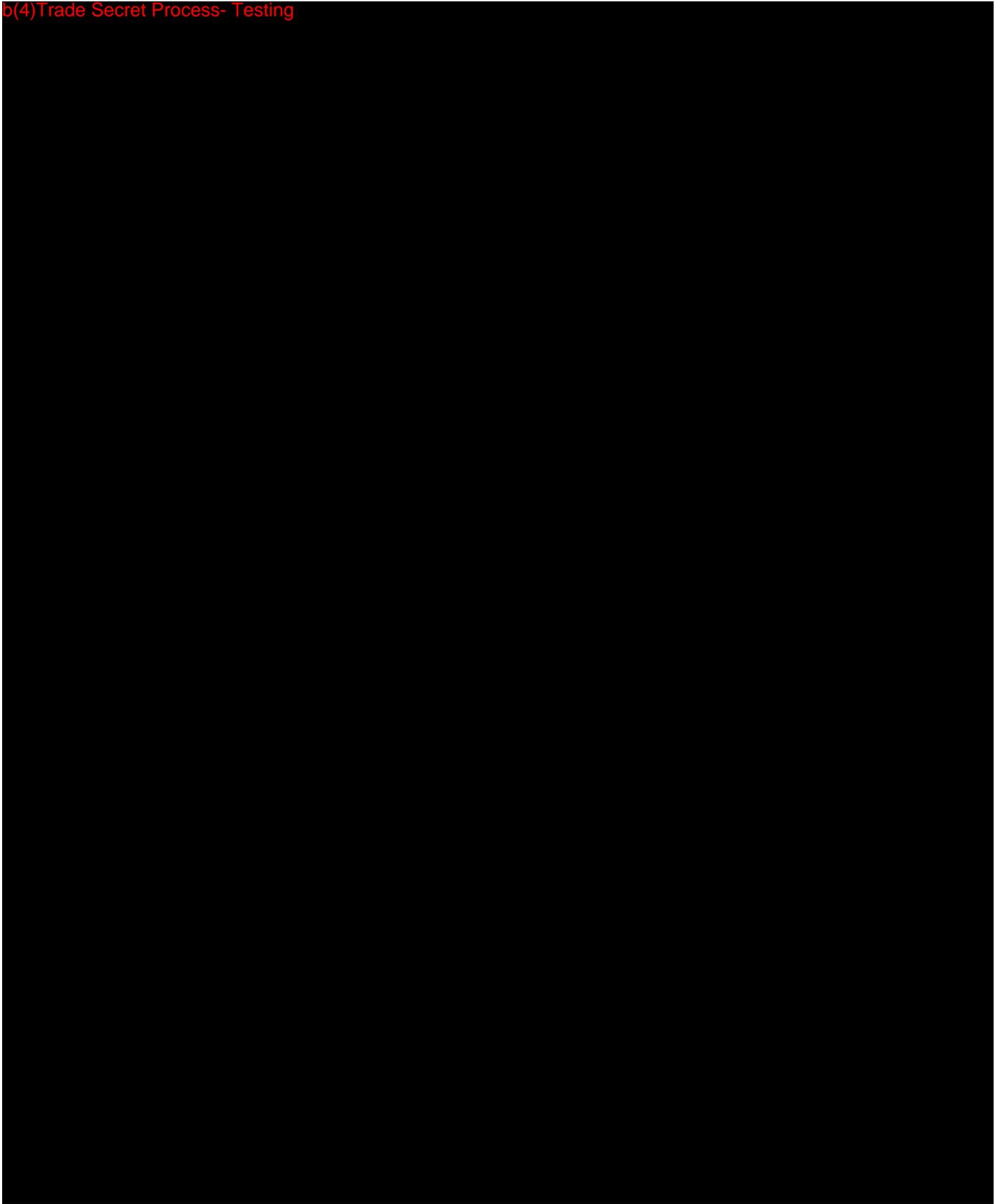
Section 20
Performance Testing - Clinical

b(4)Trade Secret Process- Testing



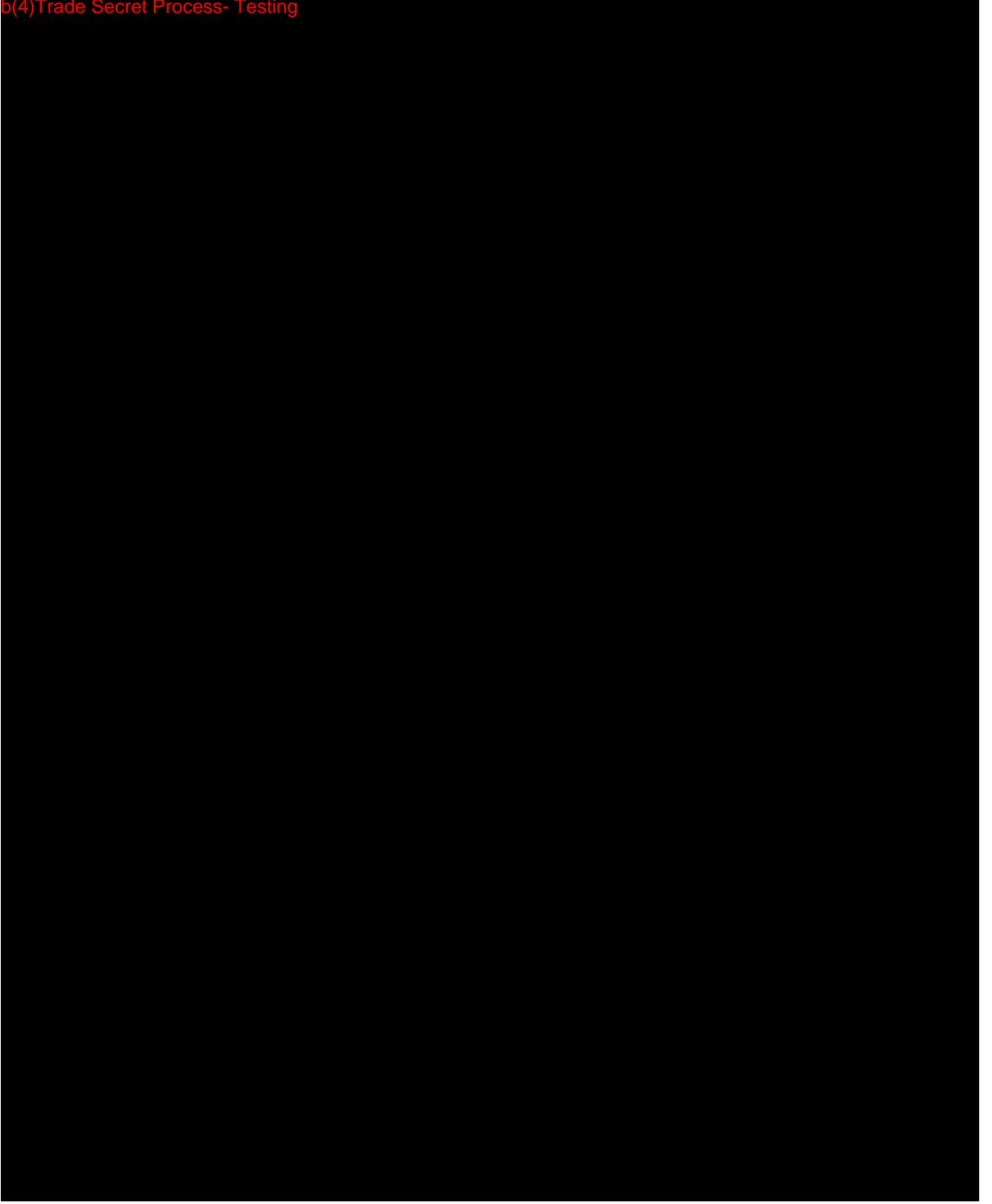
Section 20
Performance Testing - Clinical

b(4)Trade Secret Process- Testing



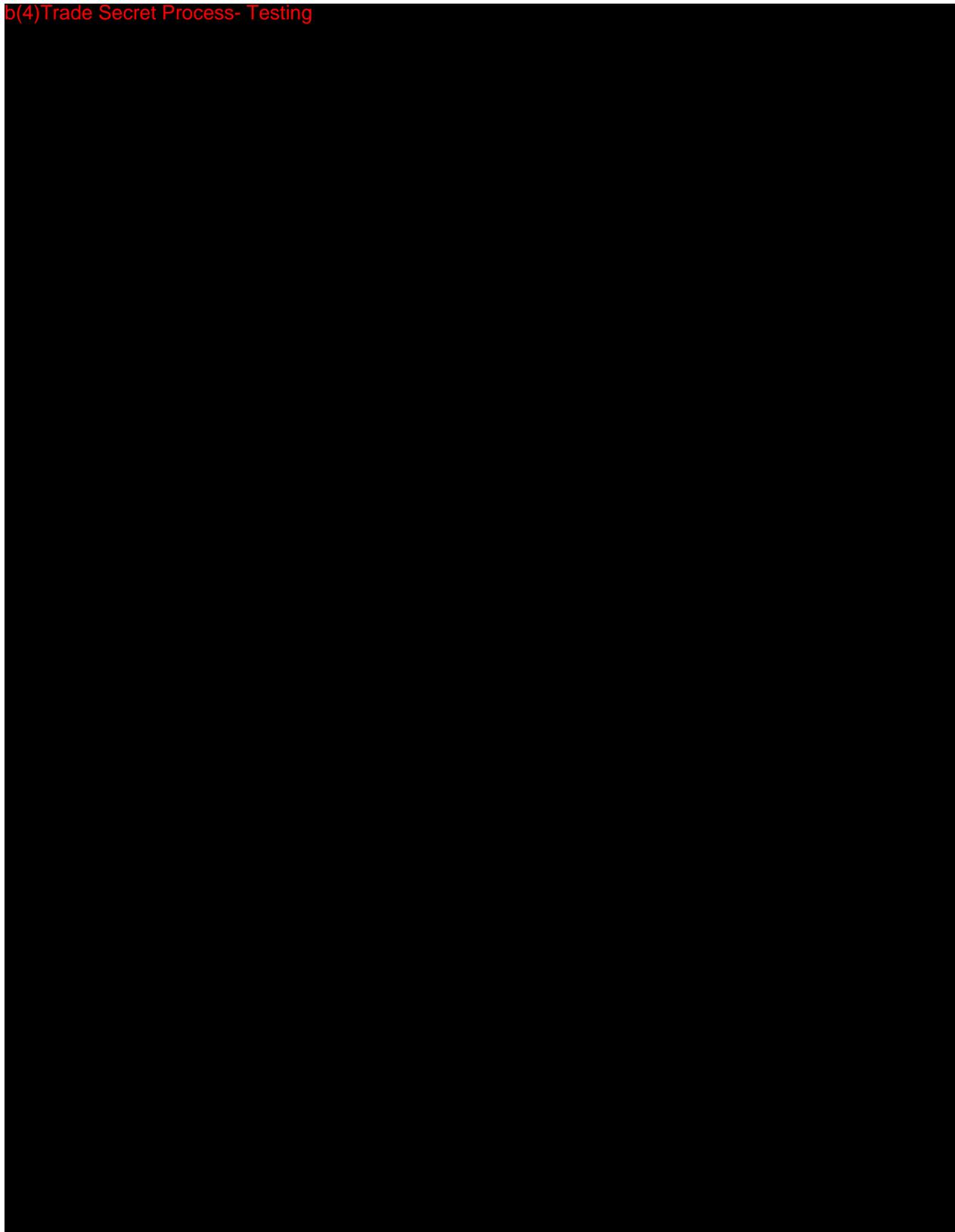
Section 20
Performance Testing - Clinical

b(4)Trade Secret Process- Testing



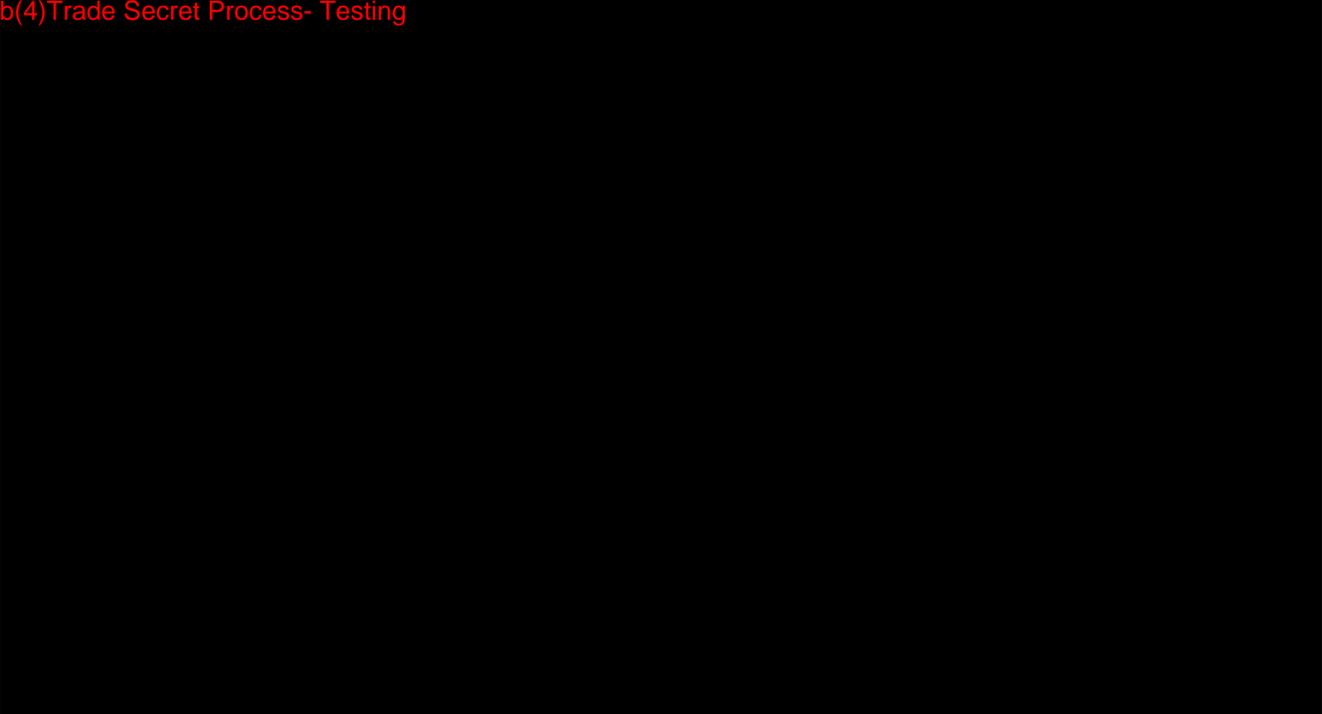
Section 20
Performance Testing - Clinical

b(4)Trade Secret Process- Testing



Section 20 Performance Testing - Clinical

b(4)Trade Secret Process- Testing



Conclusions

In the Beta and Alpha Non-Significant Risk studies, a total of 69 children, through 23 July 2014, underwent tympanostomy procedures under moderate sedation using the Preceptis HTTS to reduce surgical trauma for the patients. Results:

- The IRBs at each institution designated the studies as Non-Significant Risk due to the low risk profile of the HTTS and the fact that anesthetic regimen is determined and delivered by an anesthesia professional within the hospital.
- This approach is presented as an additional option to the current standard of care under general anesthesia. It is also an extension of current tympanostomy medical practice in which children 12 and above are treated in the office with only topical anesthetic³.
- 100% of the children received VTs as planned.
- There were no intra-operative adverse events, no unanticipated adverse events, and adverse event rates were well within normal reported rates.
- There is no additional risk in converting cases from moderate sedation to general since the conversion process simply involves turning off the nitrous oxide and turning on the flow of sevoflurane to the mask already in place over a child's nose and mouth.
- The conversion rate dropped from 30% in Beta to 7% in Alpha, indicating improvement with HTTS design and experience from the sites.

Section 20

Performance Testing - Clinical

Performing tympanostomy procedures in young children under moderate sedation in a hospital setting with anesthesia delivered by an anesthesia professional is safe and a well-reasoned alternative to the use of general anesthesia for caregivers and clinicians who are comfortable with this choice.

The use of moderate sedation rather than general anesthesia may reduce the risk of long-term learning disabilities associated with general anesthesia. Further, the use of moderate sedation has the potential to significantly reduce costs to the healthcare system while significantly improving the experience for the child and the parent.

Preceptis HTTS IFU

The Instructions for Use in this 510(k) application include the following statements in the Precaution and Restrictions sections:

Precautions:

- When using the HTTS for tympanostomy tube placement in children:
 - Either general anesthesia or moderate sedation is recommended.
 - The anesthetic regimen should be determined by the attending otolaryngologist and anesthesia professional.
 - The tympanostomy procedure should only be performed in a hospital or ambulatory surgical center setting, with the anesthesia delivered by an anesthesia professional.

Restrictions:

- When using the HTTS for tympanostomy tube placement in children:
 - The tympanostomy procedure should only be performed in a hospital or ambulatory surgical center setting, with the anesthesia delivered by an anesthesia professional.

The combined Beta and Alpha moderate sedation results presented above support the Precaution and Restriction statements in the proposed IFU.

Section 20

Performance Testing - Clinical

1. Boston M, McCook J, Burke B, Derkay C. Incidence of and risk factors for additional tympanostomy tube insertion in children. *Arch Otolaryngol Head Neck Surg.* 2003;129:293-296
2. Hartnick CJ, Shott S, Willging P, Myer CM. Methicillin-resistant *Staphylococcus aureus* otorrhea after tympanostomy tube placement. *Arch Otolaryngol Head Neck Surg.* 2000;126:1440-1443
3. Strategic Health Resources, 2011 analysis, private payer claims for tympanostomy procedures
4. Hoffmann K, Thompson G, Burke B, Derkay C. Anesthetic complications of tympanostomy tube placement in children. *Arch Otolaryngol Head Neck.* 2002; 128:1040-3.
5. Cravero J, Beach M, Dodge C, Whelan K. Emergence characteristics of sevoflurane compared to halothane in pediatric patients undergoing bilateral pressure equalization tube insertion. *J Clin Anesth.* 2000; 12:397-400
6. Ing, C, et al. Long-term differences in language and cognitive function after childhood exposure to anesthesia. *Pediatrics (aappublications.org)* 2012; 130; e476-485
7. Sprung J, Flick RP, Katusic SK, Colligan RC, Barbaresi WJ, et al. Attention-deficit/hyperactivity disorder after early exposure to procedures requiring general anesthesia. 2012 Mayo Foundation for Medical Education and Research; *Mayo Clin Proc.* 2012 Feb; 87(2):120-9.
8. Summary Minutes of the Anesthetic and Life Support Drugs Advisory Committee Meeting. March 10, 2011, 10903 New Hampshire Avenue, Silver Spring, MD 20993
9. American Society of Anesthesiology, Guide for Continuum of Depth of Sedation: Definition of General Anesthesia and Levels of Sedation/Analgesia. Approved by ASA House Delegates Oct 7, 2004, amended Oct 21, 2009
10. Thijs M.A., et al., A Trial of Treatment for Acute Otorrhea in Children with Tympanostomy Tubes,. *New England Journal of Medicine*, 2014; 370; 723-33.
11. Younis Ramzi, Prevention and Treatment of Plugged Tympanostomy Tubes. *ENT Journal*, Supplement 1, November 2007.
12. Weigal Mark, et al., A Prospective Randomized Study of Four Commonly Used Tympanostomy Tubes. *Laryngoscope* 99, March 1999.

Section 21 Appendices

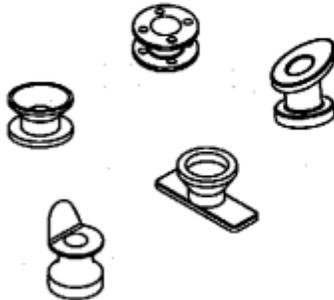
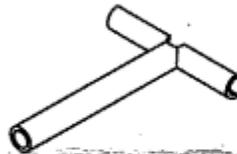
Appendices

Predicate Device Documentation	
Predicate Instructions for Use, Otologic Ventilation Tubes.....	A1
Predicate, Instructions for Use, Convenience Kit.....	A2
Predicate, Heinz-Kurz TVT Instructions for Use.....	A3
Draft Labeling	
Hummingbird™ Tympanostomy Tube System, Instructions for Use	B
Testing	
b(4)Trade Secret Process- Product Specs	C1
	C2
	C3
	C4
Packaging	
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	E2
Device Specifications/Schematics	
b(4)Trade Secret Process- Product Specs	F1
	F2
	F3
	F4
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Performance Data – Clinical	
Clinical Report – Hummingbird™ TTS	H1
FDA Form 3654, Listing of Clinical Trials	H2

Appendix A1 - Predicate Instructions for Use



Otologic Ventilation Tubes
Aérateurs transtympaniques
Paukenröhrchen
Tubos de ventilación otológicos
Tubi di ventilazione otologica
Otologische ventilatiebuisjes
Otologiske ventilasjonsrør



Instructions for Use
Mode d'emploi
Gebrauchsanweisung
Instrucciones de uso
Istruzioni per l'uso
Gebruiksaanwijzing
Bruksanvisning

Otologic Ventilation Tubes

EN

 **Before using, read the following information:**

DESCRIPTION

Otological Ventilation Tubes are an implant designed to provide ventilation to the middle ear space through the tympanic membrane. The Tubes are manufactured in numerous shapes and sizes to facilitate physician preference for treatment. A variety of materials are used such as silicone elastomer, fluoroplastic, stainless steel or titanium. Designs utilize single or dual flanges.

INDICATIONS FOR USE

Indicated where chronic Eustachian tube dysfunction does not respond to conventional therapy.

CONTRAINDICATIONS

None known. This device is not designed, sold, or intended for use except as indicated or prescribed by a physician.

PRECAUTIONS

Avoid fluid contact with ear.

The implant is intended to be single use only and should not be resterilized. Do not use if pouch is damaged.

POSSIBLE ADVERSE EFFECTS

Tube may clog
Persistent perforations of the tympanic membrane
Granulomatosis
Premature extrusion
Failure to self-extrude
Infection due to airborne or water contamination

INSTRUCTIONS FOR USE

The implant is placed in the tympanic membrane through an incision for the ventilation of the middle ear space.

Adhesive product labels are included in the package for use on patient and hospital records.

MRI INFORMATION

The Stainless Steel Vent Tubes, Titanium Vent Tube and Stainless Steel Wire have been determined to be MR-conditional according to the terminology specified in the American Society for Testing Materials (ASTM) International, Designation : F2503-05.

A patient with this device can be scanned safely immediately after placement under the following conditions:

- Static magnetic field of 3 Tesla or less
- Maximum spatial gradient magnetic field of 720-Gauss/cm or less

Additional information can be obtained by contacting Summit Medical, Inc. at 888-229-2875.

USA Rx Only

For US Audiences Only



Appendix A2 - Predicate Instructions For Use

Preceptis Tympanostomy Tube Inserter / TTI PN 05-1001-006 **INSTRUCTIONS FOR USE**

CAREFULLY READ ALL INSTRUCTIONS PRIOR TO USE.

CAUTION: Federal law restricts this device to sale by or on the order of a physician.

Indications for Use

The Tympanostomy Tube Inserter w/ tube is intended to deliver a tympanostomy tube in tympanostomy procedures in which the patient is receiving a tympanostomy tube.

Intended Use

The TTI is intended to deliver a tympanostomy tube through the tympanic membrane (TM) of the patient. It combines the separate functions of creating a myringotomy, positioning and placing a ventilation tube across the TM, and suctioning.

Warnings

- The TTI is intended for single patient use. DO NOT REUSE.
- Use the TTI with an ear speculum to avoid injury to the auditory canal.
- Do not use the TTI device if the visual depth markers provided (a visual tab located on the lateral end of the ventilation tube, and/or a marker band located on the cutting sheath) cannot be seen during use within the ear canal.
- Do not advance the visual depth markers past the tympanic membrane to avoid damage to the middle or inner ear.
- Do not bend or shape the TTI. This may cause device damage.
- Do not apply suction through the tip of the device while it is located behind the TM.
- Tympanostomy tube placement for pediatric patients should be performed under general anesthesia.

Precautions

- Follow standard hospital/clinic policies and procedures.
- Ensure the auditory canal is sufficiently clean to allow direct visualization of the TM and of the TTI device during tube placement.
- Insertion location of the TTI on the tympanic membrane should be chosen to avoid damage to the malleus and the ossicular chain.
- Avoid excessive penetration depths with the TTI device to reduce the risk of injury to vasculature or nerves in the case of abnormal anatomy.
- Completely retract the cutting sheath after tube insertion and prior to applying suction through the TTI device.
- When applying suction through the TTI device after tube insertion, ensure that the tube is not inadvertently pulled out of the myringotomy.

Appendix A2 - Predicate Instructions For Use

- Suction cannot be applied through the TTI device prior to tube deployment. Attempts to apply suction prior to tube insertion or to clear a perceived blockage prior to insertion may cause the ventilation tube to deploy erratically.
- Inspect the packages and devices carefully. Do not use if the package or device is damaged.
- Do not use if the expiration dates are exceeded.
- Use caution in opening the packaging and removing the devices to insure the devices are not damaged.

Potential Complications

Possible risks associated with the device may include but are not limited to:

- Otorrhea,
- Acute tube extrusion,
- Chronic tube extrusion,
- Tube dislocating into middle ear,
- Tube clogging,
- Bleeding,
- Vertigo,
- Nausea,
- Infection,
- Hearing loss,
- Facial nerve injury.

Restrictions

The TTI should be only operated by physicians experienced in tympanostomy procedures, which have reviewed this Instruction for Use and understood the use of the TTI.

Maintenance

The device is a single patient-use disposable product. No maintenance is required.

Appendix A2 - Predicate Instructions For Use

TTI Components

Disposable Components (provided EO Treated):

- TTI (Tympanostomy Tube Introducer with Tip Assembly)
- TTI Tip Assembly
- TTI Loading Tool

Compatible ventilation tubes (NOT included):

- Preceptis PN 05-1026-001

Other Recommended Components (NOT included)

- Ear speculum
- Vacuum system and appropriate suction tubing

Appendix A2 - Predicate Instructions For Use

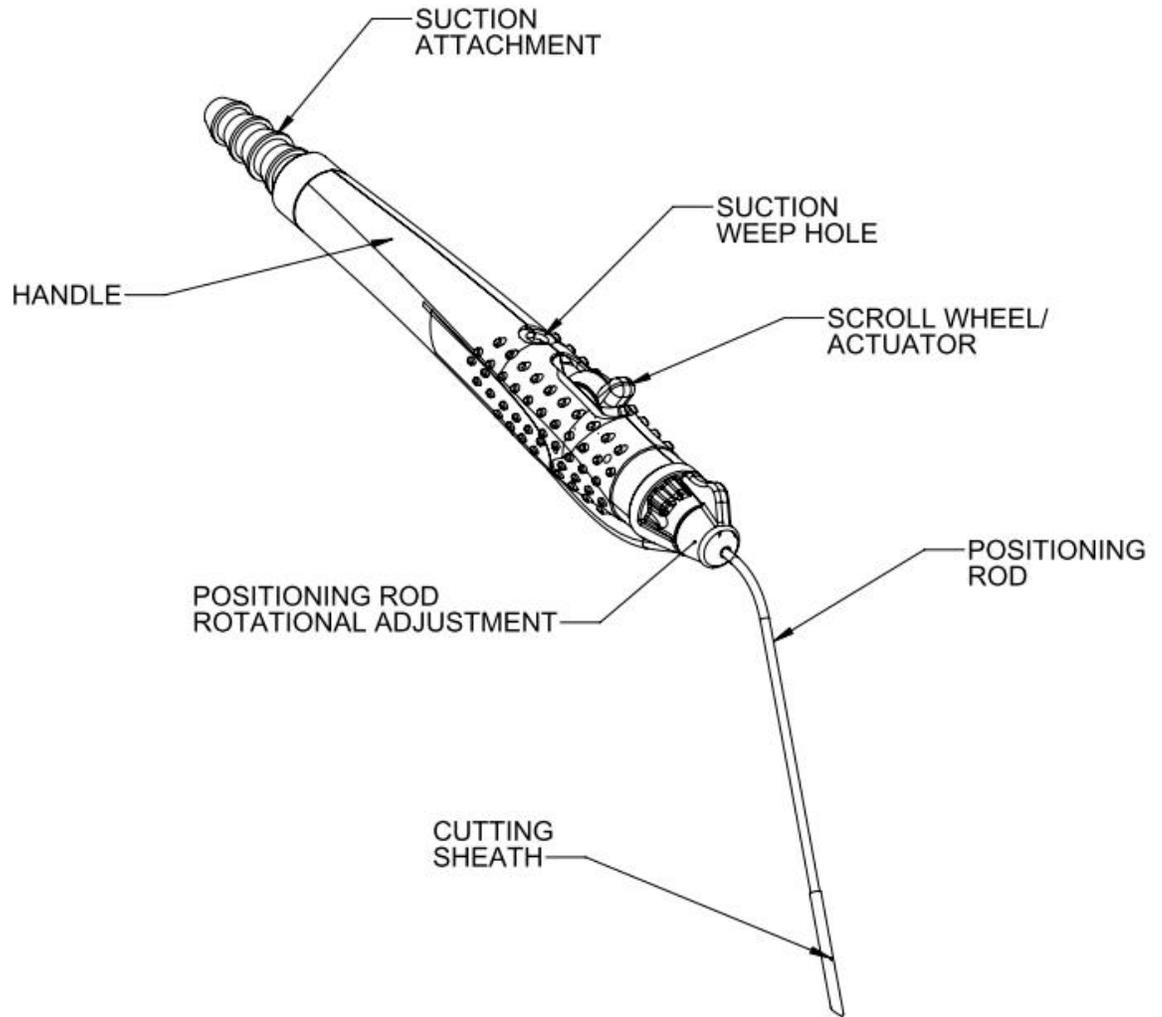
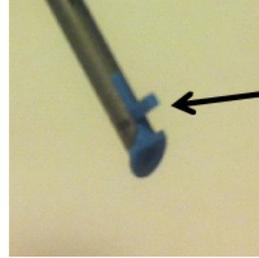


Figure 13. Tympanostomy Tube Introducer

Appendix A2 - Predicate Instructions For Use

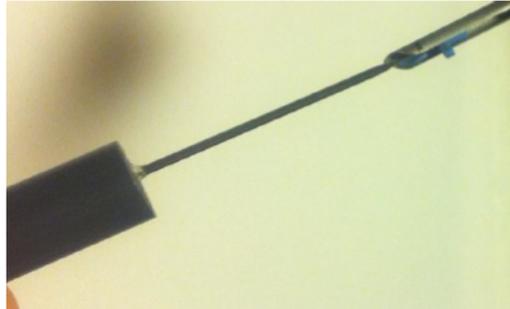
Setup

- Carefully remove the TTI from the packaging.
- Inspect the TTI upon removal from packaging to make sure the device is not damaged.
- Remove the disposable plastic tip protector from the end of the tip assembly prior to use.
- Load a ventilation tube into the cutting sheath using the loading tool provided.
 - Insert the tube into the sheath such that the visualization tab is located in the slot cut into the sheath, and the medial flange is flush with the beveled end of the sheath

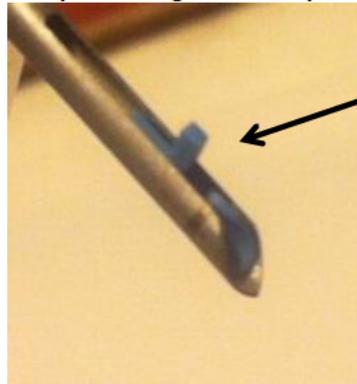


Visualization Tab

- Using the loading tool, push down on the medial flange and slide the tube into the sheath so that the medial flange does not extend past the cutting sheath, as shown in the figure



- Ensure that the visualization tab is properly positioned as shown in the figure. Repeat with the second tip assembly/tube if performing a bilateral procedure.



Visualization Tab

Appendix A2 - Predicate Instructions For Use

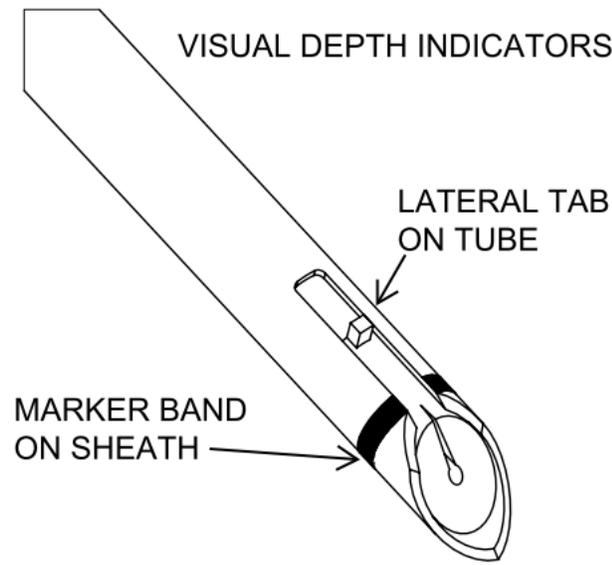
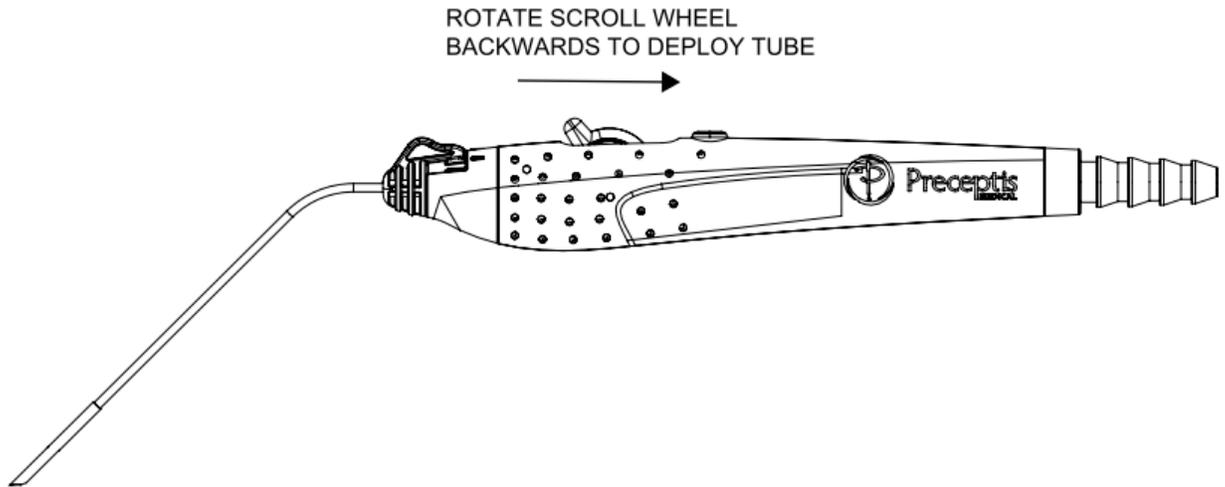


Figure 14. Close up of loaded ventilation tube showing correct placement within device and depth indicators.

Procedural steps:

1. If suction is to be used, attach suction tubing to the barbed fitting located on the TTI handle.
2. Insert an ear speculum into the outer ear canal following routine preparation. The ear canal and area around the tympanic membrane must be cleaned sufficiently to allow for good visualization of the tympanic membrane and the visual depth indicator located on the TTI.
3. Under visualization, for example through an operating microscope, manually advance the TTI through the speculum and down the ear canal such that the cutting component pierces the tympanic membrane in the location indicated for ventilation tube insertion.
4. Advance the TTI until the beveled portion of the cutting sheath is completely through the TM and the visual depth indicator (visualization tab on the tube or visualization marker band on the cutting sheath) is visible proximal to the TM.
5. Rotate the scroll wheel located on the device handle **BACKWARDS** (see figure below) to retract the cutting sheath and position the ventilation tube across the TM. Continue to rotate the scroll wheel through its full range of motion to fully retract the cutting sheath.
6. Apply suction if desired by covering the suction weep hole located on the handle.
7. Retract the TTI from the ear canal and dispose of appropriately.

Appendix A2 - Predicate Instructions For Use



The tip assembly is user adjustable to three different angular orientations to provide improved ergonomics for the user (see figures below). The following three figures show the three tip orientations possible. The tip is adjusted by grasping the tip adjustment tab and twisting it while holding the handle. Do not adjust the tip by grasping the positioning rod as this may damage the tip assembly.

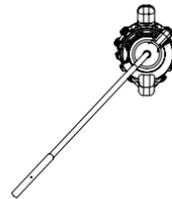
TIP ENGAGEMENT POSITION 1



TIP ENGAGEMENT POSITION 2

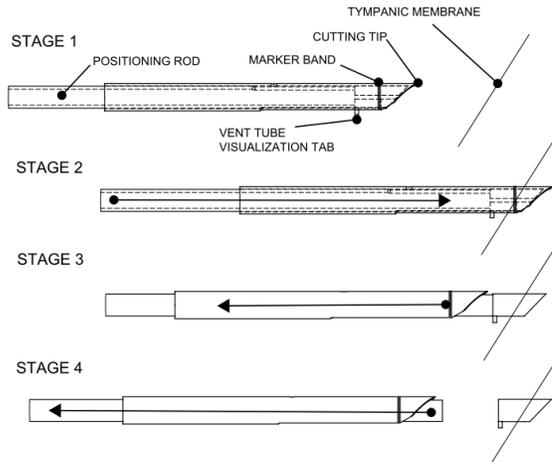


TIP ENGAGEMENT POSITION 3



Appendix A2 - Predicate Instructions For Use

The following schematic illustrates the steps taken with the device to perform ventilation tube placement. A close up of the front of the device is shown illustrating the tympanic membrane, the stainless steel positioning/suction tube, the cutting component, and the ventilation tube. The ventilation tube is constrained within the cutting component and is held in place by friction. A slot in the cutting component allows direct visualization of the vent tube throughout the procedure.



Stage 1 – The device is manually advanced down the ear canal.

Stage 2 – The entire device is manually advanced so that the cutting tip pierces the tympanic membrane. A slot in the cutting component allows visualization of the vent tube, ensuring it is positioned correctly in relation to the TM.

Stage 3 – Using the scroll wheel on the handle, the clinician retracts the cutting component. The positioning rod tube remains stationary and pushes the vent tube out of the cutting component, leaving it correctly positioned across the TM.

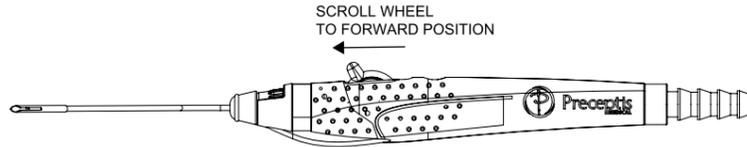
Stage 4 – The sharp edge of the cutting component is protected after retraction.

Appendix A2 - Predicate Instructions For Use

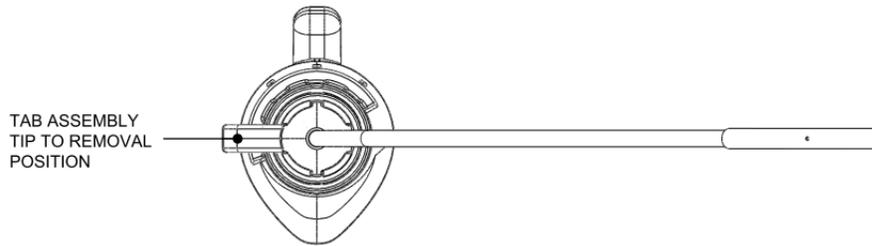
Tip Assembly Replacement:

Tip Assembly Removal

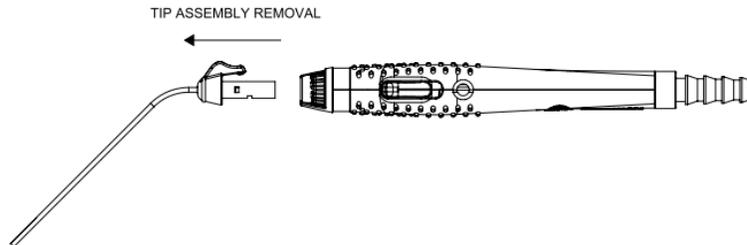
1. Return scroll wheel to the fully forward position.



2. Rotate Tip Assembly counterclockwise as far as it will turn, until the tab on rotating nosepiece is aligned with the insertion groove on the handle nosepiece.



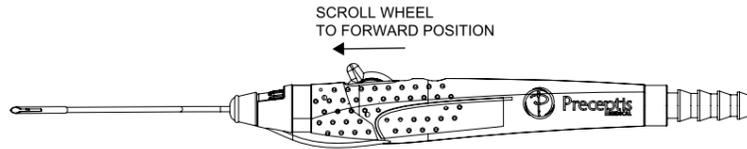
3. Grasping the plastic rotating nosepiece, firmly pull straight out on the tip assembly until it is fully disengaged from the handle.



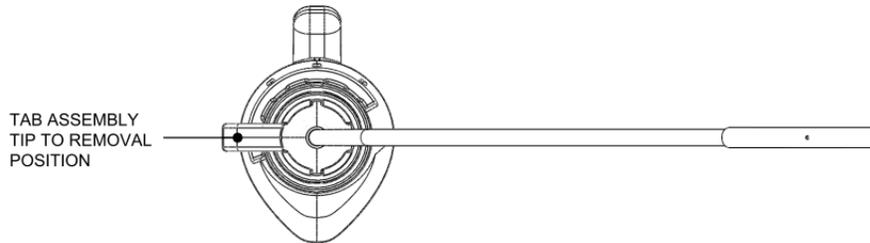
Appendix A2 - Predicate Instructions For Use

Tip Assembly Insertion:

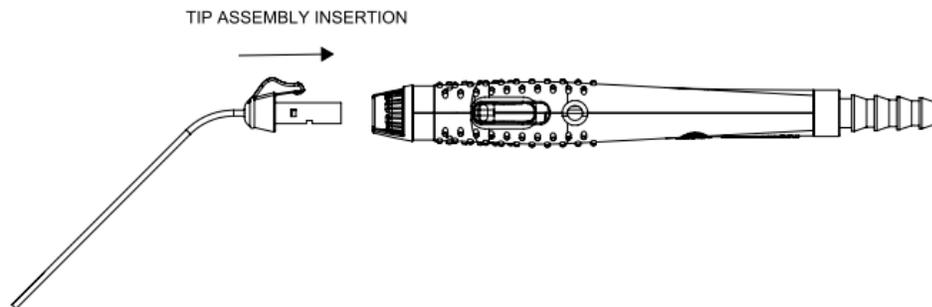
1. Position scroll wheel in the fully forward position.



2. Align tab on rotating nosepiece with insertion groove on handle nosepiece.

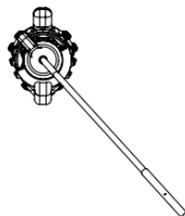


3. Insert rotating nosepiece into handle, ensuring that scroll wheel remains in fully forward position



4. Once the tip assembly is fully inserted, rotate clockwise to desired orientation to engage with the handle.

TIP ENGAGEMENT POSITION 1



TIP ENGAGEMENT POSITION 2



TIP ENGAGEMENT POSITION 3



Appendix A2 - Predicate Instructions For Use

Operating and Storage Conditions

Disposal

All components of the TTI are single patient-use.

Functional Life

All components of the TTI are single patient-use devices and must be used prior to the stated expiration date.

Definitions of Symbols

	DO NOT REUSE		Date of Manufacture
	Batch/Lot Code		Catalog Number
	Serial Number		Ethylene Oxide Sterilized
	Use by		

Appendix A2 - Predicate Instructions For Use

Specifications Table

System Component	Specification	
Tympanostomy Tube Inserter – Replaceable Tip <i>PN 05-1008-004</i>	Cutting Sheath Diameter	0.072" (1.8 mm)
	Positioning Rod	0.060" (1.5 mm)
	Working Length	2.6" (65 mm)
Tympanostomy Tube Introducer - Handle <i>PN 05-1001-004</i>	Length	5.125 in. (13 cm)

Contact Information:

Preceptis Medical, Inc.
505 Highway 169 N
Suite #365
Plymouth, MN 55441
Telephone: (952) 568-7819

Appendix A3 - Predicate Instructions For Use

Heinz Kurz TVT Instructions for Use

Important Medical Information



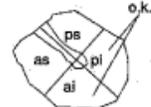
Trocar Ventilation Tube (TVT)



DESIGN/TYPE	MATERIAL	REF	SIZE/INNER Ø (mm)	OUTER Ø (mm)	FEATURE
 Type PR with Trocar	Gilded Silver	1015 074	1.25	2.5 / 2.8	with Trocar
	Titanium (ASTM F 67 Medical Grade)	1015 075	1.25	2.5 / 2.8	with Trocar
	Trocar: AISI 303 Stainless Steel				

Instruction for Use KURZ Trocar Ventilation Tubes (TVT)

Vent Tube placement Tympanic Membrane



Description and Intended Situs: Ventilation tubes are small implants for the ventilation and drainage of the middle ear which are inserted into the lower quadrants of the membrane (ai, pi), creating a passage between the middle ear and external ear canal. This design allows simultaneous incision of the tympanic membrane and implant placement for a shorter and less invasive procedure. The retention wire facilitates implant retrieval and secures the ventilation tube if – upon insertion – the tube extends too far into the tympanic cavity.
Attention: A drop of sterile saline solution between ventilation tube and trocar facilitates insertion.

Indication: Effusion of the tympanic cavity of different causes

Purpose: The purpose of a ventilation tube is to ventilate and/or drain the tympanic cavity. This allows the pathologically changed mucous tissue of the middle ear to regenerate and prevents serious damage to the middle ear.

Surgical Technique: The manufacturer recommends performing the surgery through an ear speculum. The lower quadrants of the tympanic membrane should be in clear view. The tube comes mounted on the trocar tip in the sterile package. Screw KURZ Trocar Holder (REF 8000143) into trocar tip before use.

CAUTION:

- For CHILDREN, apply TVT only with general anesthesia, preferably in hospital or comparable surgical environment.
- DO NOT USE TVT in atelectasis of the tympanic membrane due to the required distance from the tympanic membrane to the promontory
- Do not attempt placement of the TVT if patient's ear canal is noted to be narrow. The surgeon should see the lower anterior or posterior quadrant of the tympanic membrane in direct vision for safe placement of the TVT. In a patient with a high floor of the bony external auditory canal, placement of the TVT is not recommended.
- Do not place in upper quadrants to prevent harm to ossicles

Contraindications: Known allergy to the implant materials. Patients with otitis media reacting positively to other therapies, and patients with otitis media for whom, from a medical point of view, the physician considers paracentesis sufficient. Shallow or filled tympanic cavity (including but not limited to retraction of the tympanic membrane, adhesive process, cholesteroloma, glomus tumor), clinical history of tympanoplasty.

Side Effects, interactions: In very rare cases, the following side effects/interactions have been observed:

- skin irritations or allergies: Remove the ventilation tube according to well-known surgical procedures;
- early extrusion of the ventilation tube;
- permanent perforation of the tympanic membrane after completion of treatment;
- damage to the ossicular chain due to incorrect placement of the ventilation tube in the tympanic membrane (see drawing above)
- infections caused by bacteria that enter the middle ear via the ventilation tube;
- Myringosclerosis / Tympanosclerosis
- Medial displacement of the vent tube

Instruments: Use ONLY implantation instrument developed for this purpose: Trocar Holder REF 8000143. The handle is sterilizable and intended for multiple use.

Sterility: KURZ ventilation tubes are provided sterile. Packaging contents remains sterile as long as the packaging is not damaged or opened. The ventilation tubes are sterilized with gamma radiation; validation procedures are strictly observed according to internationally accepted standards. Open storage package only directly before implantation. Upon withdrawal of the ventilation tube/trocar tip from the packaging, observe the respective instructions for asepsis.

Packaging: Packaging of the ventilation tube with trocar tip consists of:

- non-sterile storage packaging
- one detachable sticker per TVT for the patient's file
- sterile primary packaging made of plastic containing the sterile ventilation tube and trocar tip

Restertization / Reprocessing: Ventilation tubes are for single use only. Heinz Kurz GmbH Medizintechnik does not consider the reprocessing/restertization of used ventilation tubes advisable. A product is considered "used" when it has come into contact with foreign tissue or blood or when it has been removed from its packaging and touched, thereby undergoing mechanical stress. The ventilation tubes can potentially exhibit the following flaws following renewed cleaning, disinfection, restertization:

- Insufficient sterility
- Insufficient non-pyrogenicity
- Development of hazardous substances
- Presence of particles and / or endotoxins
- Microcracking
- Deterioration of material properties

Due to the delicate designs and geometric structures of the ventilation tubes, the properties that prove safety can not be appraised by implication. Therefore we do not recommend reprocessing/restertization. Should medical devices intended for single use be reprocessed, potential deterioration of the product quality has to be anticipated. In cases of possible injury or damage resulting from reprocessing, the operator and user are liable, not the manufacturer. The safety and performance of the original product - endorsed with the CE marking - can no longer be guaranteed for reprocessed or restertized medical devices intended for single use.

Warning: The ventilation tube forms a passage between the middle ear and the external ear canal. Thus, pathogenic germs may reach the middle ear by means of water or air. Therefore, the auditory canal ought to be appropriately protected. The physician must inform the patient about the following: The patient may hear a short cracking sound when the trocar perforates the tympanic membrane. Patients with metallic implants may not be exposed to microwave radiation. Severe variations in ambient pressure (scuba diving, diving headlamps, explosions, etc.) are to be avoided, as they may result in injuries of the tympanic membrane and/or the remaining ossicles, and as a consequence, in auditory and equilibratory dysfunctions.

MRI (NMP): See www.kurzmed.com about detailed information about MRI.

Storage: At room temperature in the unopened original packaging. Each TVT is marked with a batch number.
CAUTION: Do not use after expiration date or if the package is open or appears to be damaged.

Safe Restriction: KURZ ventilation tubes are restricted to sale to specialist physicians or to physicians' prescriptions - they are not to be sold to patients. Federal US law restricts KURZ ventilation tubes to sale to or on the order of a specialist physician.

Documentation: The manufacturer recommends complete clinical, radiological and statistic documentation. Batch and reference numbers must be recorded in the patient's file and the surgeon's or hospital's surgical record.

Manufacturer: Heinz Kurz GmbH Medizintechnik, Tuebinger Strasse 3, 72144 Dusslingen, Germany
Tel.: +49 (0)7072 / 81 79-0; Fax: +49 (0)7072 / 81 79-79; www.kurzmed.de; info@kurzmed.de
USA: KURZ Medical, Inc., 5126 South Royal Atlanta Drive, Tucker, GA 30084 - USA
Phone: +1-770-349-6330; Fax: +1-770-634-3384; www.kurzmed.com; info@kurzmed.de
921308002-10/2013-8501320

Version:

Symbols:

Manufacturer
 Expiration date
 Sterilized using irradiation
 Keep away from heat
 Do not reuse
 Observe instructions
 Fragile, handle with care
 Item Number
 Batch code
 Do not use if package is damaged
 Do not restertize

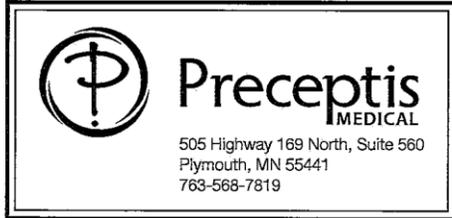


Appendix B – Draft Labeling & Instructions for Use

Ventilation Tube Instructions for Use.

Otologic Ventilation Tubes

Distributed by :



Instructions for Use

DESCRIPTION

Otological Ventilation Tubes are an implant designed to provide ventilation to the middle ear space through the tympanic membrane. **Material** : Medical grade silicone.

INDICATIONS FOR USE

Indicated where chronic Eustachian tube dysfunction does not respond to conventional therapy.

CONTRAINDICATIONS

None known. This device is not designed, sold, or intended for use except as indicated or prescribed by a physician.

PRECAUTIONS

Avoid fluid contact with ear.
The implant is intended to be single use only and should not be resterilized. Do not use if pouch is damaged.

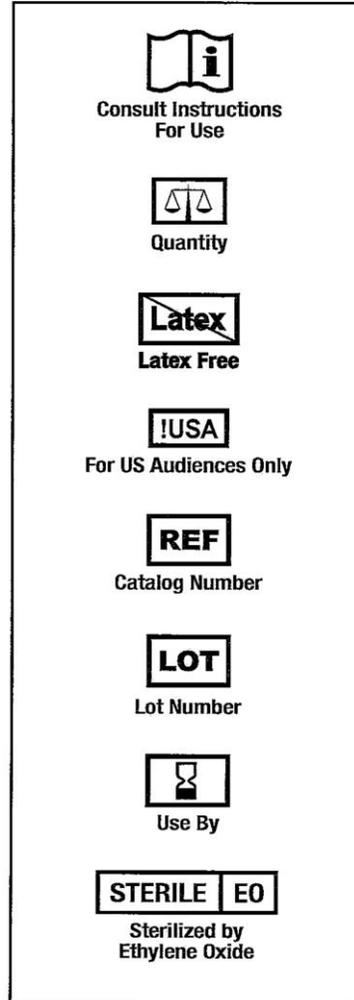
POSSIBLE ADVERSE EFFECTS

Tube may clog
Persistent perforations of the tympanic membrane
Granulomatosis
Premature extrusion
Failure to self-extrude
Infection due to airborne or water contamination

INSTRUCTIONS FOR USE

The implant is placed in the tympanic membrane through an incision for the ventilation of the middle ear space.

Symbol Reference Key



!USA Rx Only
For US Audiences Only

Single-use, one-patient device will degrade if reprocessed. No effective cleaning process has been developed to prevent cross contamination. Contamination of a reprocessed device may lead to injury, illness or death of the patient.

Manufactured by :

summit
medical
815 Northwest Parkway, Suite 100
St. Paul, MN 55121 | USA
P: 651-789-3939 | 888-229-2875
F: 651-789-3979 | 888-229-1941
www.summitmedicalusa.com

CE 0297
EC REP
MDSS GmbH
Schiffgraben 41
D-30175 Hannover, Germany

25195 Rev. A

Appendix B – Draft Labeling & Instructions for Use

HUMMINGBIRD™ TYMPANOSTOMY TUBE SYSTEM With PRE-LOADED VENTILATION TUBE (TTS) INSTRUCTIONS FOR USE (DRAFT)

CAREFULLY READ ALL INSTRUCTIONS PRIOR TO USE.

CAUTION: Federal law restricts this device to sale by or on the order of a physician.

Indications for Use

The Hummingbird™ Tympanostomy Tube System (TTS) is intended to deliver a tympanostomy tube in tympanostomy procedures in which the patient is receiving a tympanostomy tube.

Intended Use

The TTS is intended to deliver a tympanostomy tube through the tympanic membrane (TM) of the patient. It combines the separate functions of creating a myringotomy, positioning and placing a ventilation tube across the TM, and suctioning.

Warnings

- The TTS is intended for single patient use. DO NOT REUSE.
- Use the TTS with an ear speculum to avoid injury to the auditory canal.
- Do not use the TTS device if the visual depth markers provided (a visual tab located on the lateral end of the ventilation tube, and/or a marker band located on the cutting sheath) cannot be seen during use within the ear canal.
- Do not advance the visual depth markers past the tympanic membrane to avoid damage to the middle or inner ear.
- Do not attempt to re-load a deployed myringotomy tube or to load a new myringotomy tube into the TTS device.
- Do not bend or shape the device. This may cause device damage.
- Do not apply suction through the tip of the device while it is located behind the TM.
- When using the TTS for tympanostomy tube placement in children the tympanostomy procedure should only be performed in a hospital or ambulatory surgical center setting, with the anesthesia delivered by an anesthesia professional.

Precautions

- When using the TTS for tympanostomy tube placement in children:
 - Either general anesthesia or moderate sedation is recommended.
 - The anesthetic regimen should be determined by the attending otolaryngologist and anesthesia professional.
 - The tympanostomy procedure should only be performed in a hospital or ambulatory surgical center setting, with the anesthesia delivered by an anesthesia professional.

Appendix B – Draft Labeling & Instructions for Use

- Follow standard hospital/clinic policies and procedures.
- Ensure the auditory canal is sufficiently clean to allow direct visualization of the TM and of the TTS device during tube placement.
- Insertion location of the TTS on the tympanic membrane should be chosen to avoid damage to the malleus and the ossicular chain.
- Avoid excessive penetration depths with the TTS device to reduce the risk of injury to vasculature or nerves in the case of abnormal anatomy.
- Completely retract the cutting sheath after tube insertion and prior to applying suction through the TTS device.
- When applying suction through the TTS device after tube insertion, ensure that the tube is not inadvertently pulled out of the myringotomy.
- Suction cannot be applied through the TTS device prior to tube deployment. Attempts to apply suction prior to tube insertion or to clear a perceived blockage prior to insertion may cause the ventilation tube to deploy erratically.
- Inspect the packages and devices carefully. Do not use if the package or device is damaged.
- Do not use if the expiration dates are exceeded.
- Use caution in opening the packaging and removing the devices to insure the devices are not damaged.

Potential Complications

Possible risks associated with the device may include but are not limited to:

- Otorrhea,
- Acute tube extrusion,
- Chronic tube extrusion,
- Tube dislocating into middle ear,
- Tube clogging,
- Bleeding,
- Vertigo,
- Nausea,
- Infection,
- Hearing loss,
- Facial nerve injury.

Restrictions

The TTS should be only operated by physicians experienced in tympanostomy procedures, which have reviewed this Instruction for Use and understood the use of the TTS.

Maintenance

The device is a single patient-use disposable product. No maintenance is required.

TTS Components

Appendix B – Draft Labeling & Instructions for Use

Disposable Components (provided EO Treated):

- TTS (Tympanostomy Tube System with Tip Assembly)
- TTS Tip Assembly
- Ventilation tubes (PN 05-1026-009)

Other Recommended Components (not provided)

- Ear speculum
- Vacuum system and appropriate suction tubing

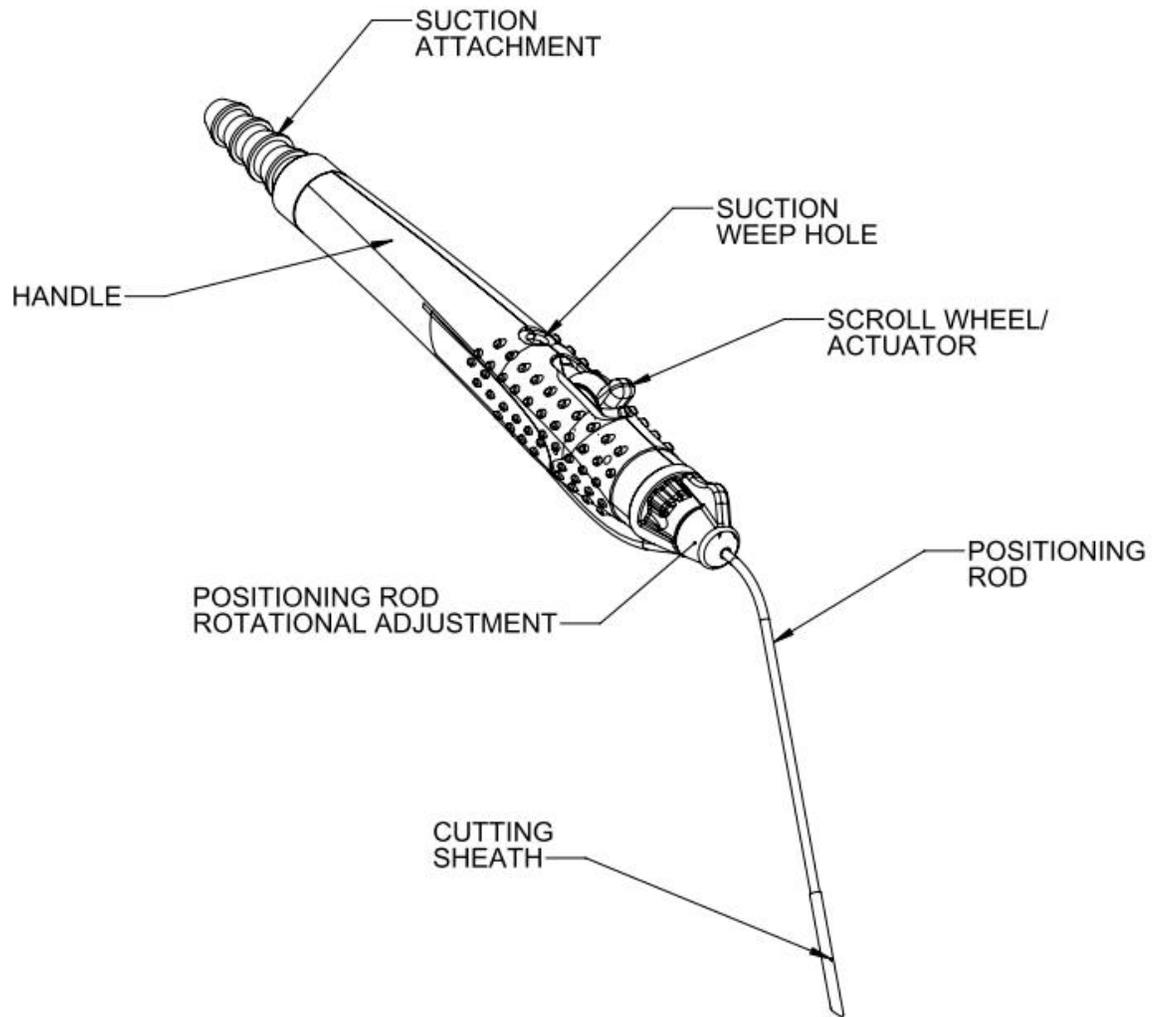


Figure 1. Tympanostomy Tube Inserter

Appendix B – Draft Labeling & Instructions for Use

Setup

- Carefully remove the TTS from the packaging.
- Inspect the TTS upon removal from packaging to make sure the device is not damaged.
- Verify that the ventilation tube is properly loaded within the device and that the depth indicator is visible (see figure 2).

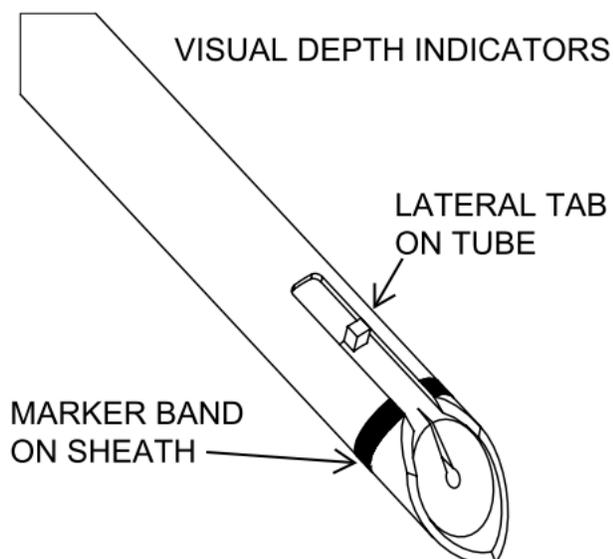


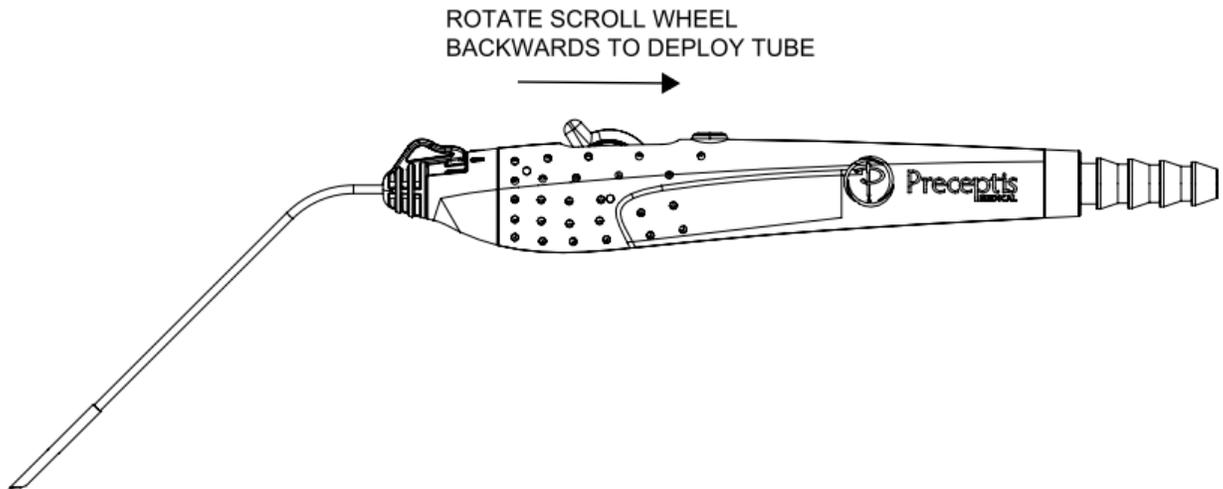
Figure 2. Close up of loaded ventilation tube showing correct placement within device and depth indicators.

Procedural steps:

8. If suction is to be used, attach suction tubing to the barbed fitting located on the TTS handle.
9. Insert an ear speculum into the outer ear canal following routine preparation. The ear canal and area around the tympanic membrane must be cleaned sufficiently to allow for good visualization of the tympanic membrane and the visual depth indicator located on the TTS.
10. Under visualization, for example through an operating microscope, manually advance the TTS through the speculum and down the ear canal such that the cutting component pierces the tympanic membrane in the location indicated for ventilation tube insertion.

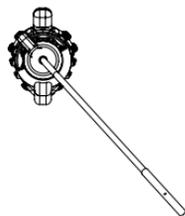
Appendix B – Draft Labeling & Instructions for Use

11. Advance the TTS until the beveled portion of the cutting sheath is completely through the TM and the visual depth indicator (visualization tab on the tube or visualization marker band on the cutting sheath) is visible proximal to the TM.
12. Rotate the scroll wheel located on the device handle BACKWARDS (see figure below) to retract the cutting sheath and position the ventilation tube across the TM. Continue to rotate the scroll wheel through its full range of motion to fully retract the cutting sheath.
13. Apply suction if desired by covering the suction weep hole located on the handle.
14. Retract the TTS from the ear canal and dispose of appropriately.



The tip assembly is user adjustable to three different angular orientations to provide improved ergonomics for the user (see figures below). The following three figures show the three tip orientations possible. The tip is adjusted by grasping the tip adjustment tab and twisting it while holding the handle. Do not adjust the tip by grasping the positioning rod as this may damage the tip assembly.

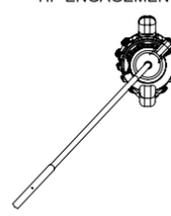
TIP ENGAGEMENT POSITION 1



TIP ENGAGEMENT POSITION 2

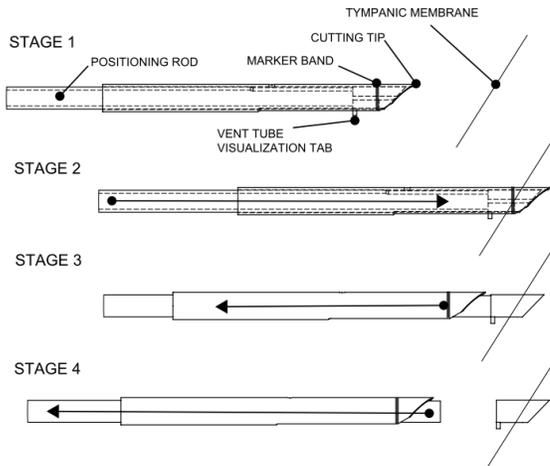


TIP ENGAGEMENT POSITION 3



Appendix B – Draft Labeling & Instructions for Use

The following schematic illustrates the steps taken with the device to perform ventilation tube placement. A close up of the front of the device is shown illustrating the tympanic membrane, the stainless steel positioning/suction tube, the cutting component, and the ventilation tube. The ventilation tube is constrained within the cutting component and is held in place by friction. A slot in the cutting component allows direct visualization of the vent tube throughout the procedure. The cutting component retracts axially along the positioning tube when the scroll wheel on the handle is turned.



Stage 1 – The device is manually advanced down the ear canal.

Stage 2 – The entire device is manually advanced so that the cutting tip pierces the tympanic membrane. A slot in the cutting component allows visualization of the vent tube, ensuring it is positioned correctly in relation to the TM.

Stage 3 – Using the scroll wheel on the handle, the clinician retracts the cutting component. The positioning rod tube remains stationary and pushes the vent tube out of the cutting component, leaving it correctly positioned across the TM.

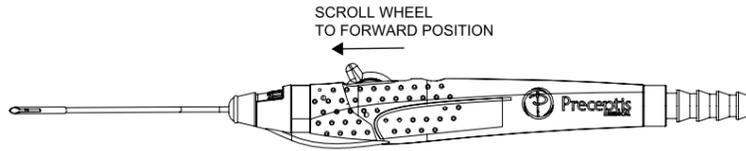
Stage 4 - The sharp edge of the cutting component is protected after retraction.

Appendix B – Draft Labeling & Instructions for Use

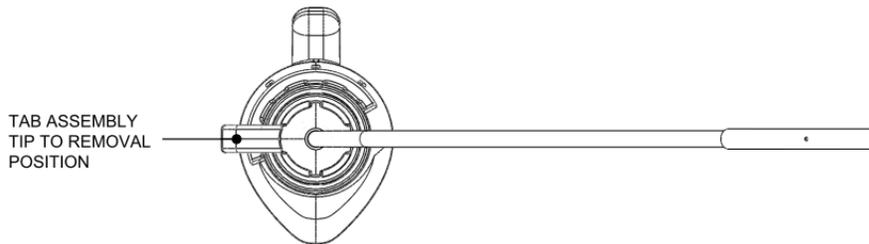
Tip Assembly Replacement:

Tip Assembly Removal

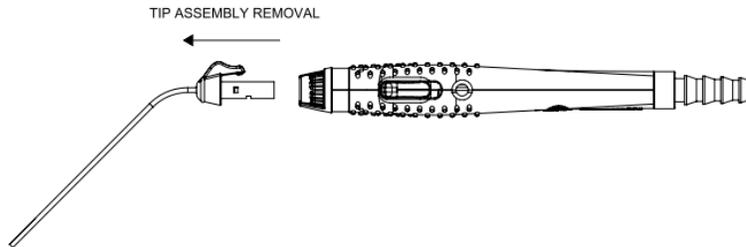
4. Return scroll wheel to the fully forward position.



5. Rotate Tip Assembly counterclockwise as far as it will turn, until the tab on rotating nosepiece is aligned with the insertion groove on the handle nosepiece.



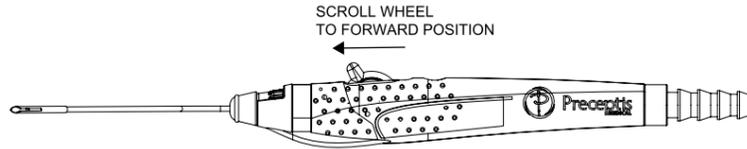
6. Grasping the plastic rotating nosepiece, firmly pull straight out on the tip assembly until it is fully disengaged from the handle.



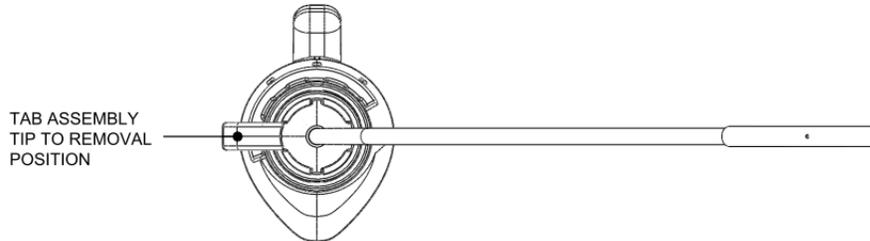
Appendix B – Draft Labeling & Instructions for Use

Tip Assembly Insertion:

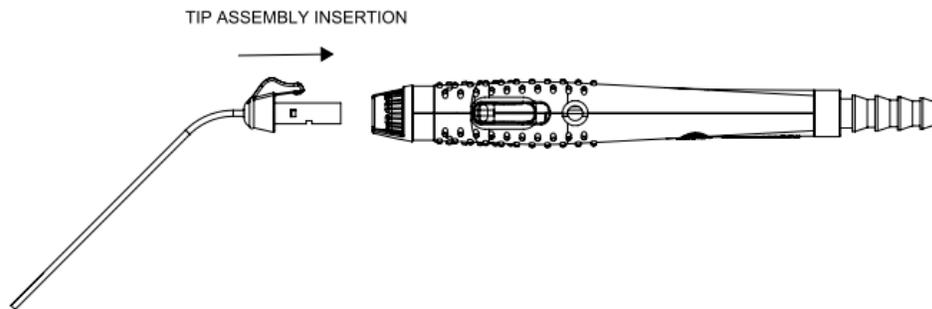
5. Position scroll wheel in the fully forward position.



6. Align tab on rotating nosepiece with insertion groove on handle nosepiece.

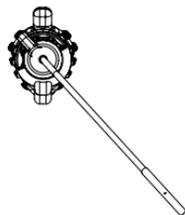


7. Insert rotating nosepiece into handle, ensuring that scroll wheel remains in fully forward position



8. Once the tip assembly is fully inserted, rotate clockwise to desired orientation to engage with the handle.

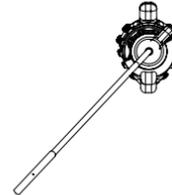
TIP ENGAGEMENT POSITION 1



TIP ENGAGEMENT POSITION 2



TIP ENGAGEMENT POSITION 3



Appendix B – Draft Labeling & Instructions for Use

Operating and Storage Conditions

Disposal

All components of the TTS are single patient-use.

Functional Life

All components of the TTS are single patient-use devices and must be used prior to the stated expiration date.

Definitions of Symbols

	DO NOT REUSE		Date of Manufacture
	Batch/Lot Code		Catalog Number
	Serial Number		Sterilized Using Ethylene Oxide
	Use by		

Appendix B – Draft Labeling & Instructions for Use

Specifications Table

System Component	Specification	
Tympanostomy Tube Inserter – Replaceable Tip <i>PN 05-1008-005</i> <i>PN 05-1008-006</i>	Cutting Sheath Diameter	0.072" (1.8 mm)
	Positioning Rod	0.060" (1.5 mm)
	Working Length	2.6" (65 mm)
Tympanostomy Tube Introducer - Handle <i>PN 05-1001-007</i> <i>PN 05-1001-008</i>	Length	5.125 in. (13 cm)
Ventilation Tube	05-1026-009	Inside Diameter 0.039" (1.0 mm)
05-1001-501	-90 Handle Assembly, 05-1001-007 +90 Tip Assembly, 05-1008-005 Two tubes, 05-1029-009	
05-1001-502	+90 Handle Assembly, 05-1001-008 +90 Tip Assembly, 05-1008-006 Two tubes, 05-1029-009	
05-1001-503	-90 Handle Assembly, 05-1001-007 -90 Tip Assembly, 05-1008-005 Two tubes, 05-1029-009	

Contact Information:

Preceptis Medical, Inc.
 505 Highway 169 N
 Suite #365
 Plymouth, MN 55441
 Telephone: (952) 568-7819

Appendix B – Draft Labeling & Instructions for Use

Preceptis Tympanostomy Tube Inserter Single Unit Label

	Hummingbird™ Tympanostomy Tube System
---	--

	REF	LOT	QTY
TTS	05-1001-50X	YMMDD-N	1
Vent Tube	05-1026-009	YMMDD-N	2

CAUTION: Federal law restricts this device to sale by or on the order of a physician.

 MONTH YEAR
 Use within 6 Months
 Of date of manufacture

STERILE EO


Distributed by:

Preceptis Medical Inc., 505 Highway 169 N, #356, Plymouth MN 55441

Manufactured By:

Summit Medical, 815 NW Parkway, Suite 100, St. Paul, MN 55121

60-1067-001 Rev XX

Preceptis Tympanostomy Tube Inserter Multi-Pack Label

	Hummingbird™ Tympanostomy Tube System
---	--

	REF	LOT	QTY
TTS	05-1001-50X	YMMDD-N	5

CAUTION: Federal law restricts this device to sale by or on the order of a physician.

 MONTH YEAR
 Use within 6 Months
 Of date of manufacture

STERILE EO


Distributed by:

Preceptis Medical Inc., 505 Highway 169 N, #356, Plymouth MN 55441

Manufactured By:

Summit Medical, 815 NW Parkway, Suite 100, St. Paul, MN 55121

60-1068-001 Rev XX

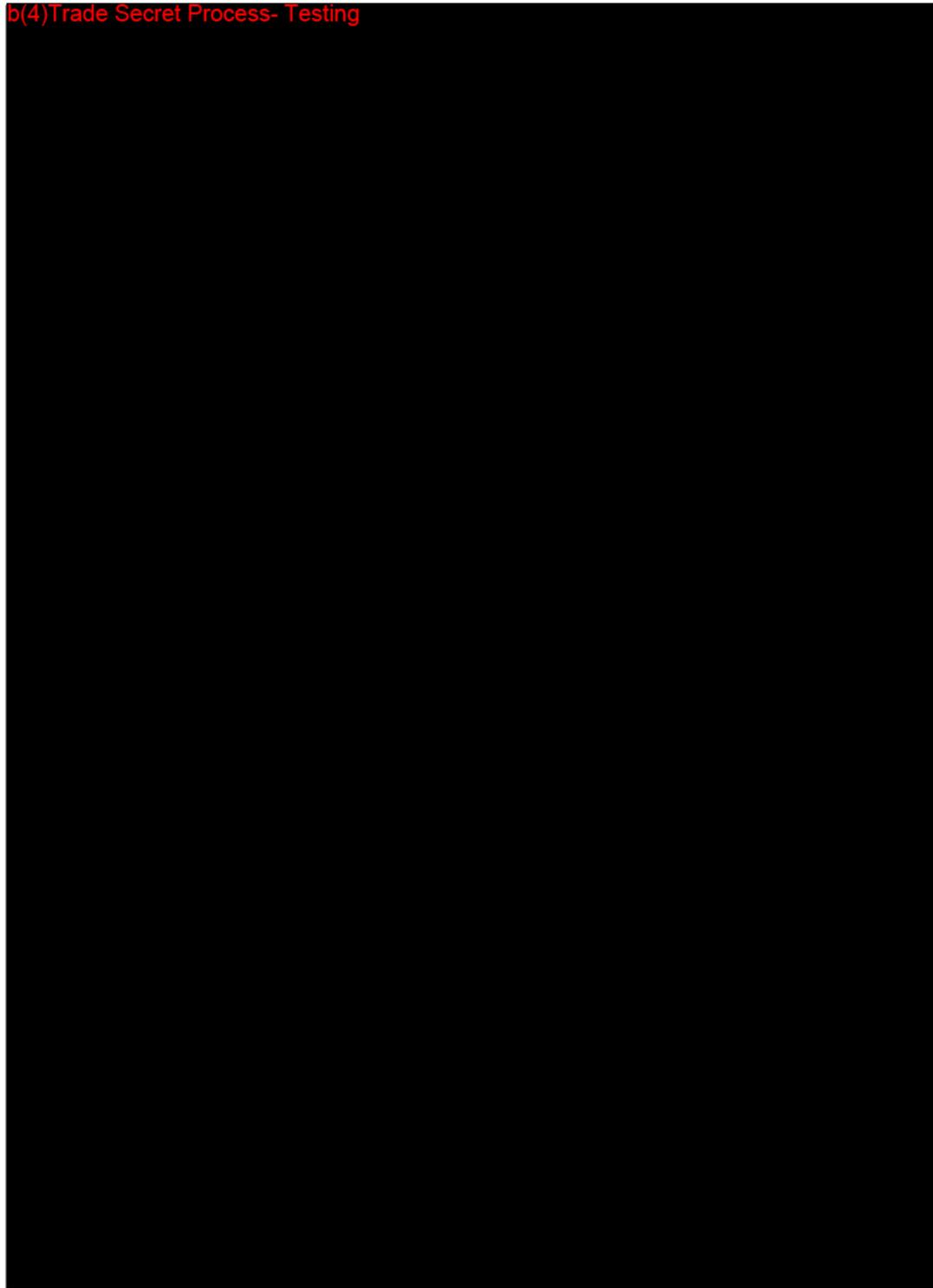
Appendix C1

b(4) Trade Secret Process- Testing



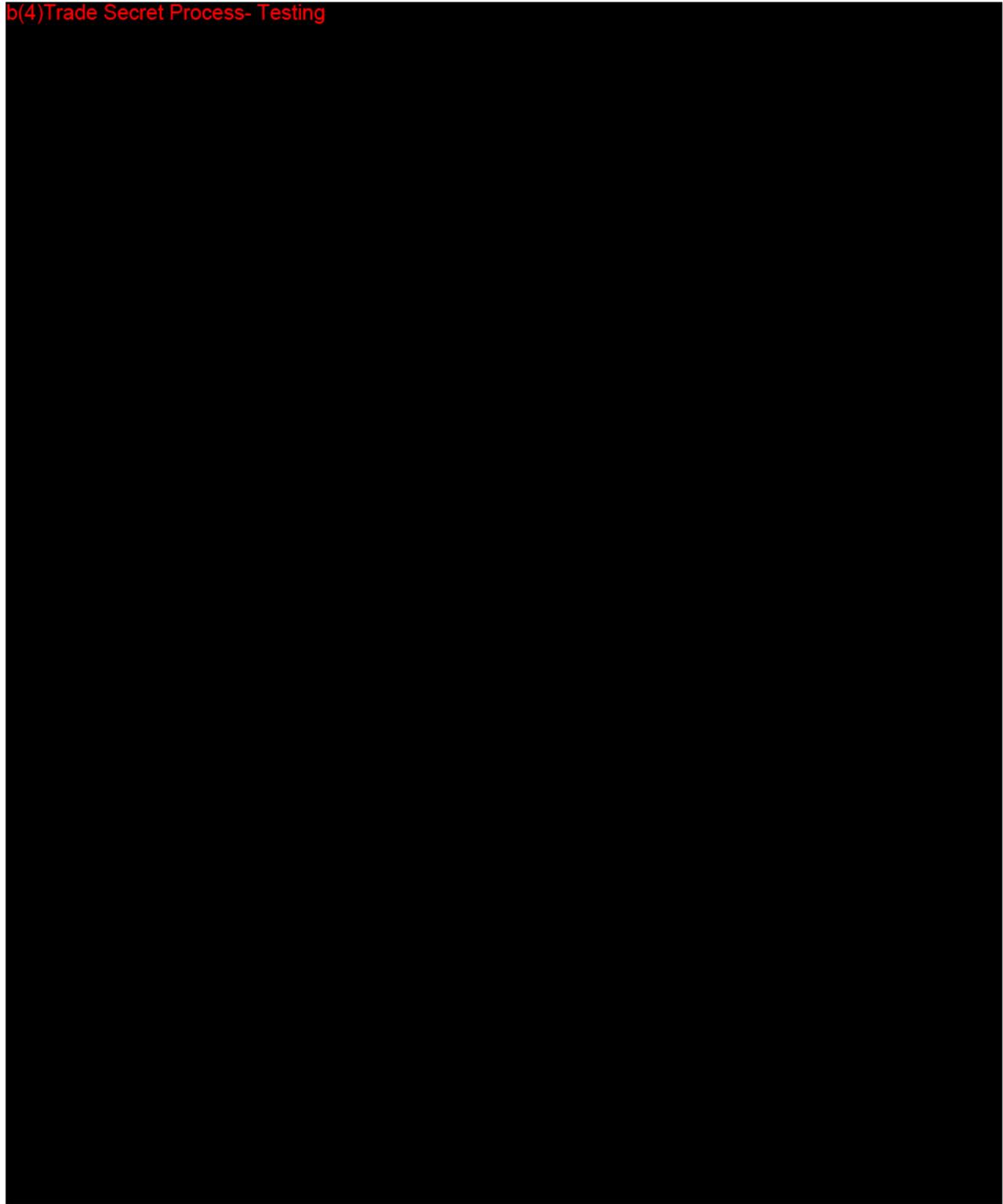
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b(4)Trade Secret Process- Testing



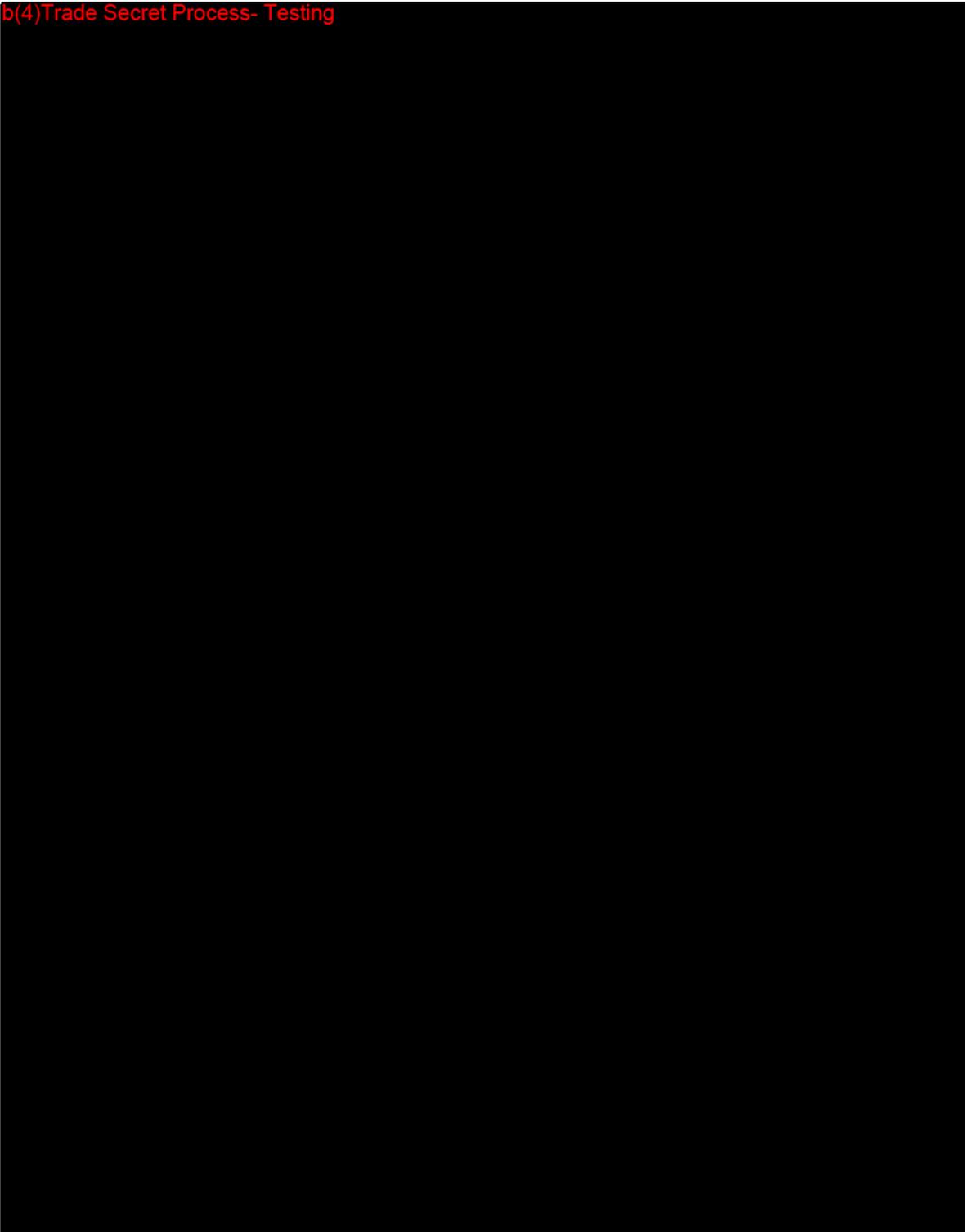
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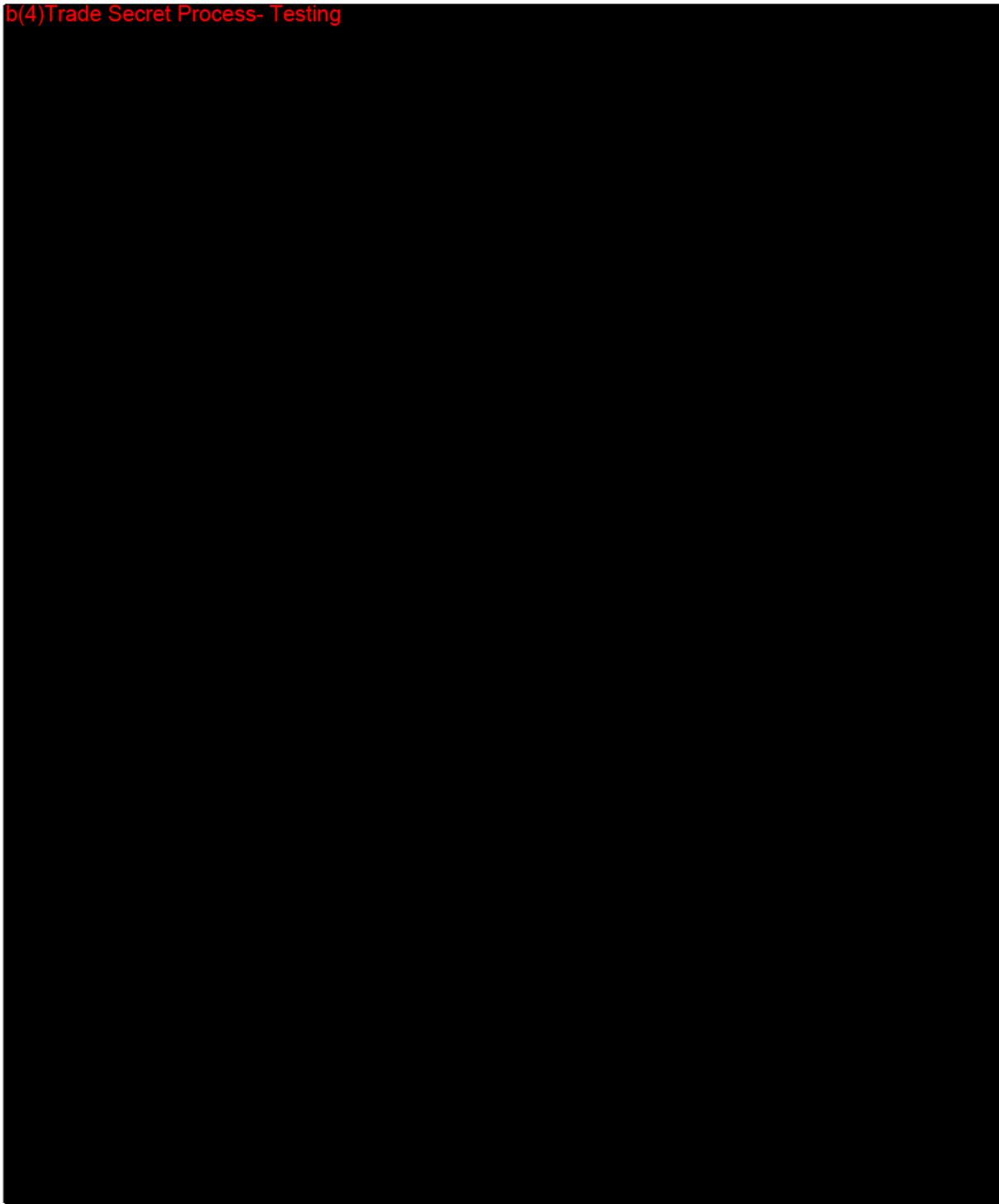
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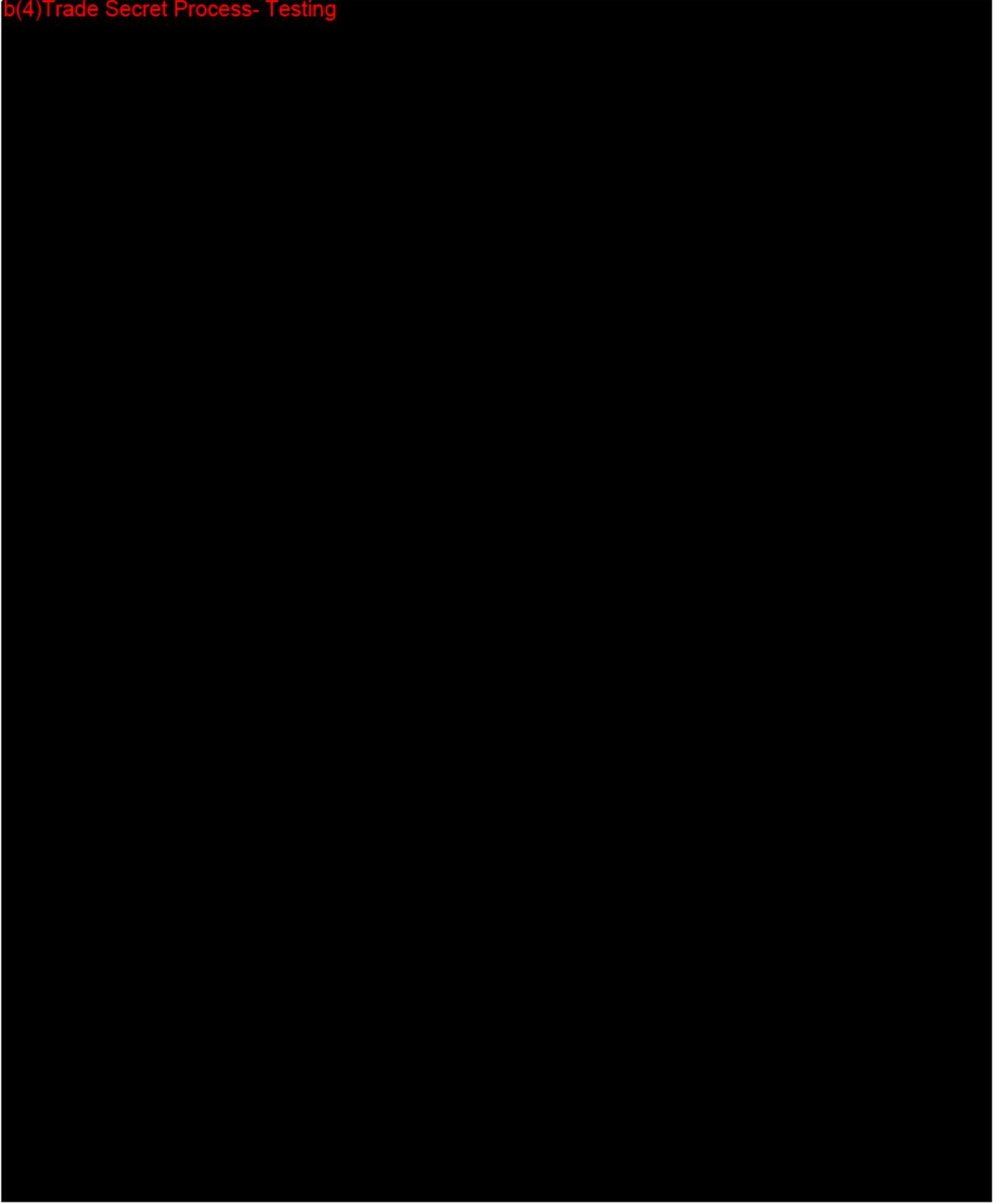
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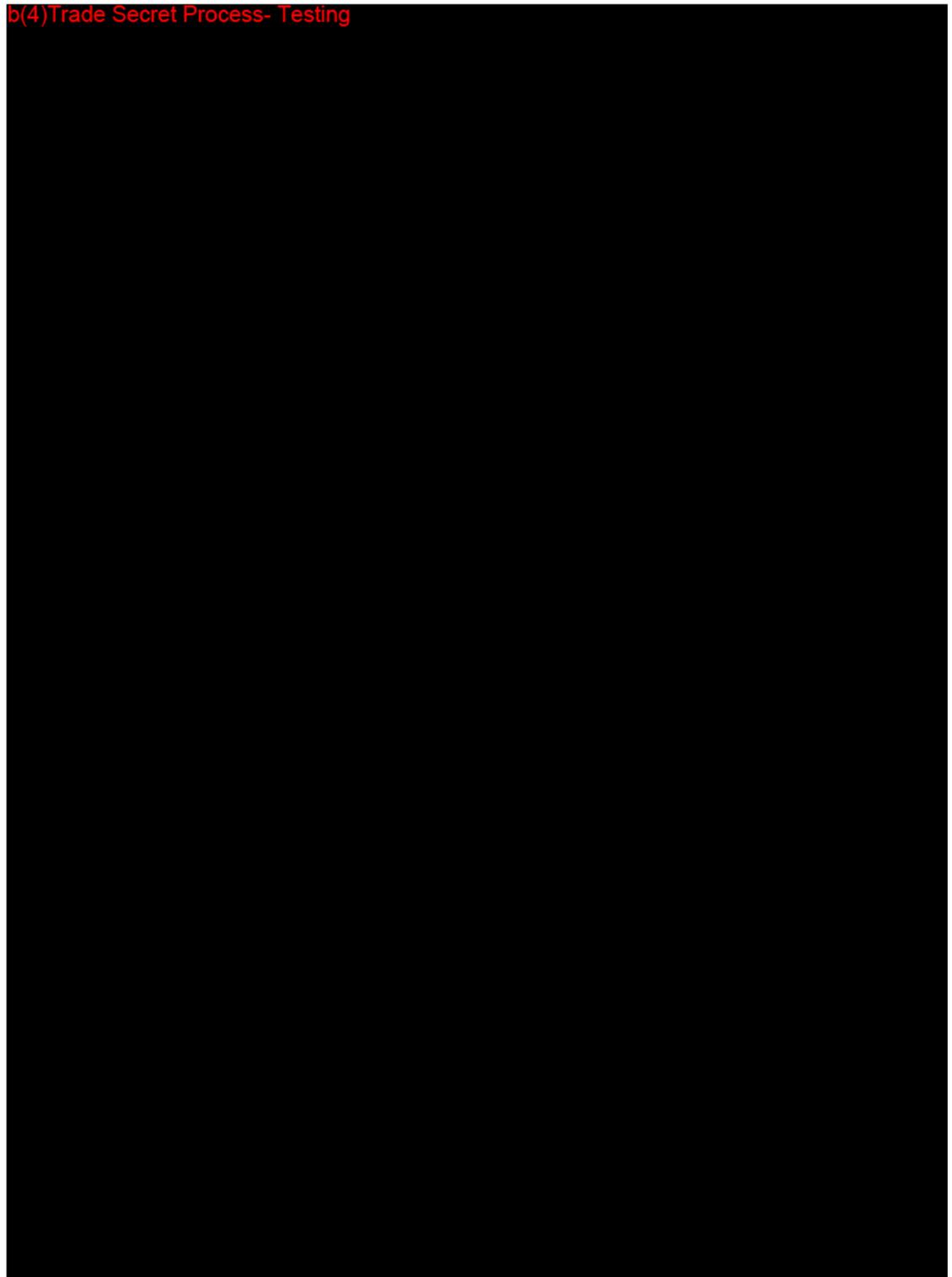
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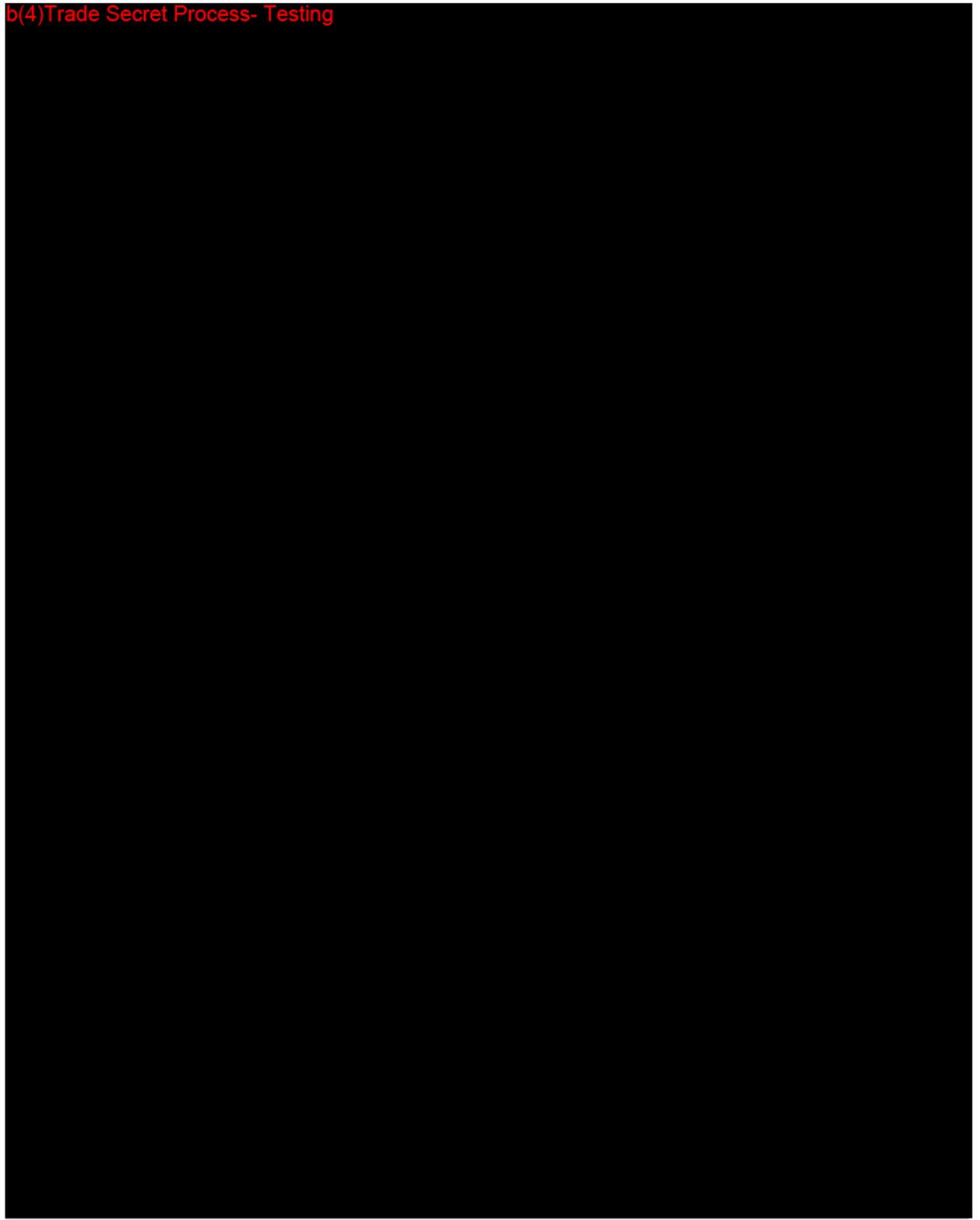
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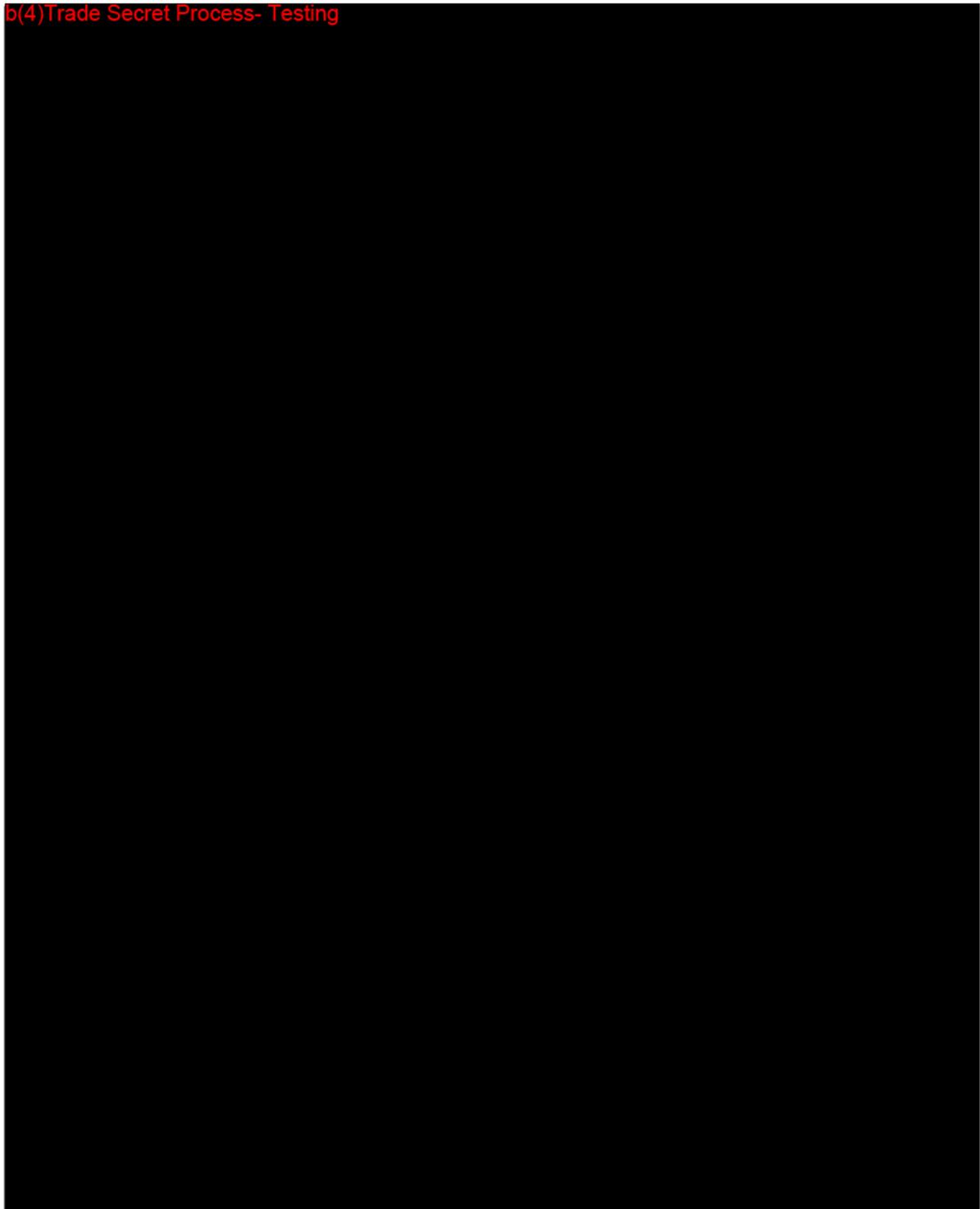
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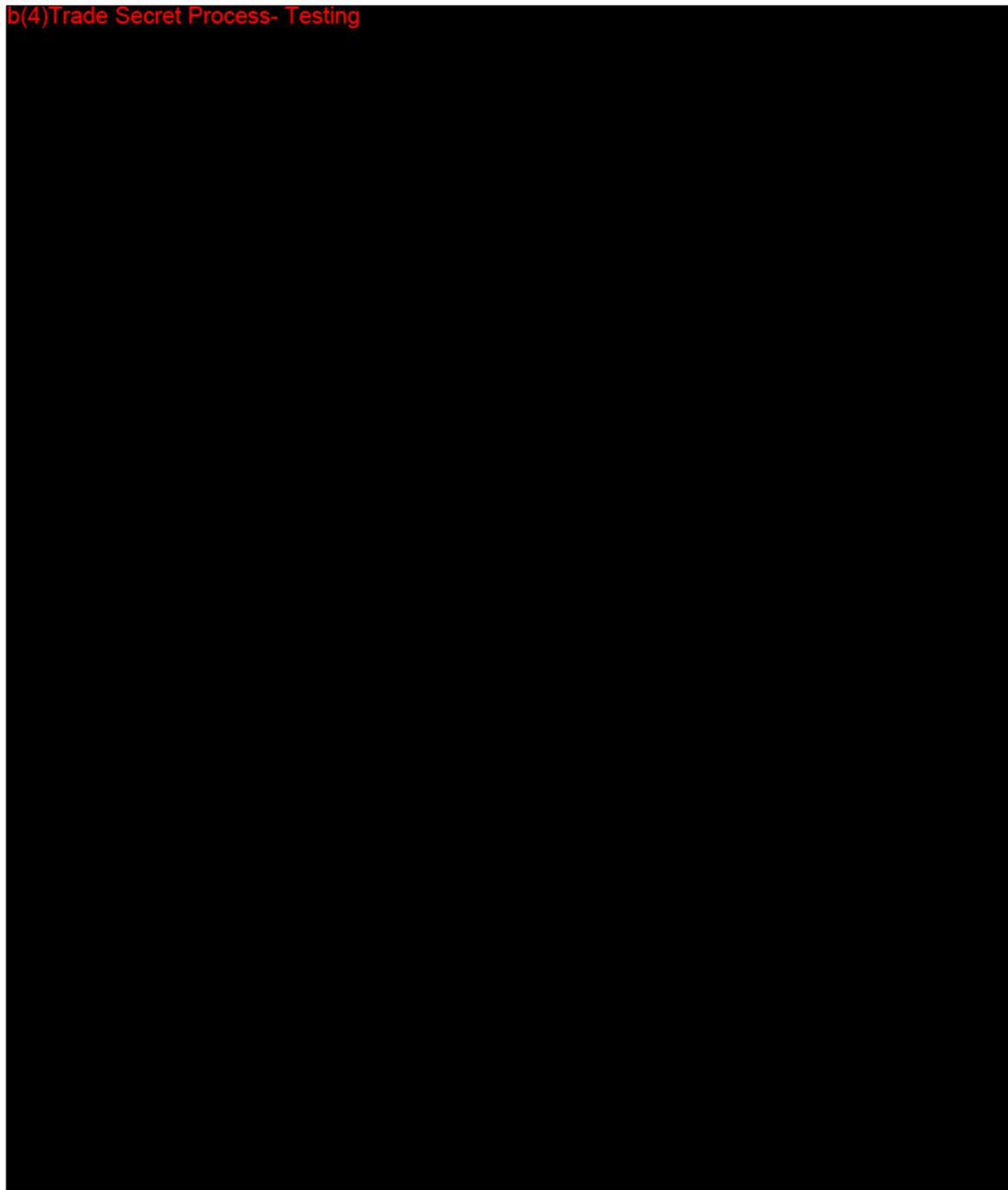
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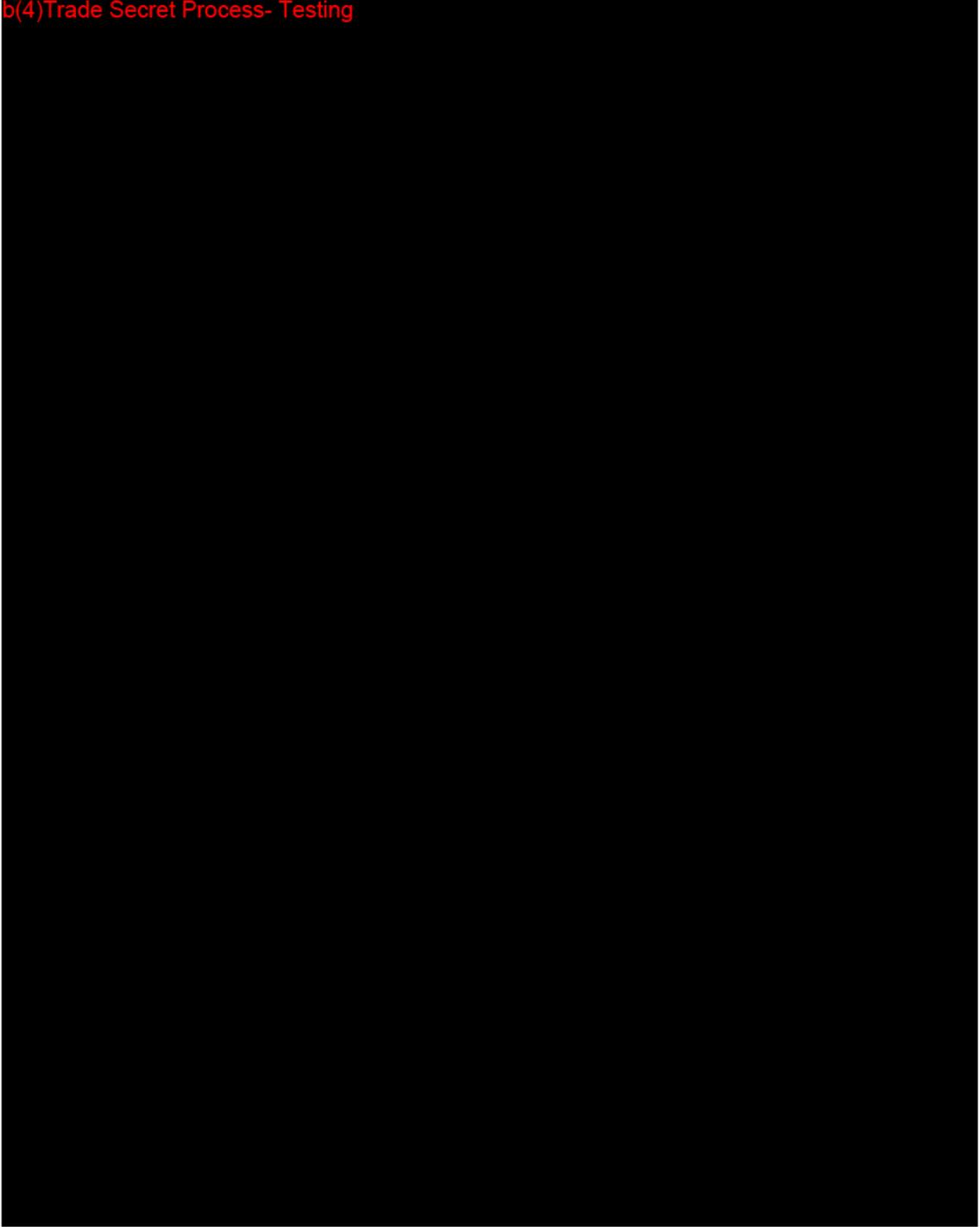
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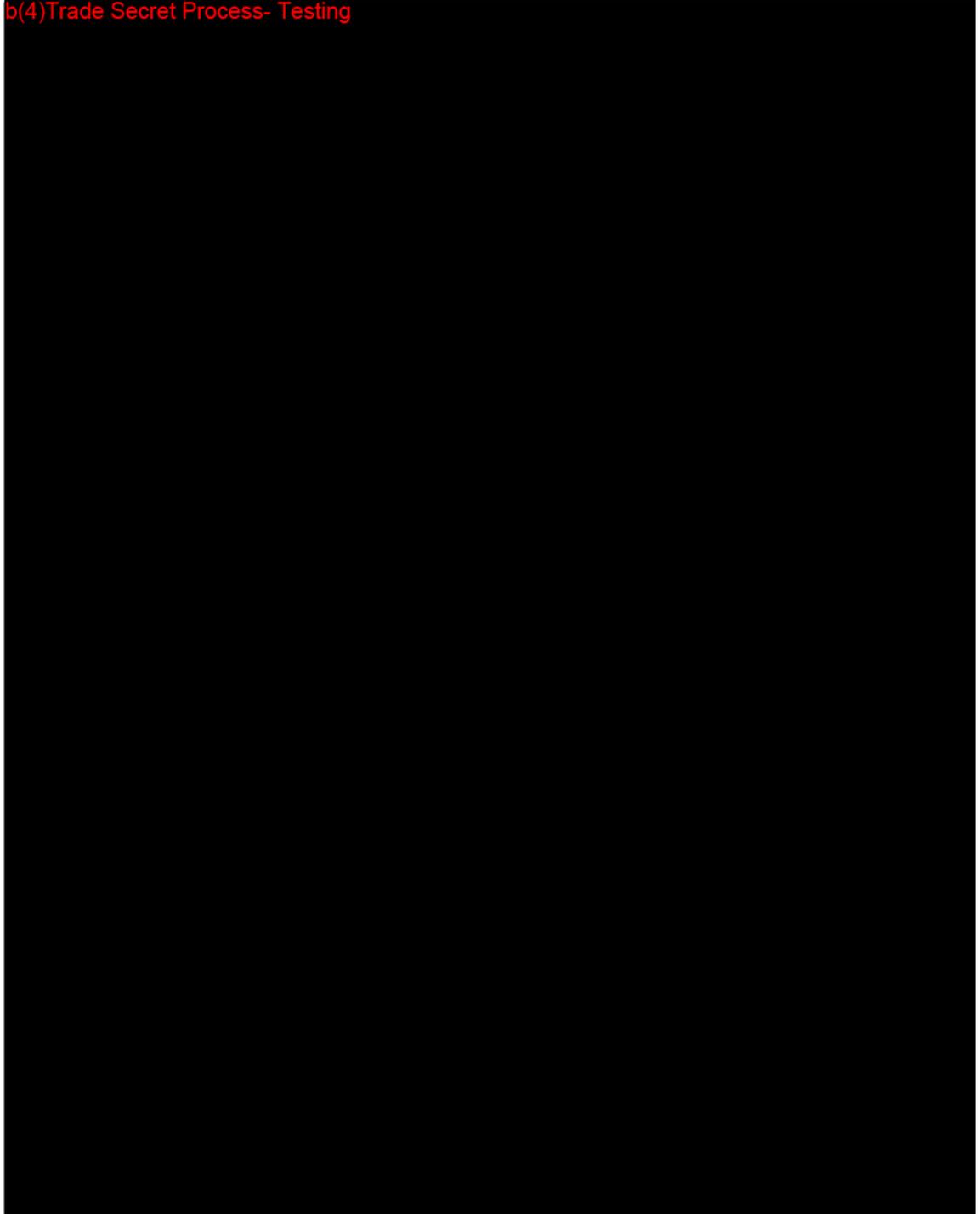
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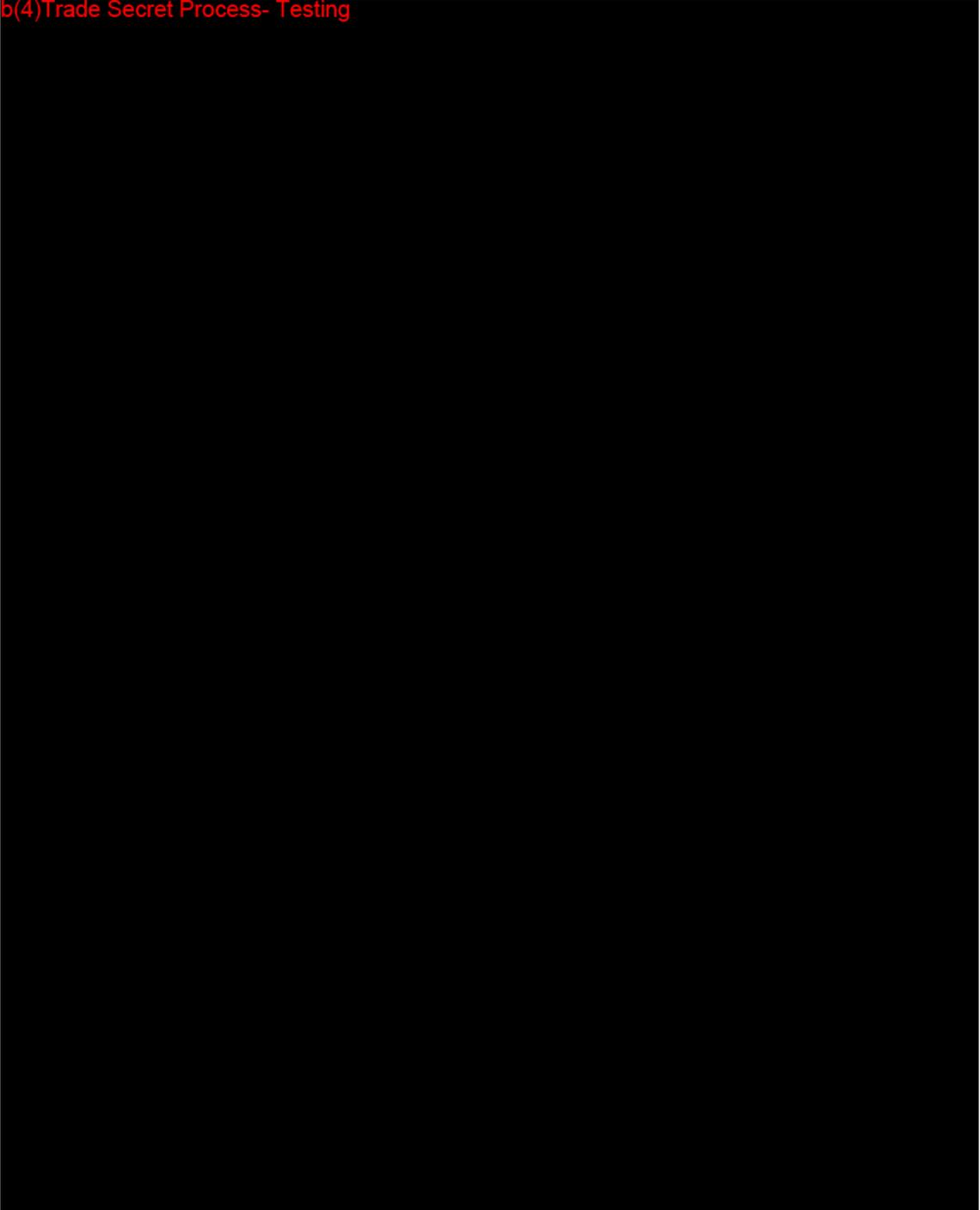
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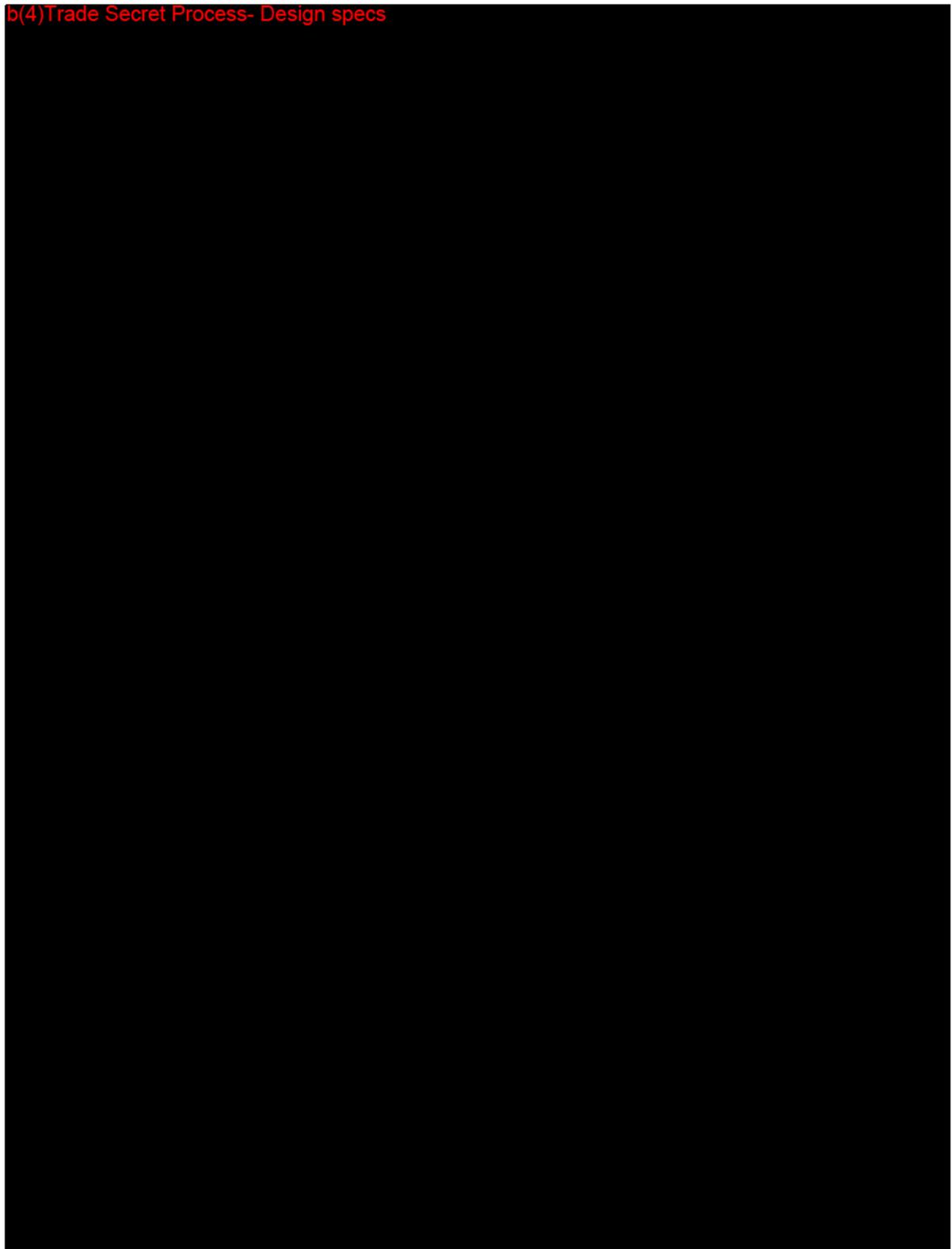
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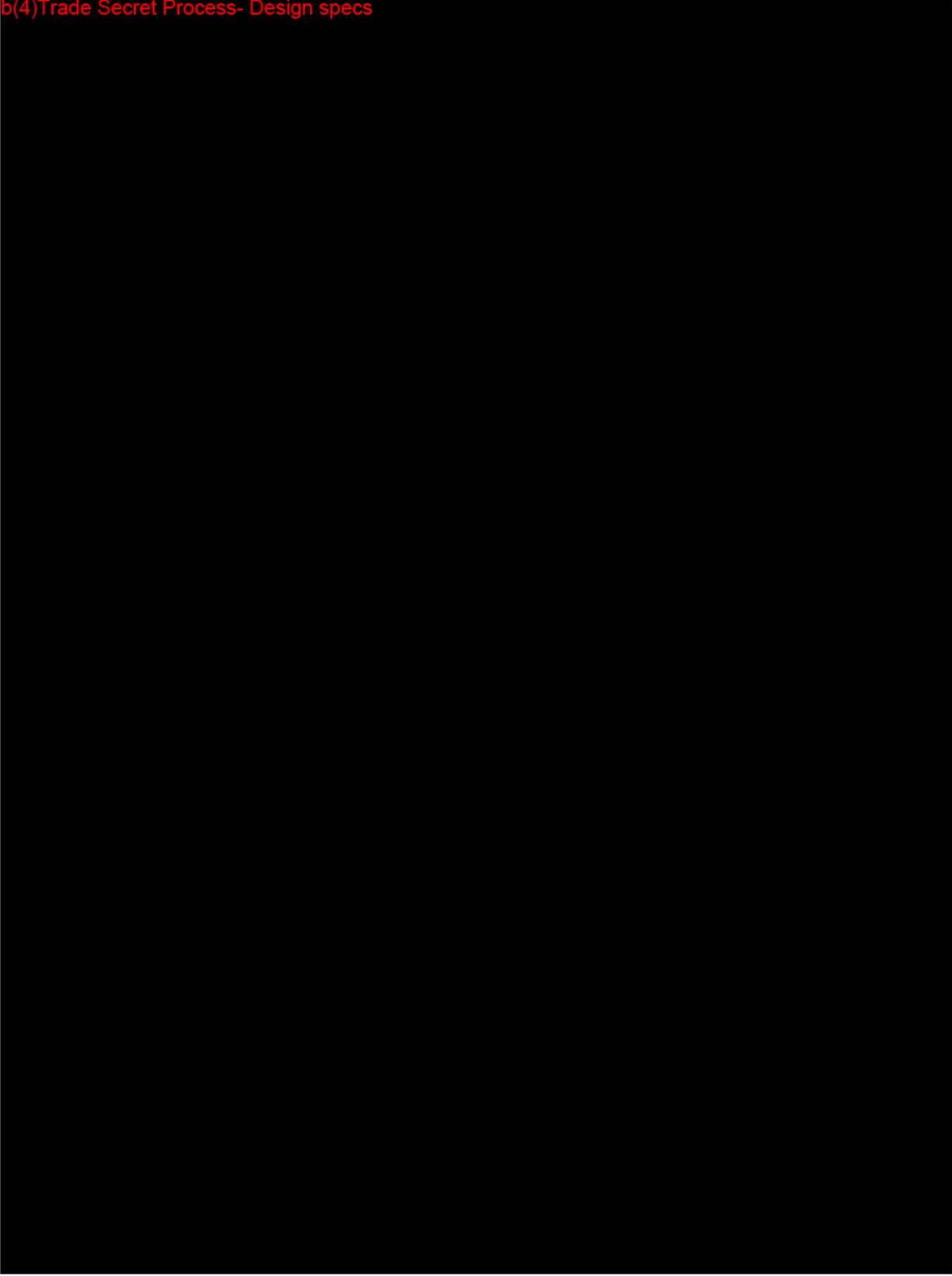
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b(4)Trade Secret Process- Design specs



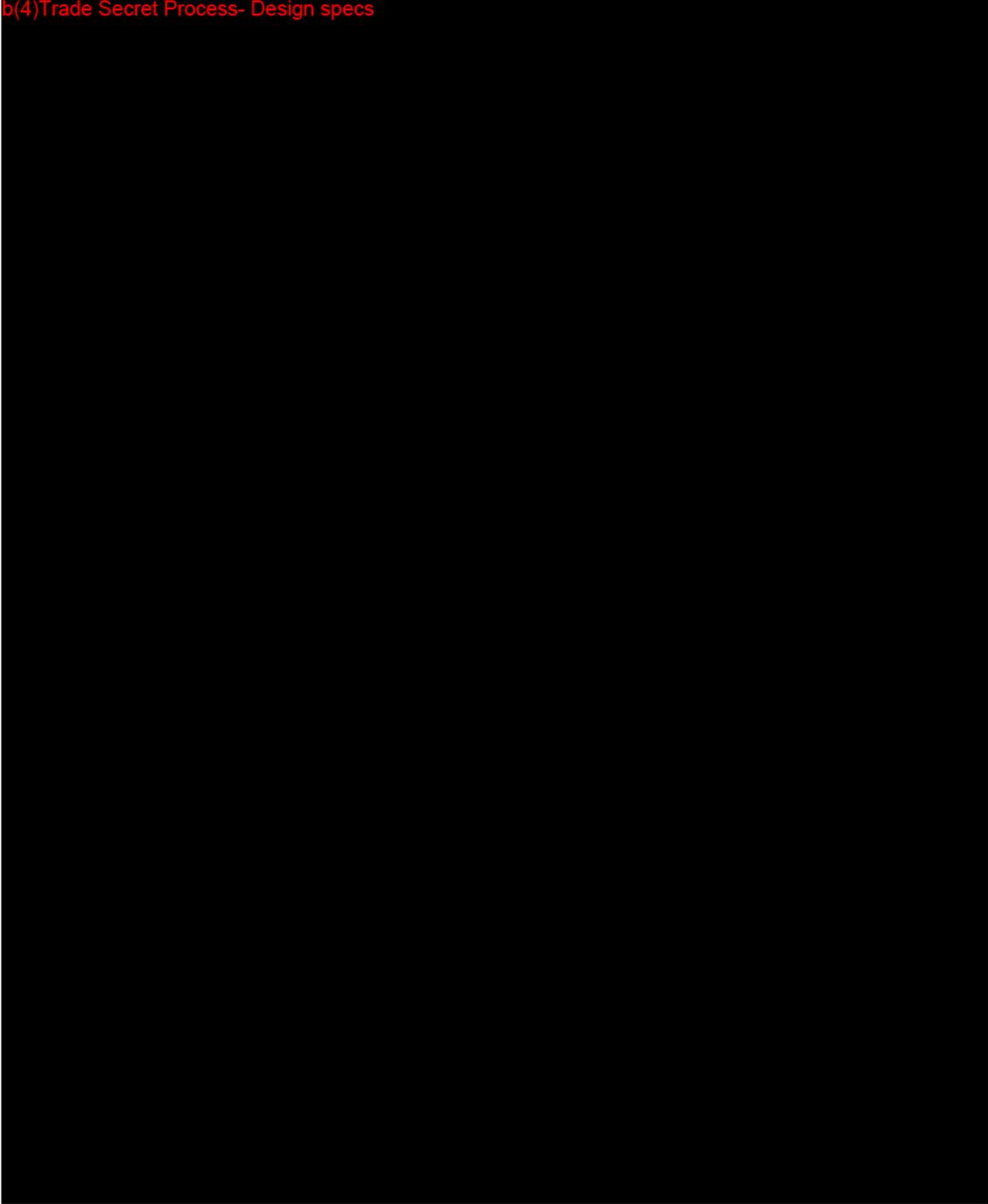
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b(4) Trade Secret Process- Design specs



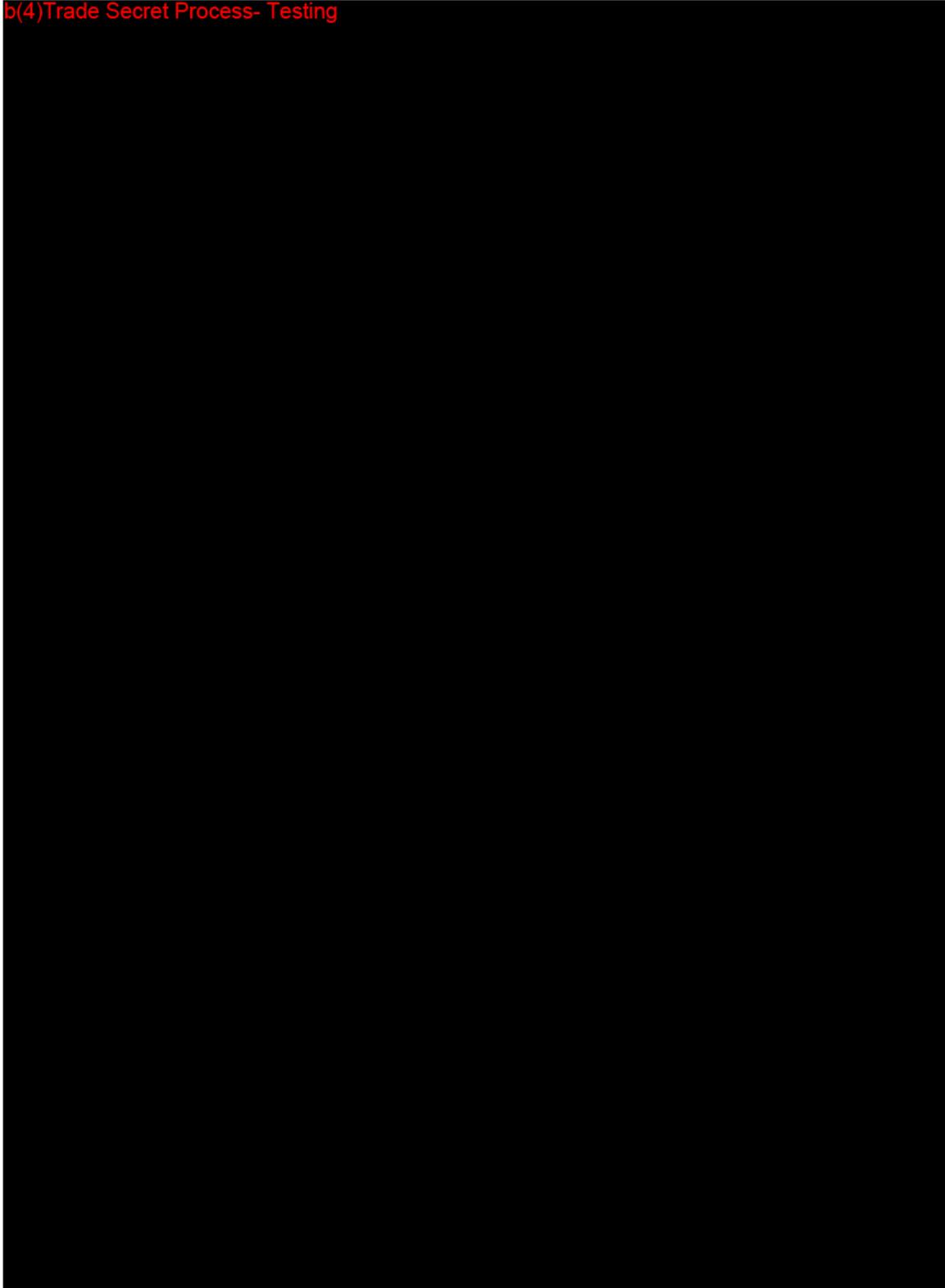
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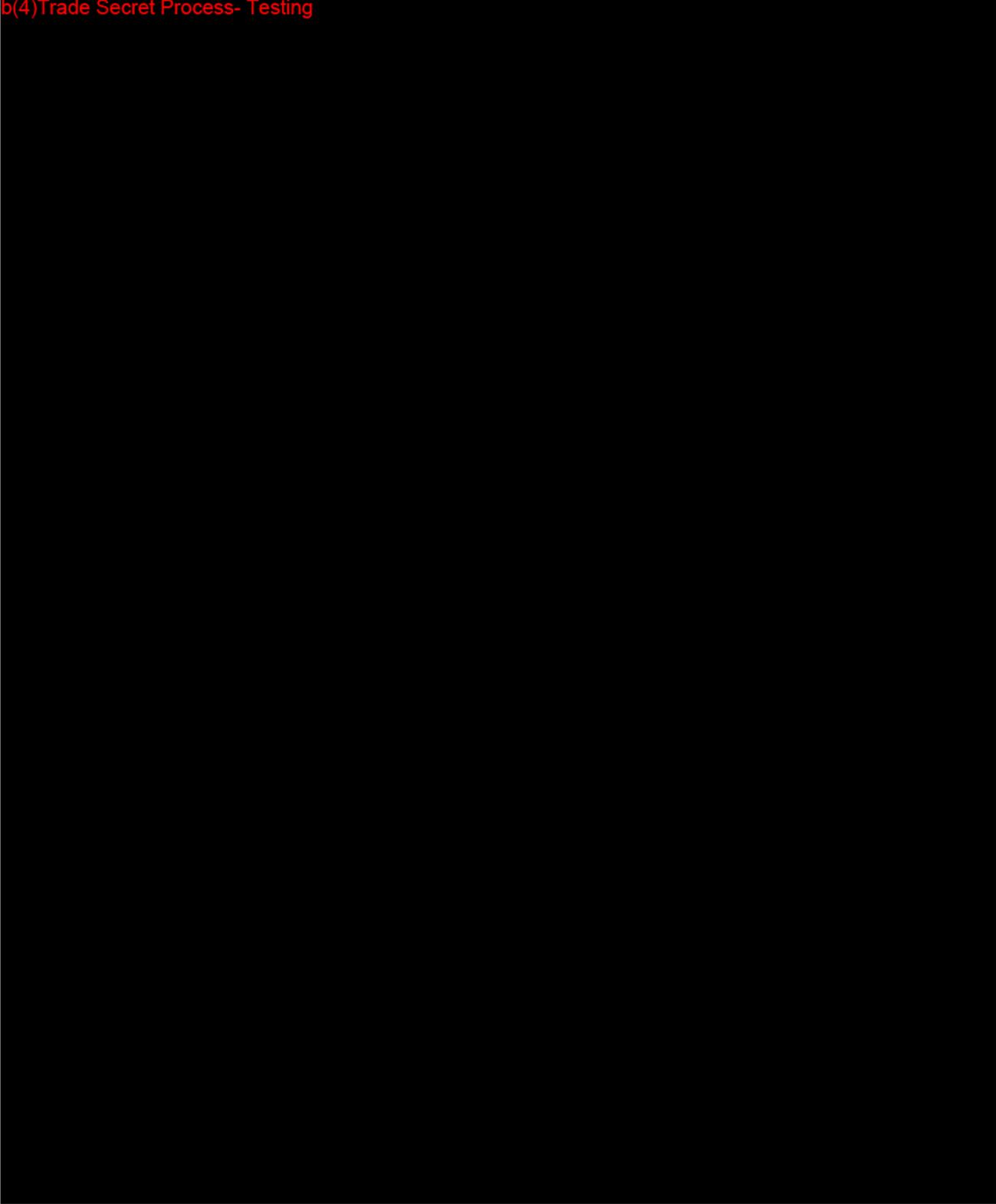
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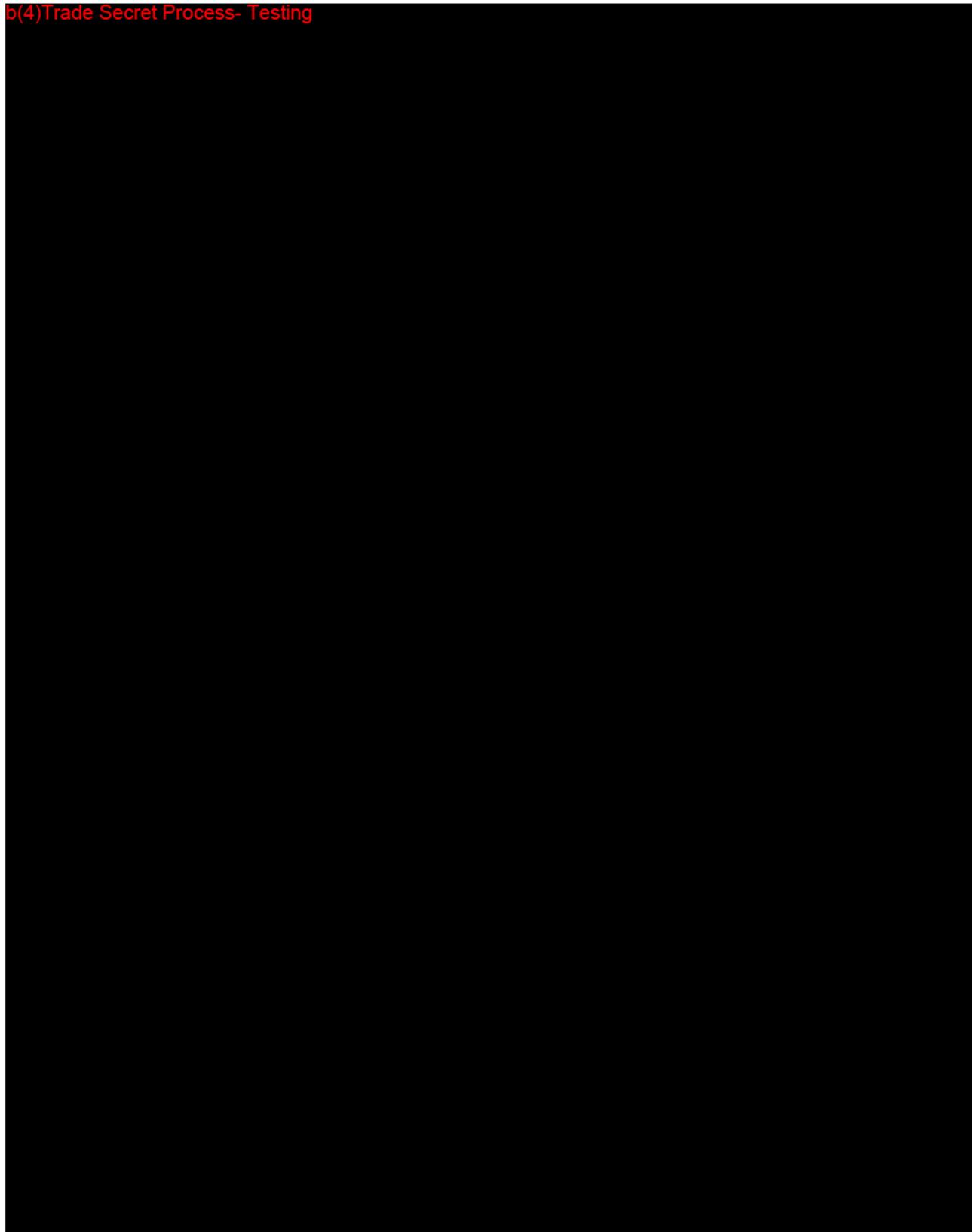
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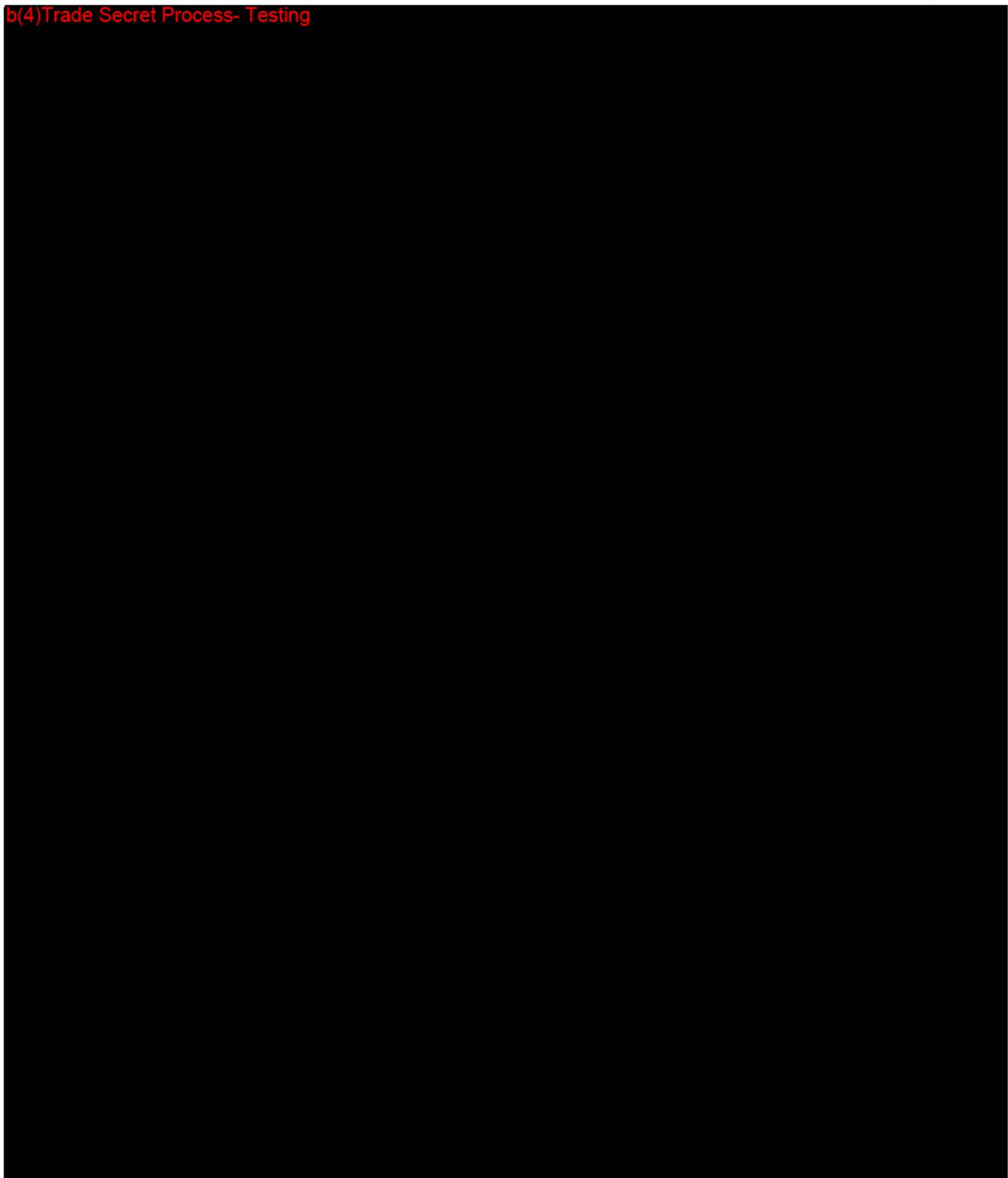
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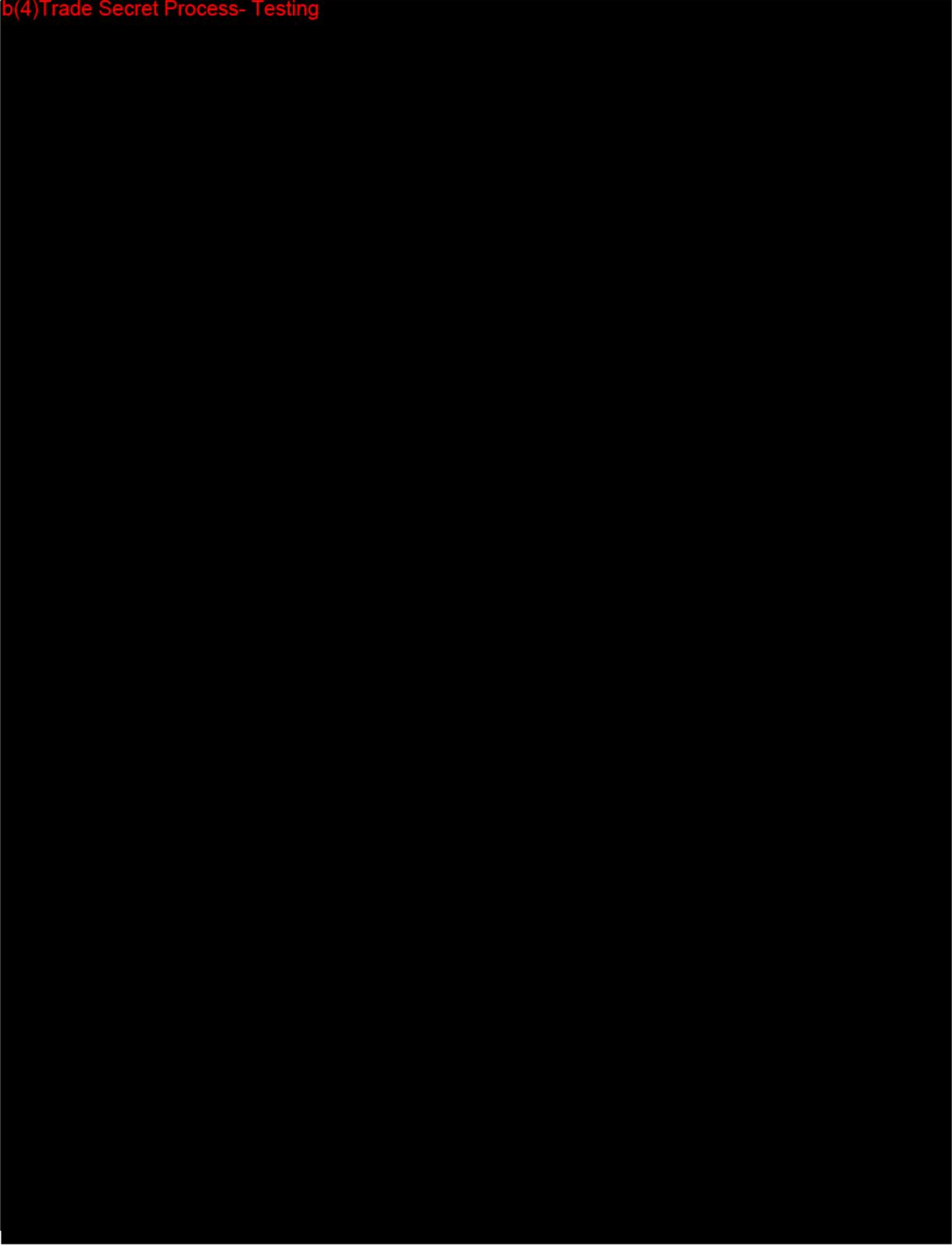
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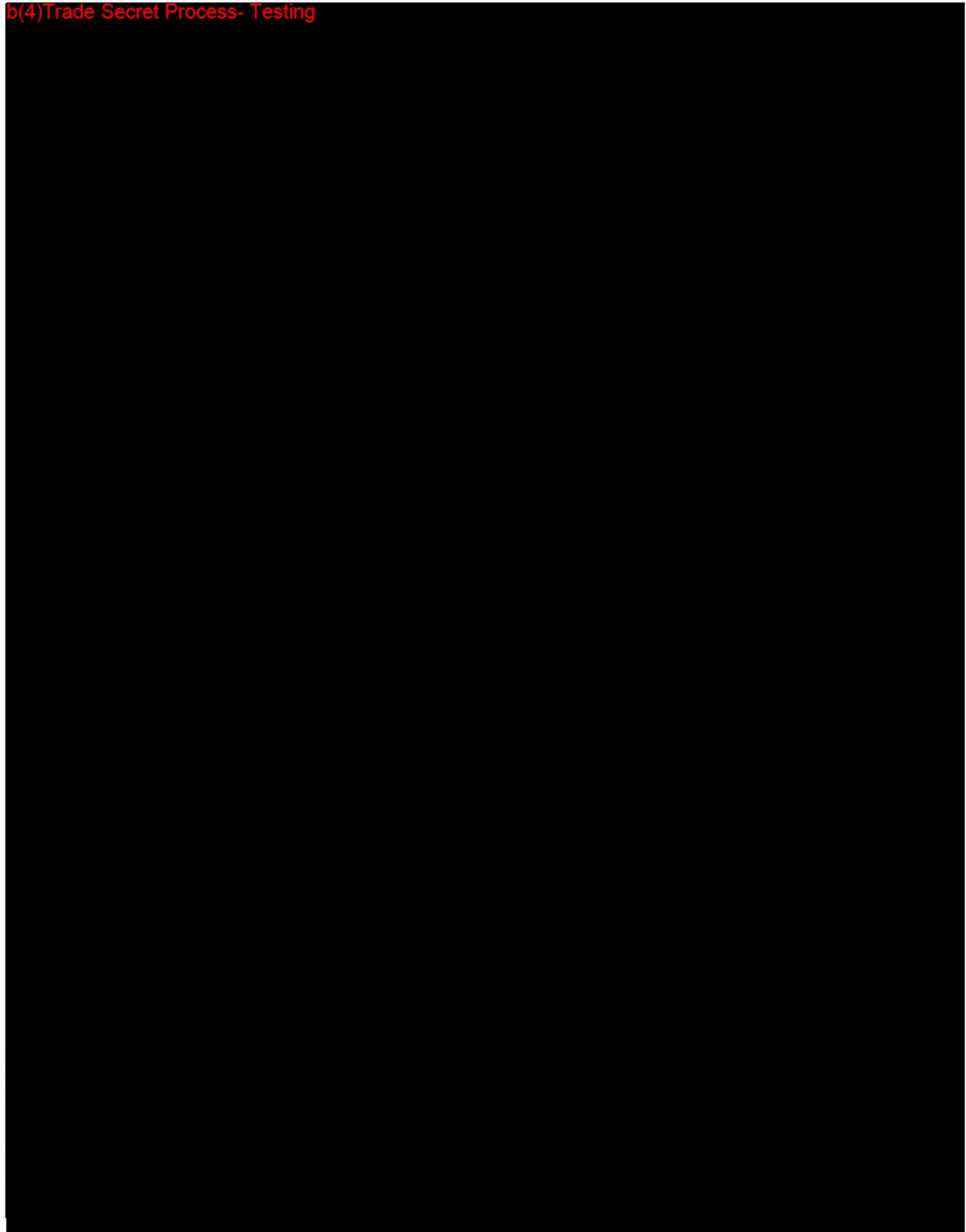
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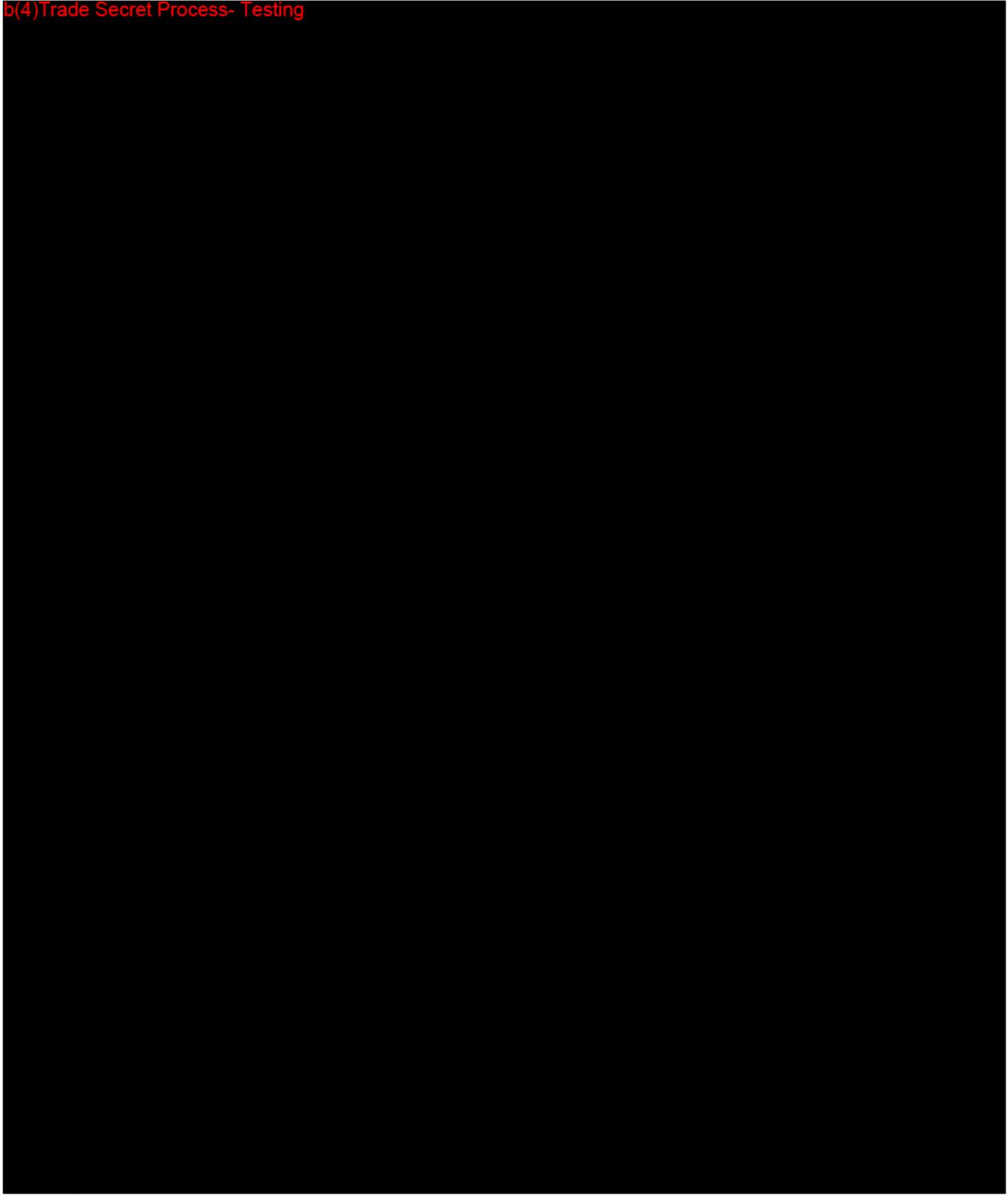
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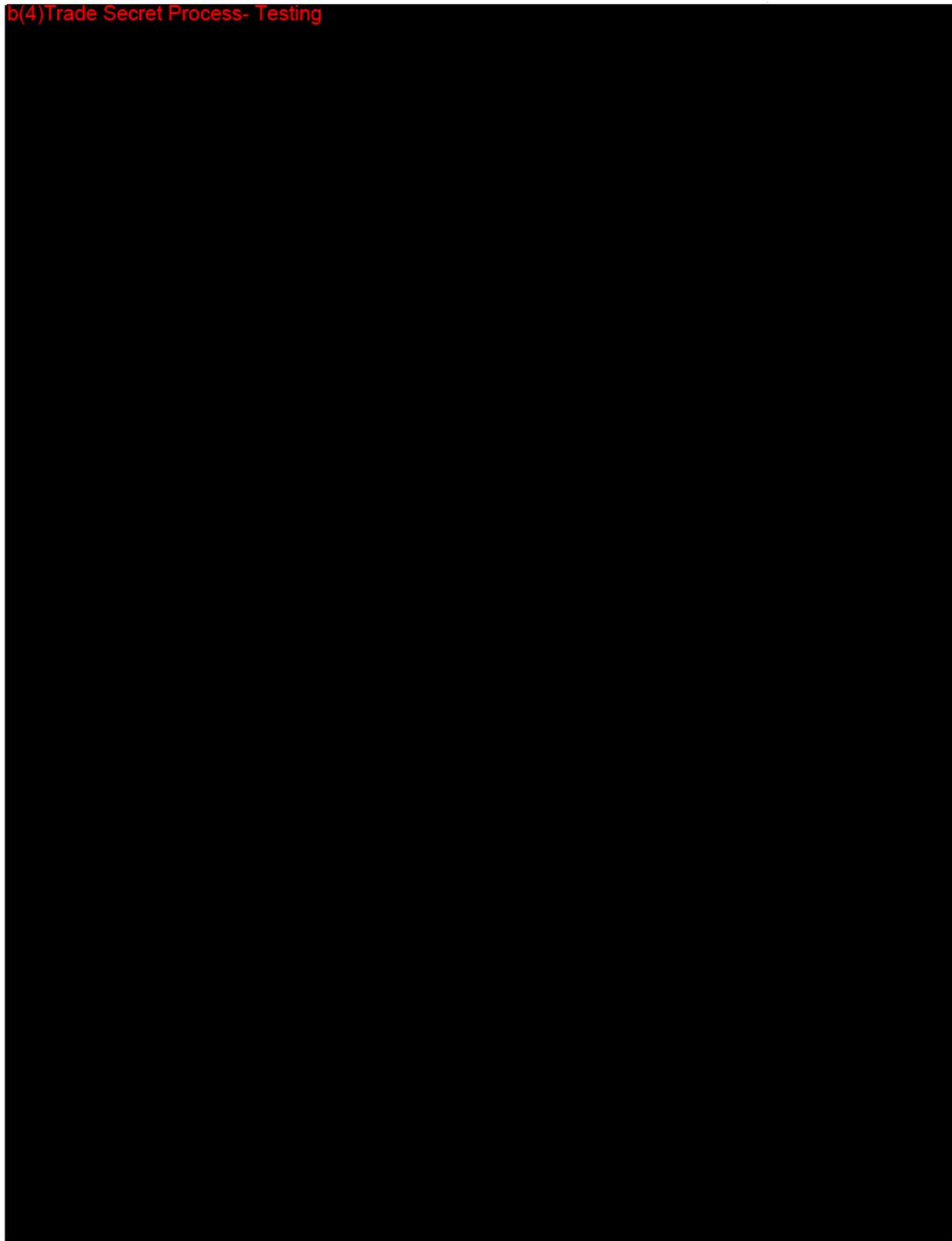
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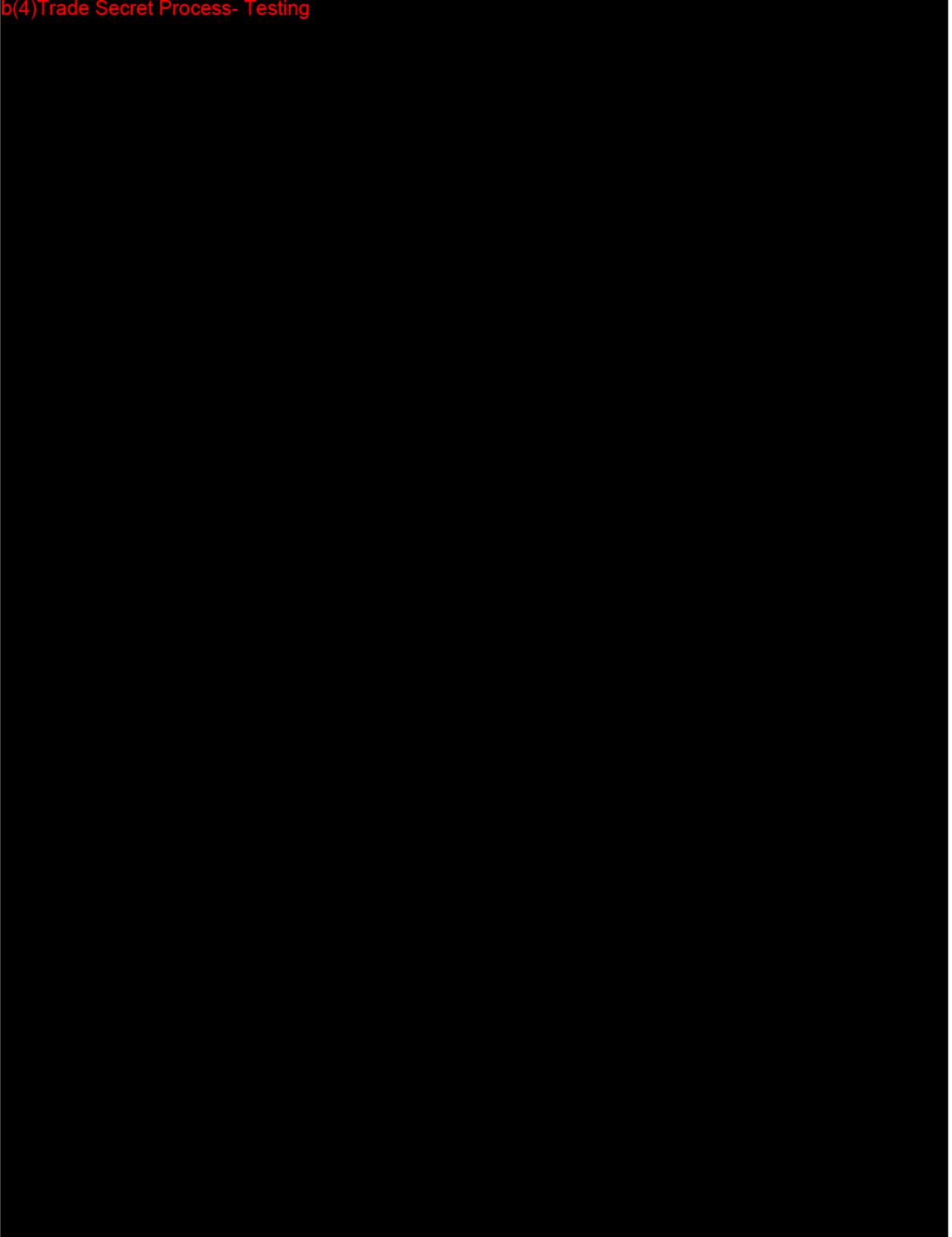
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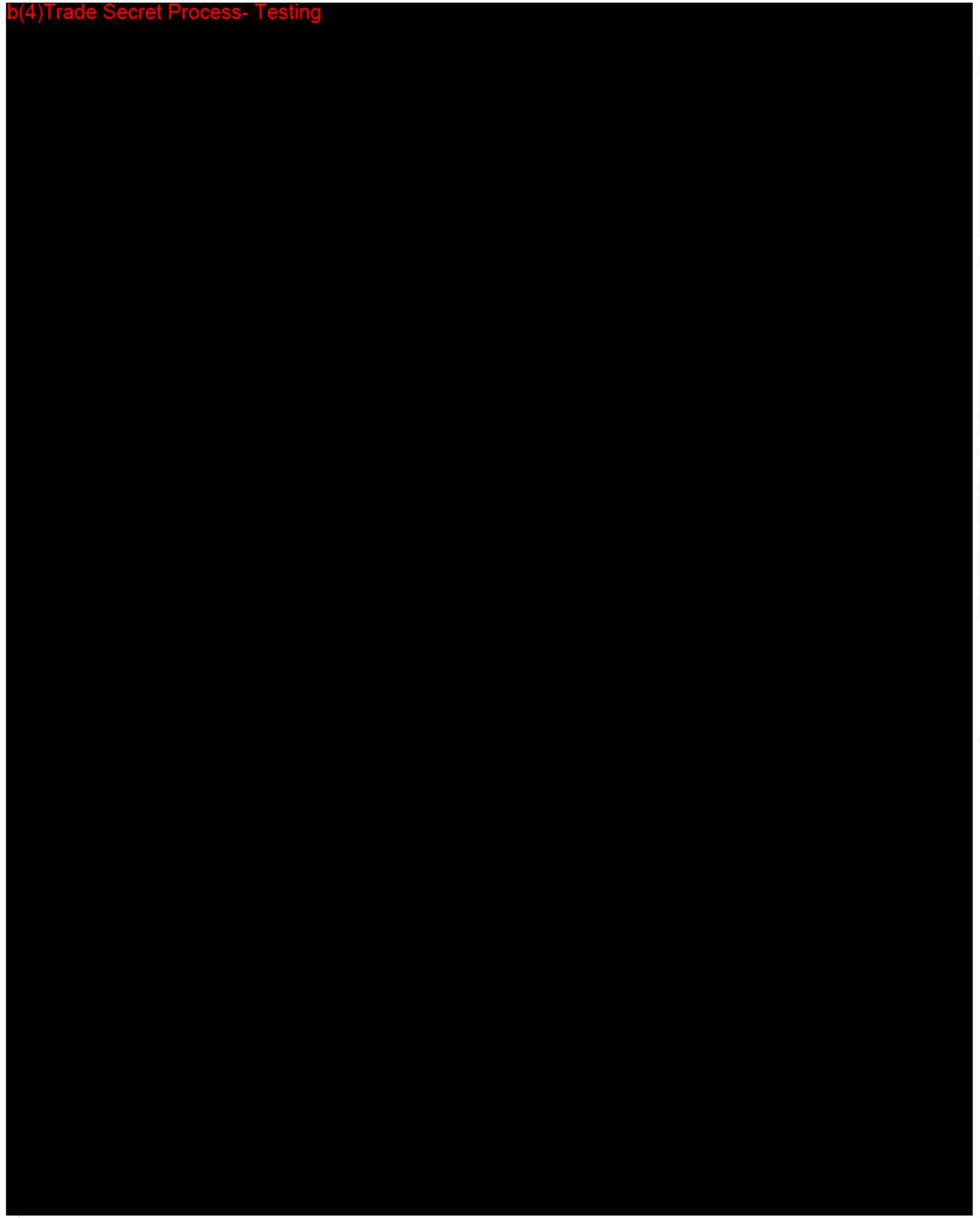
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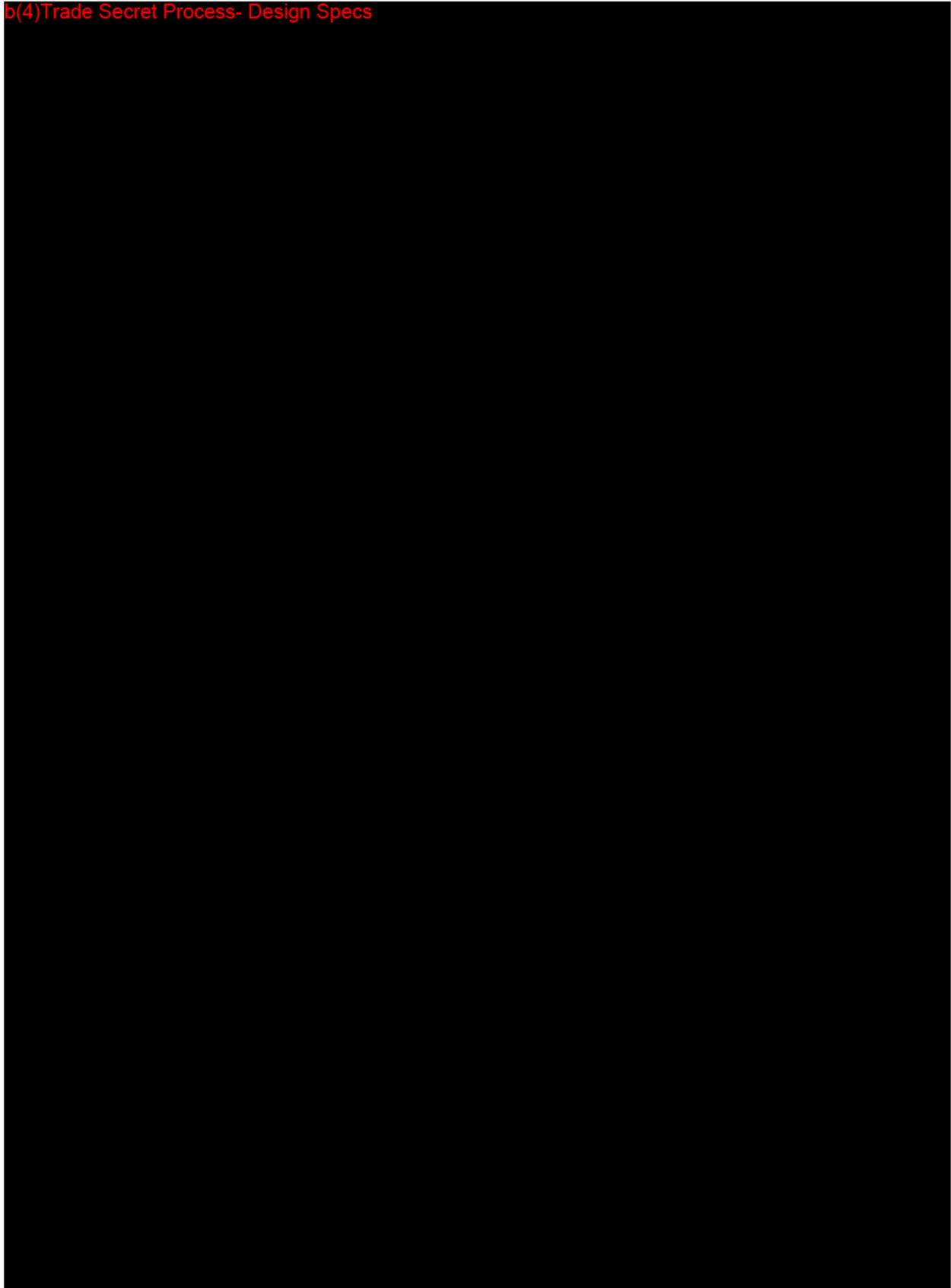
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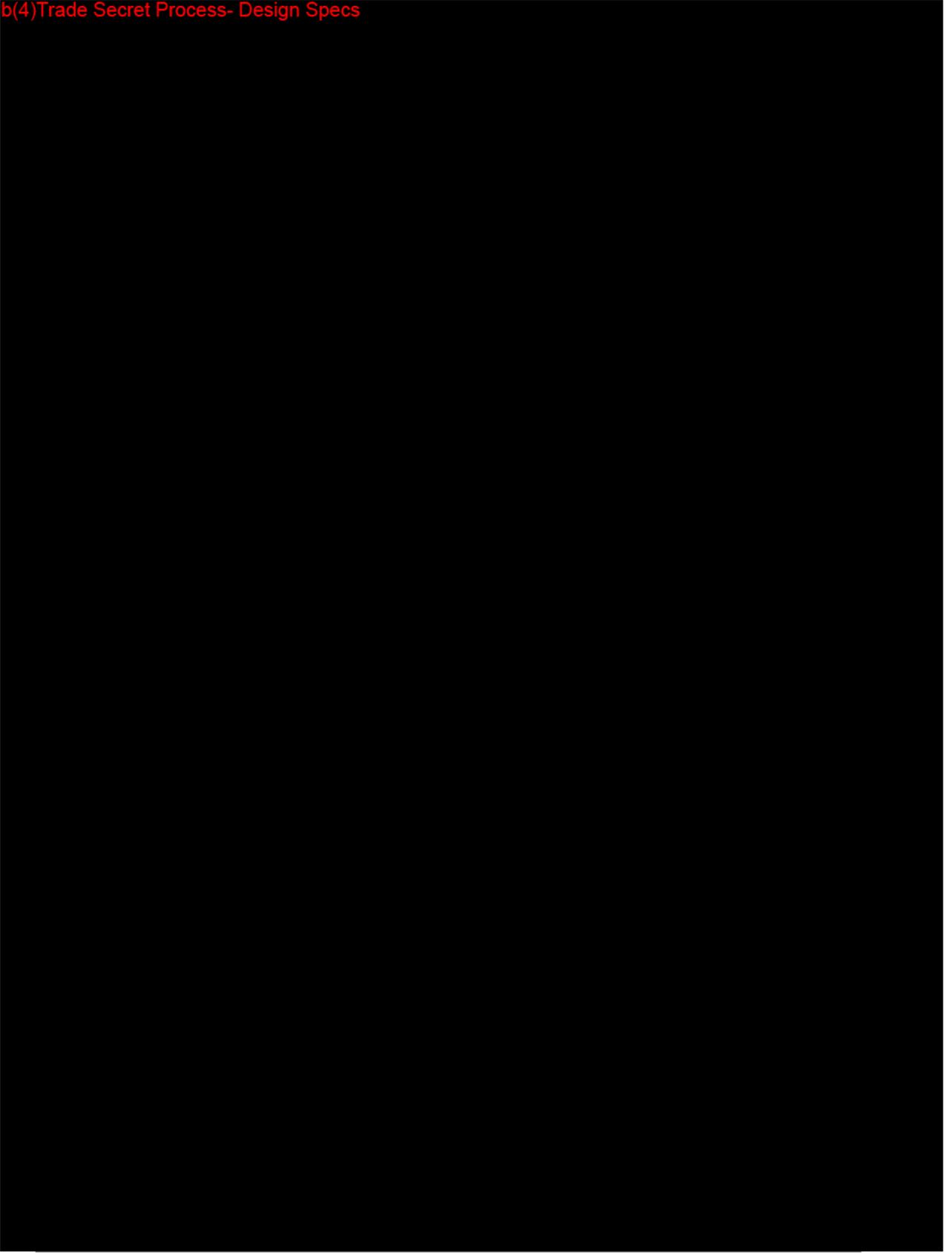
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b(4)Trade Secret Process- Design Specs



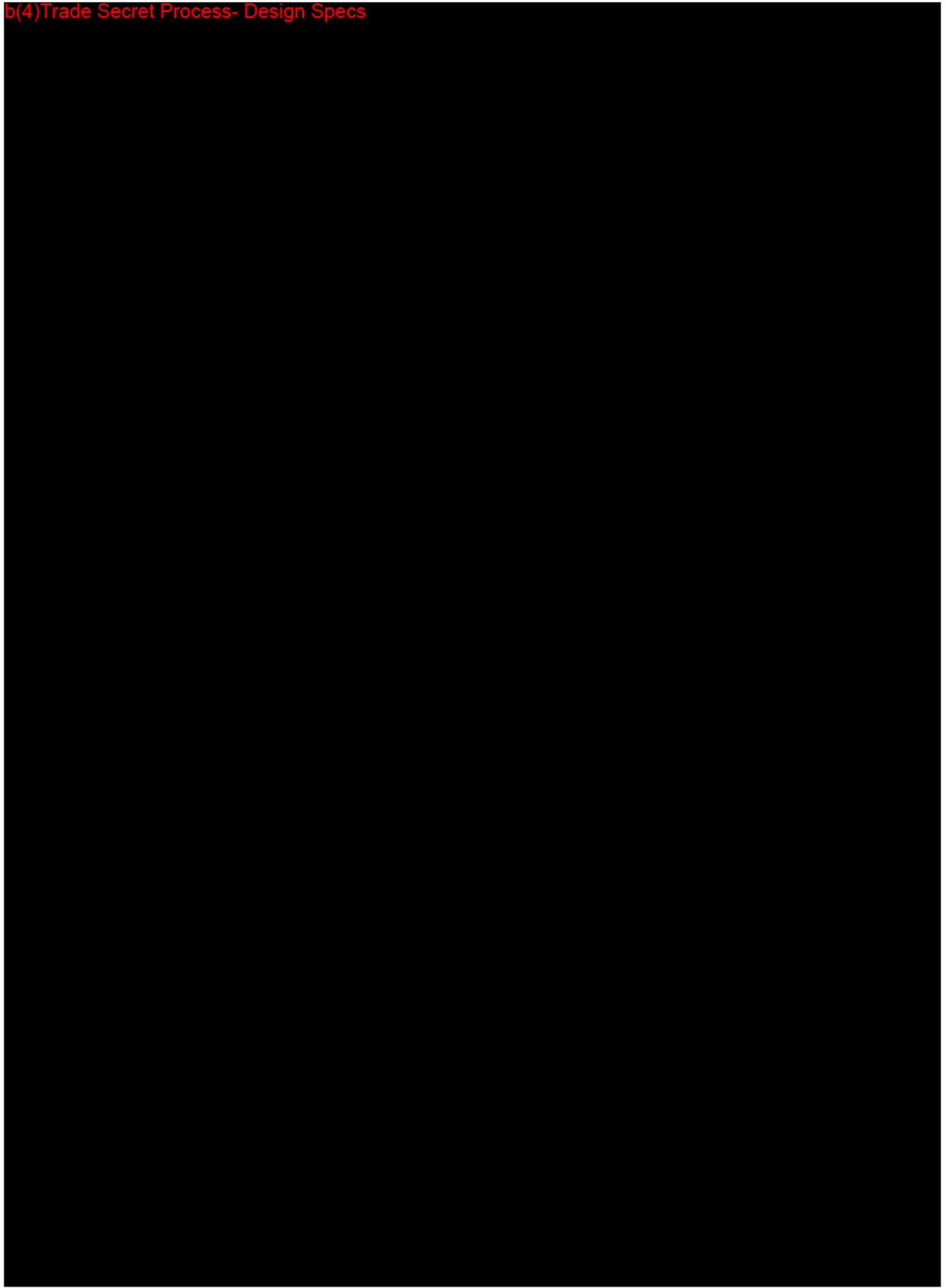
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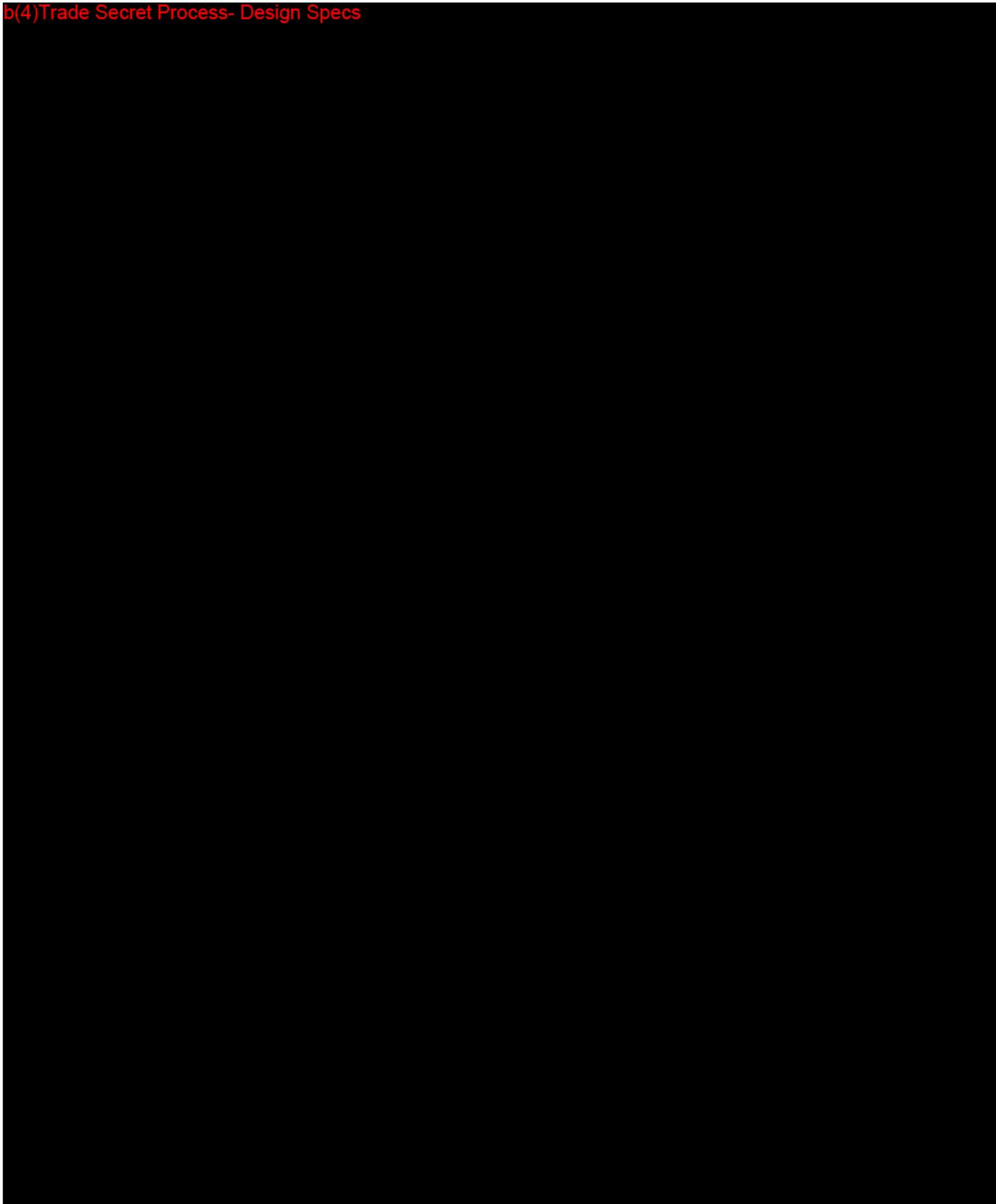
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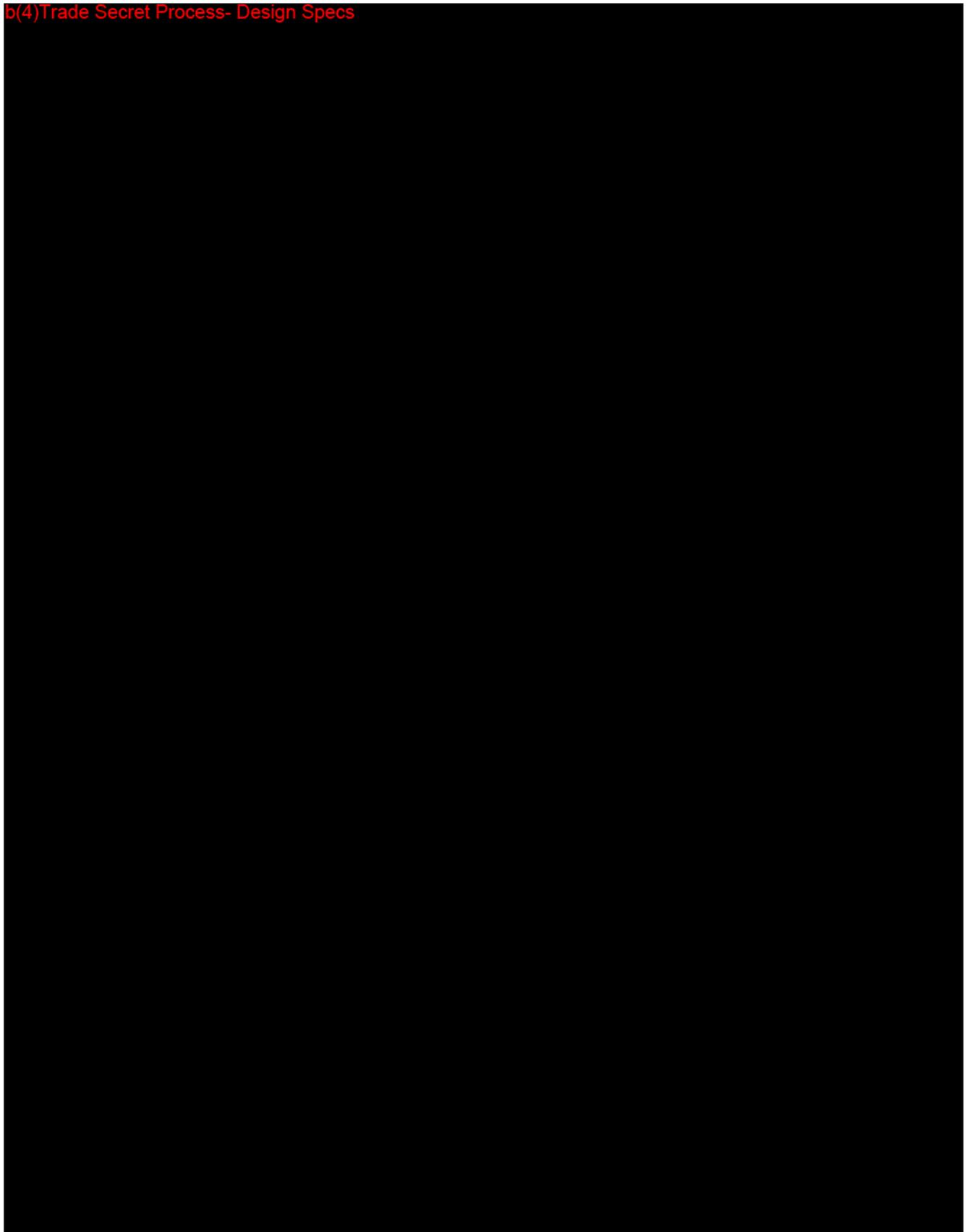
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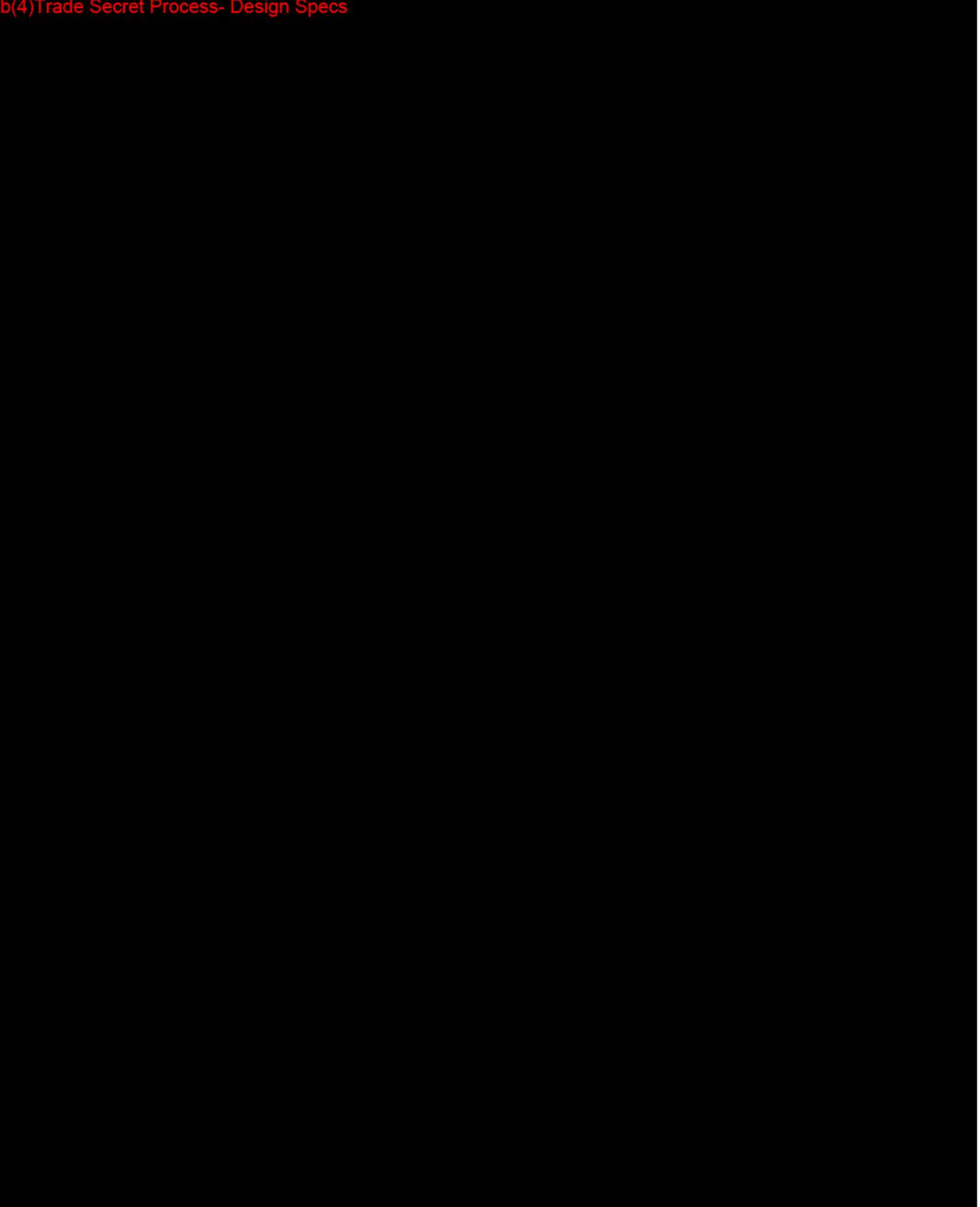
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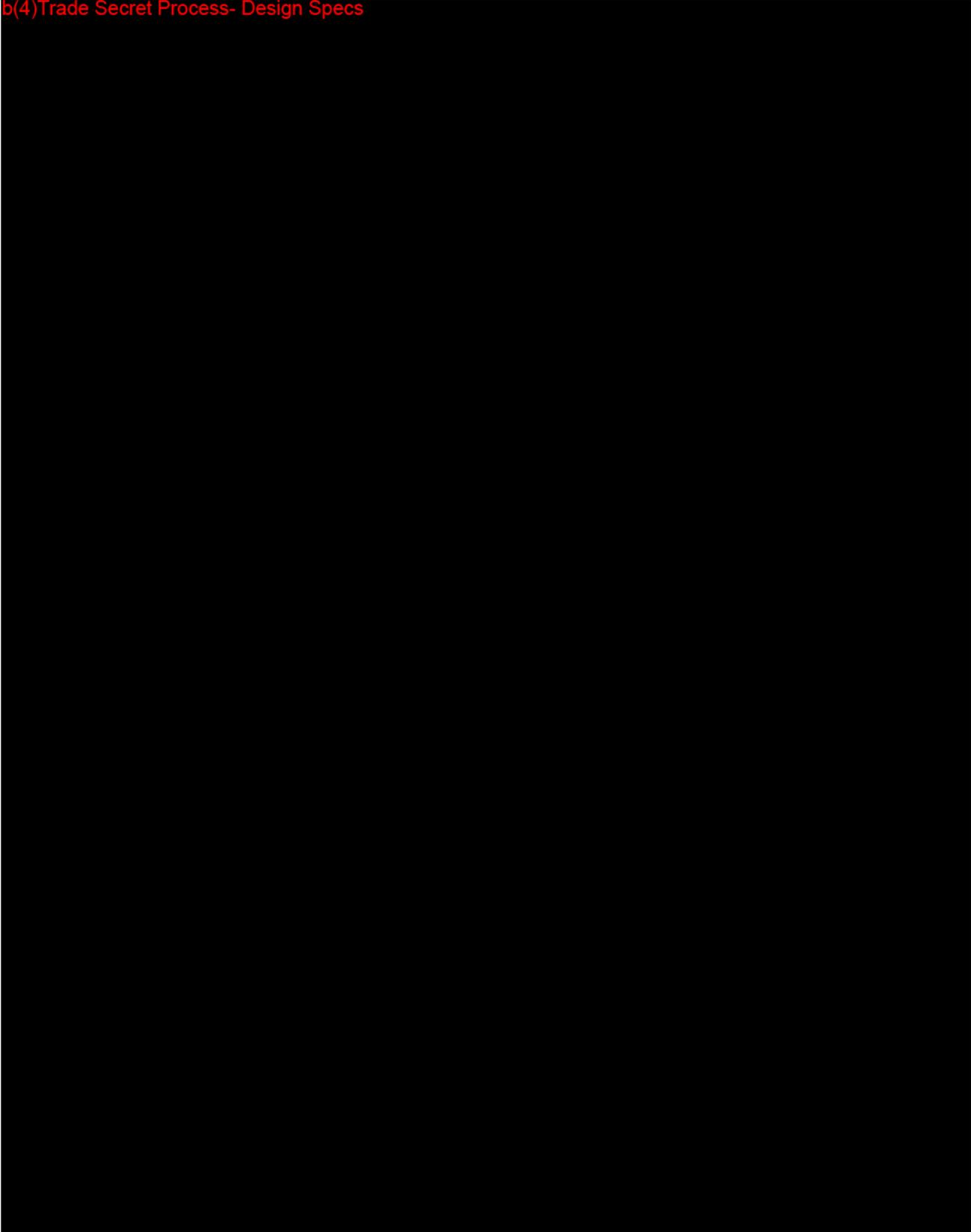
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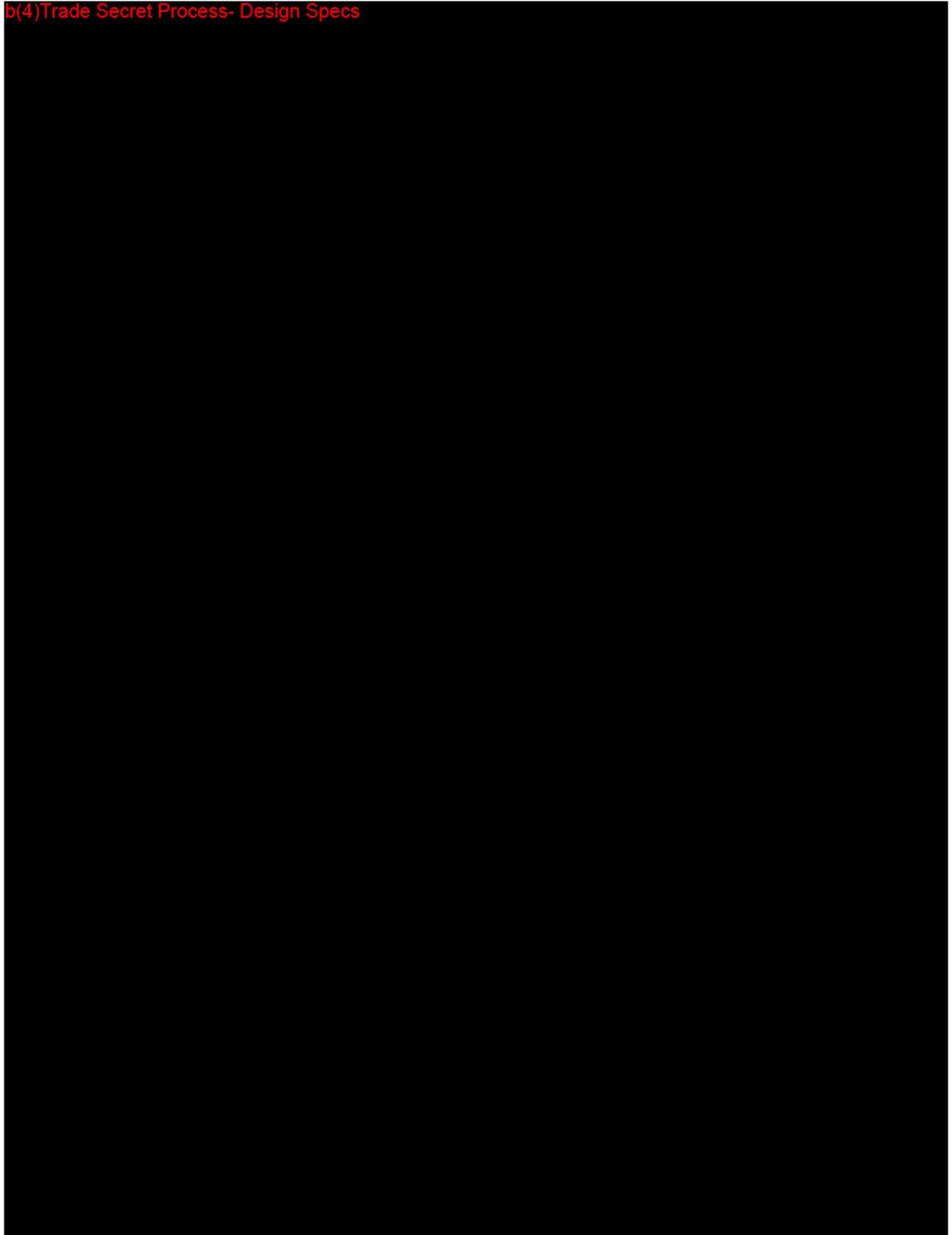
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Appendix F3

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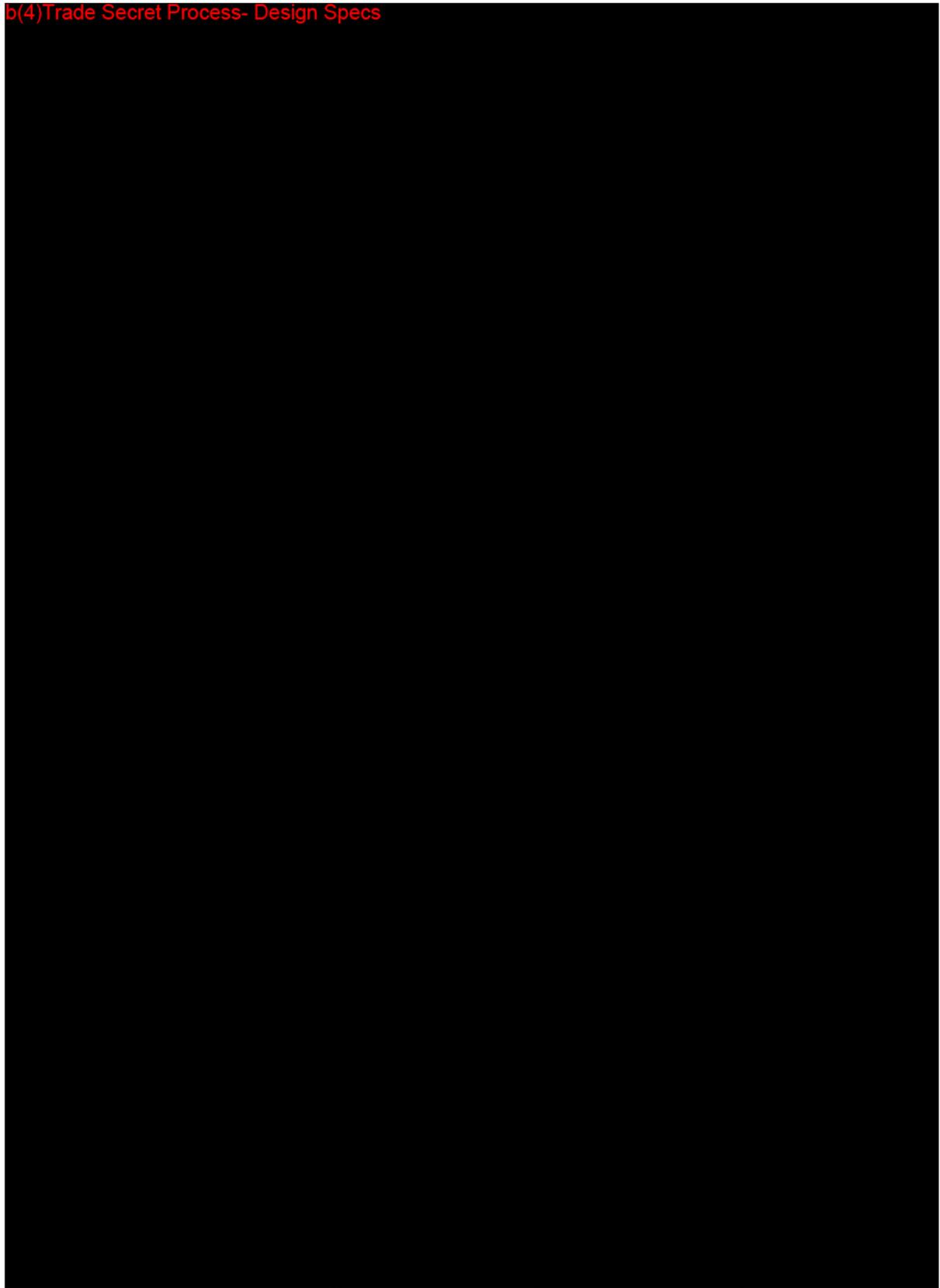
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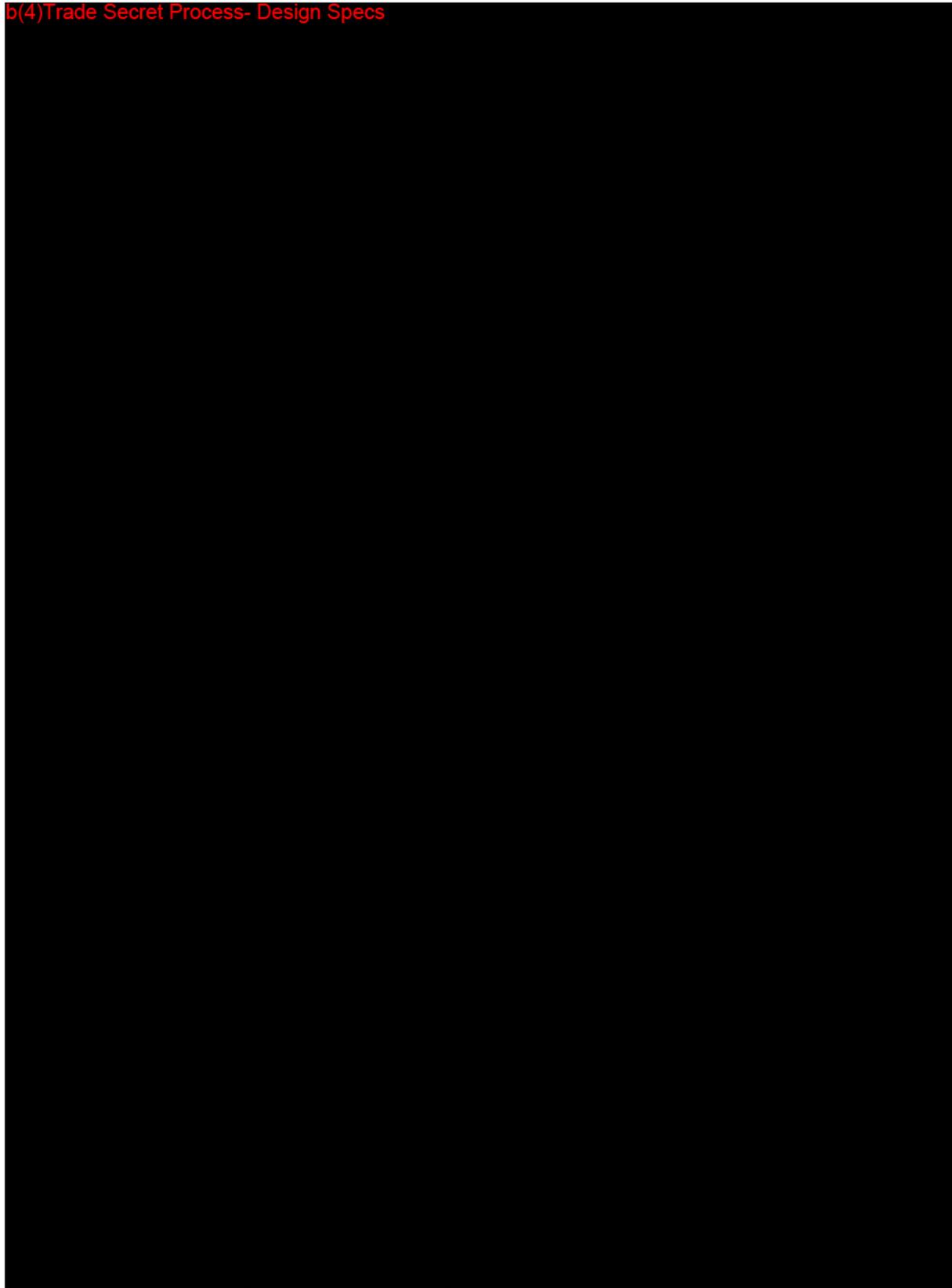
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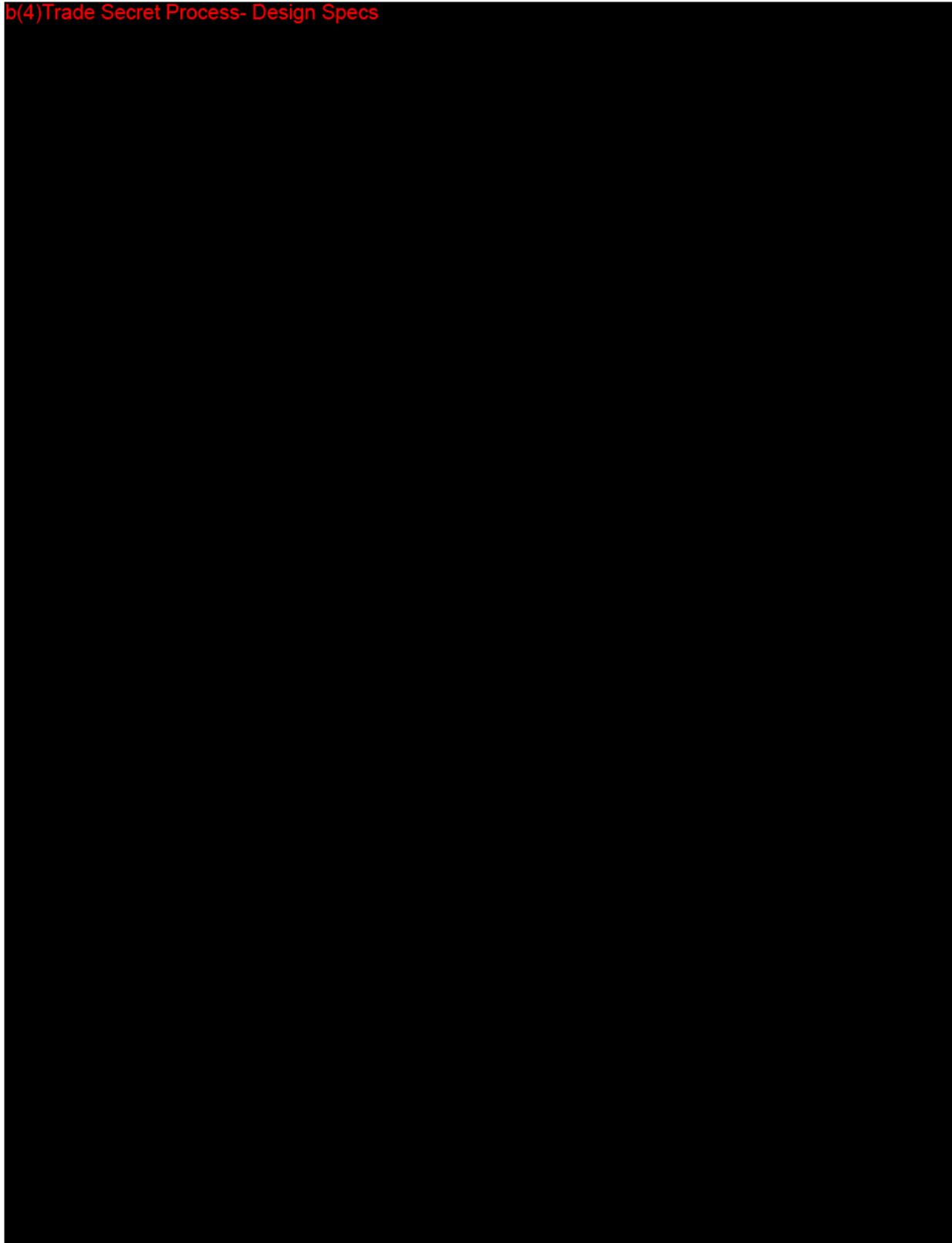
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b(4)Trade Secret Process- Design Specs



Appendix F4

b(4)Trade Secret Process- Design Specs



Appendix G

b(4) Trade Secret Process- Technical Specs



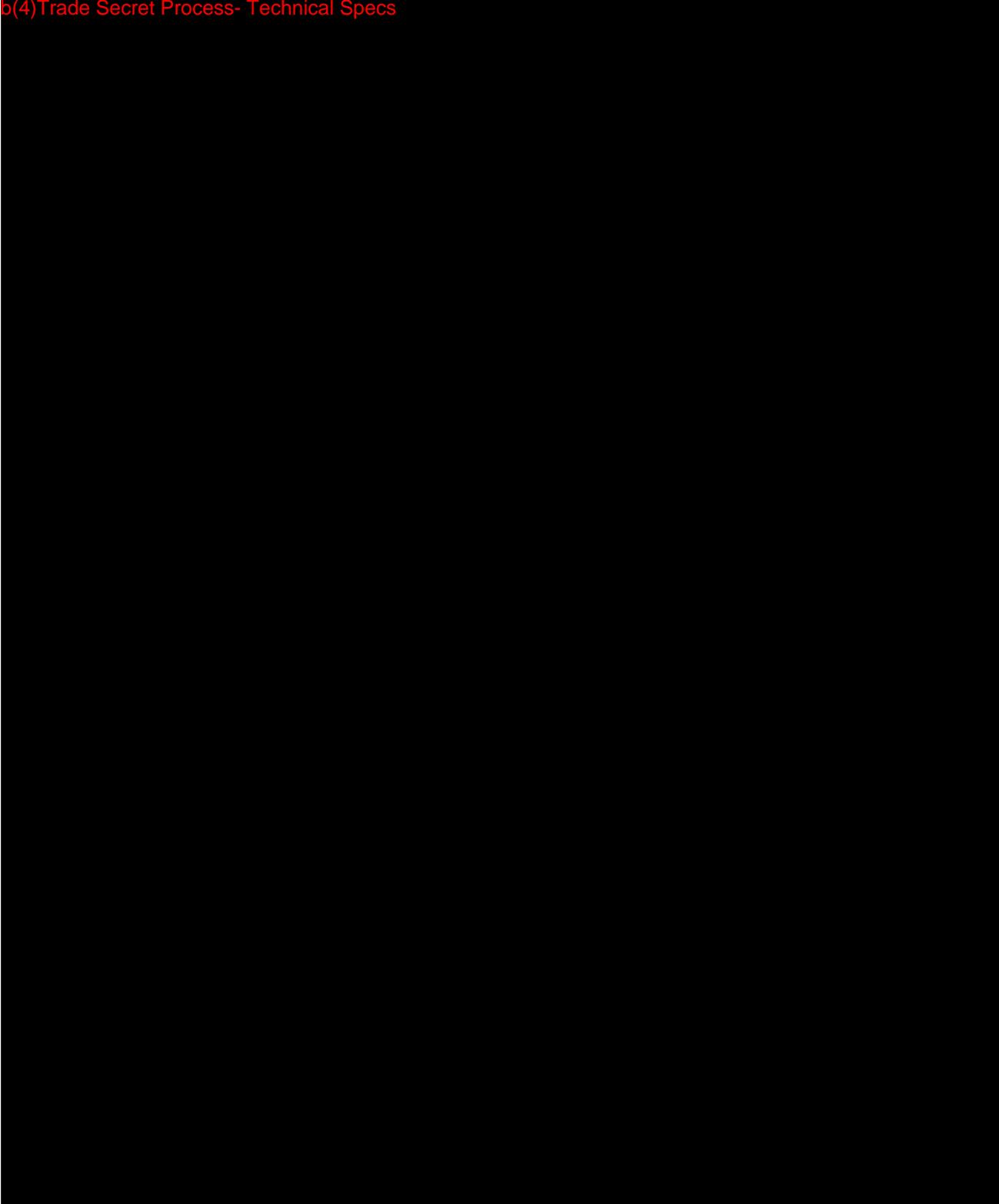
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b(4) Trade Secret Process- Technical Specs



Appendix G

b(4) Trade Secret Process- Technical Specs



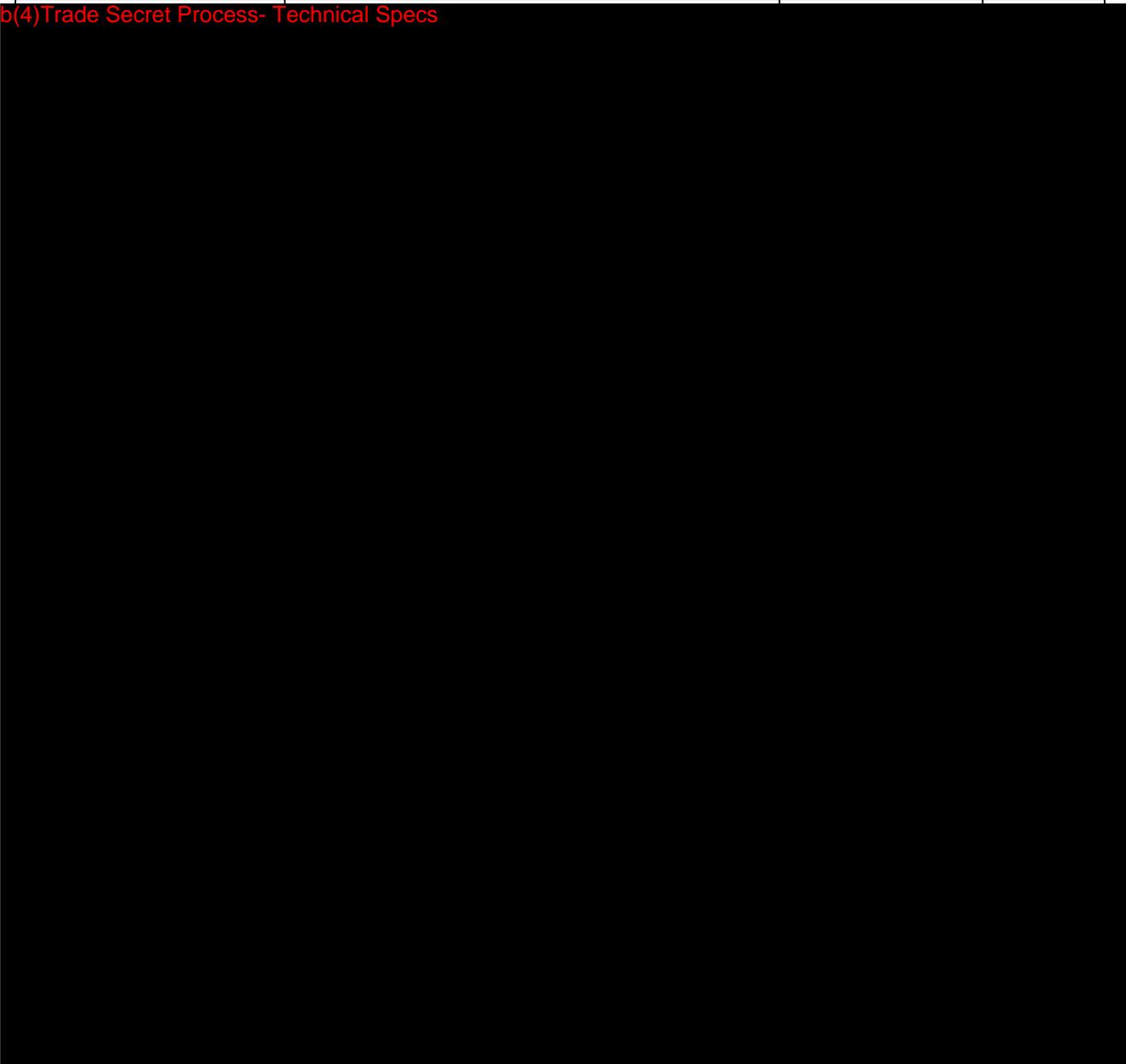
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b(4)Trade Secret Process- Technical Specs



Appendix G

b(4)Trade Secret Process- Technical Specs



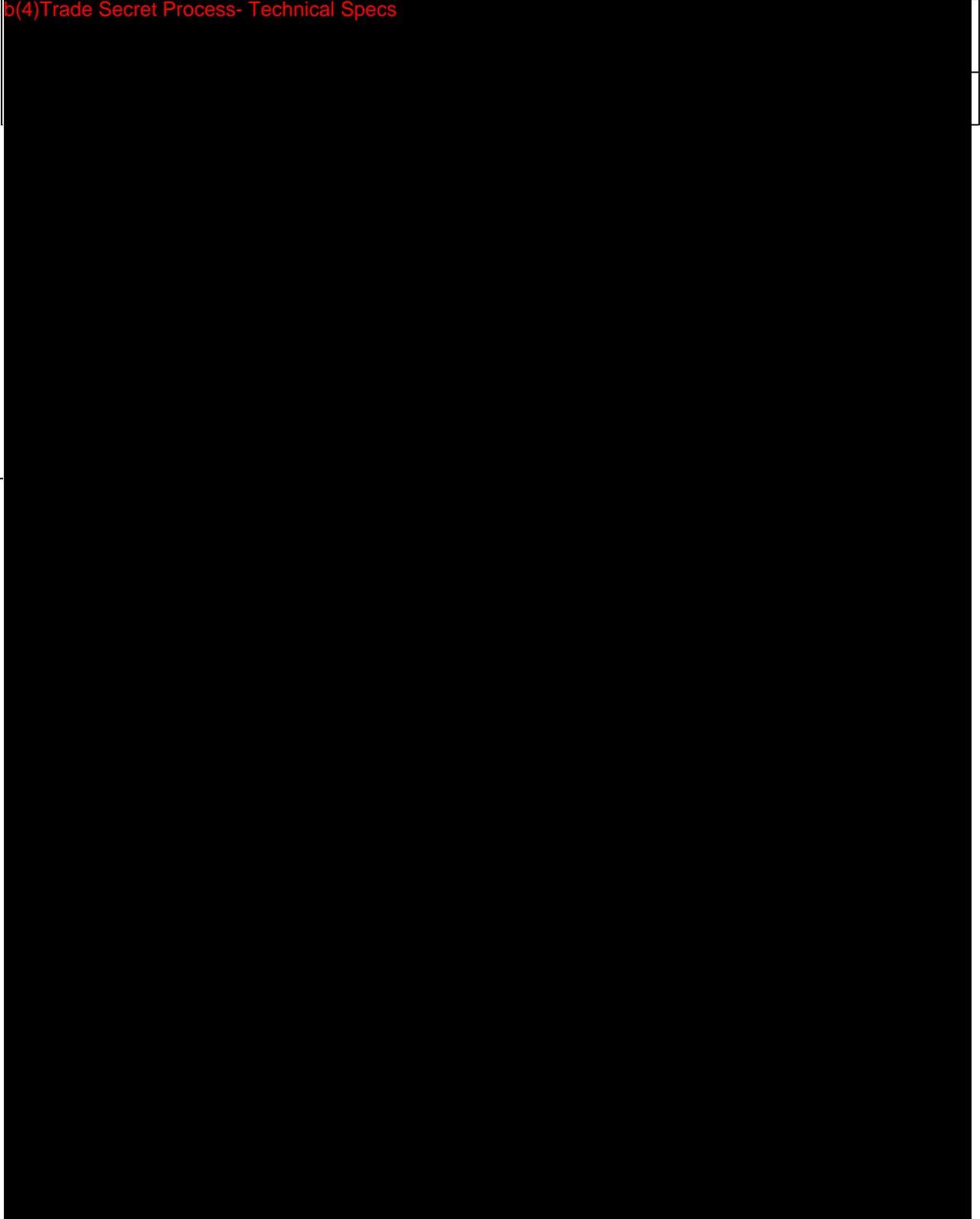
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b(4)Trade Secret Process- Technical Specs



Appendix G

b(4)Trade Secret Process- Technical Specs

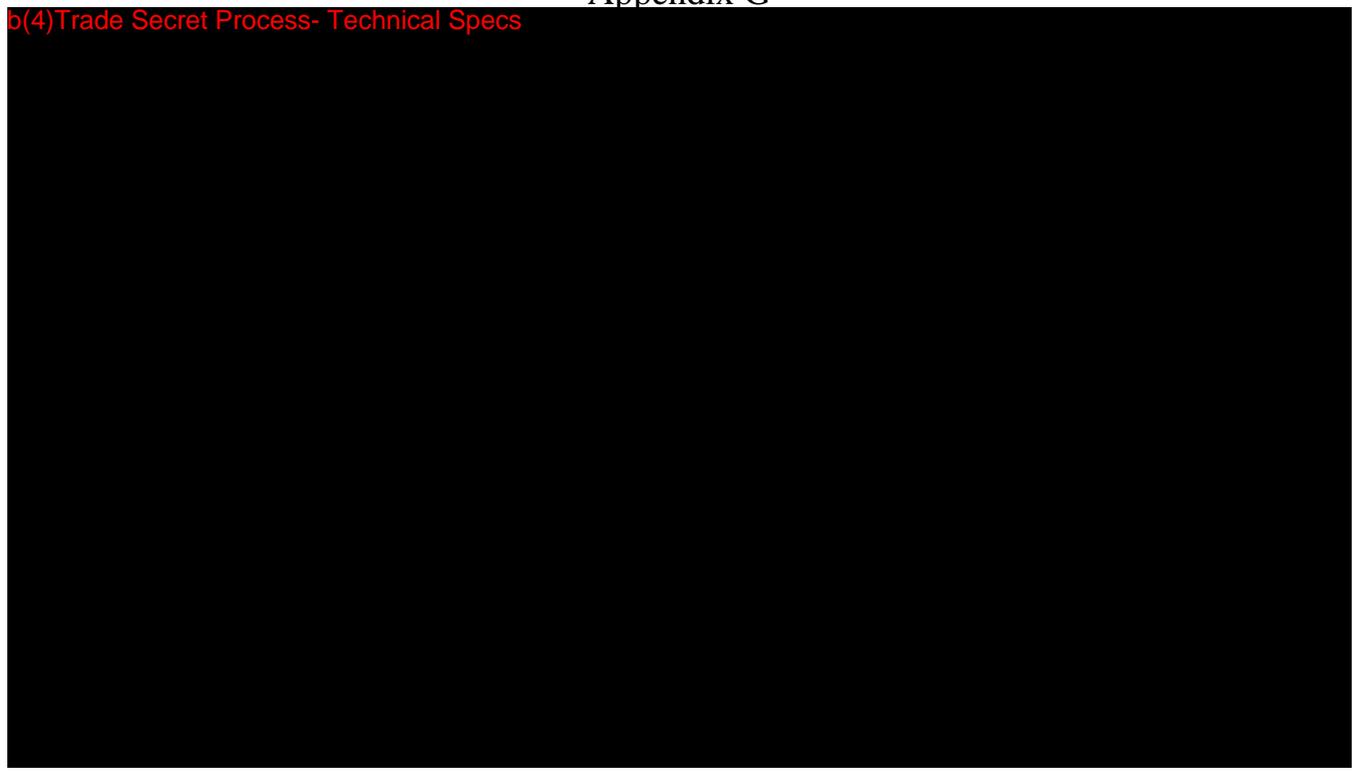


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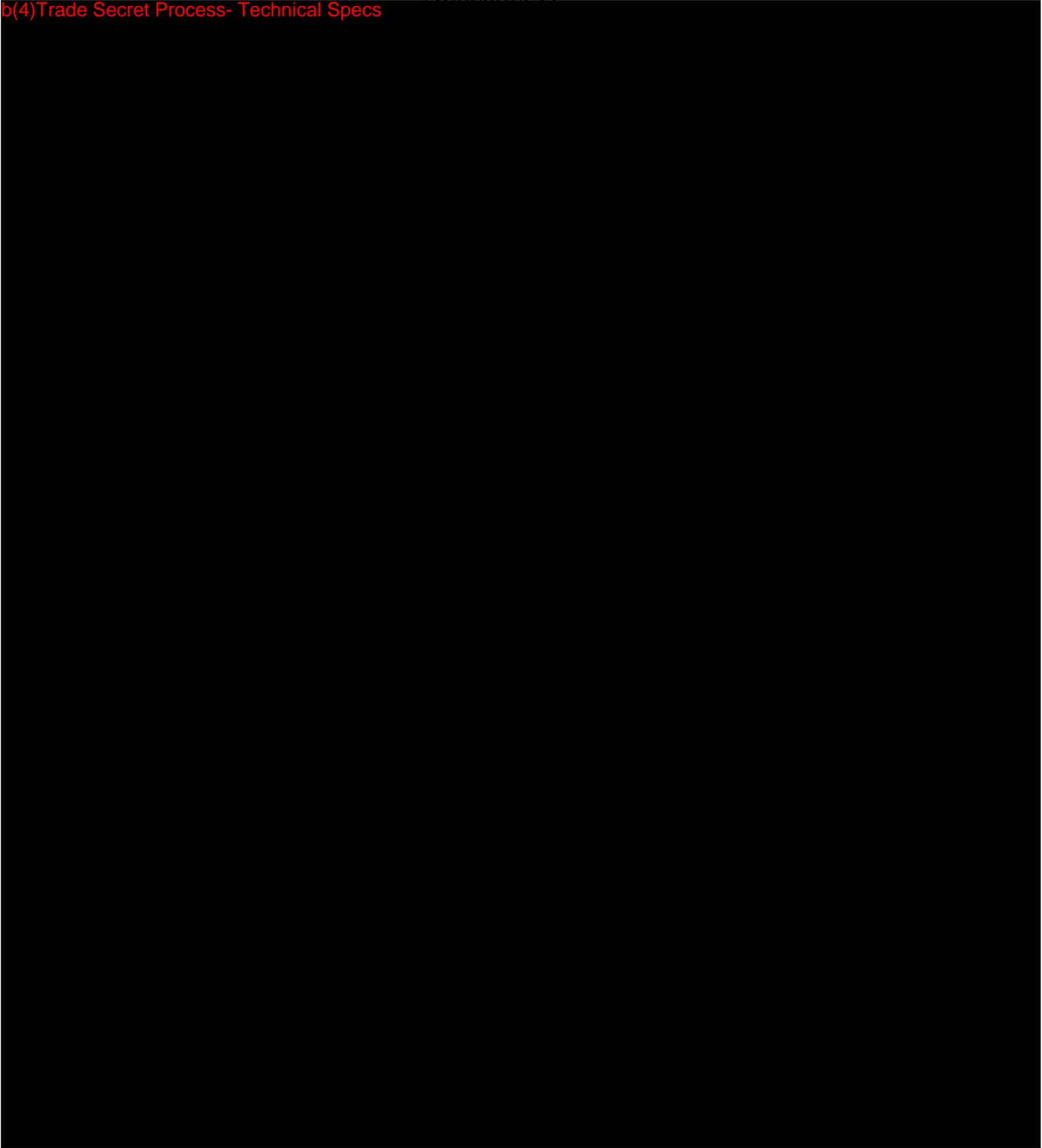
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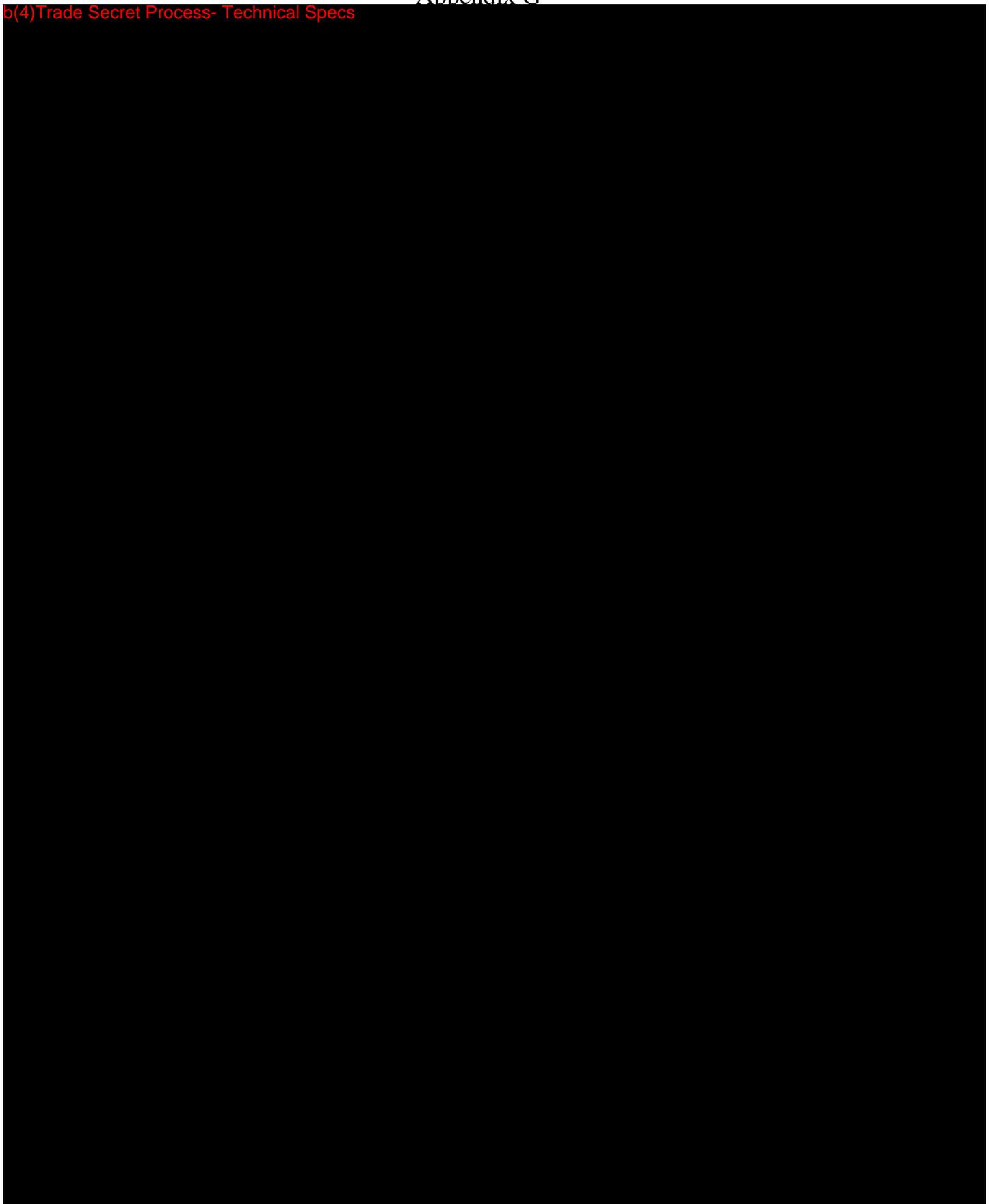
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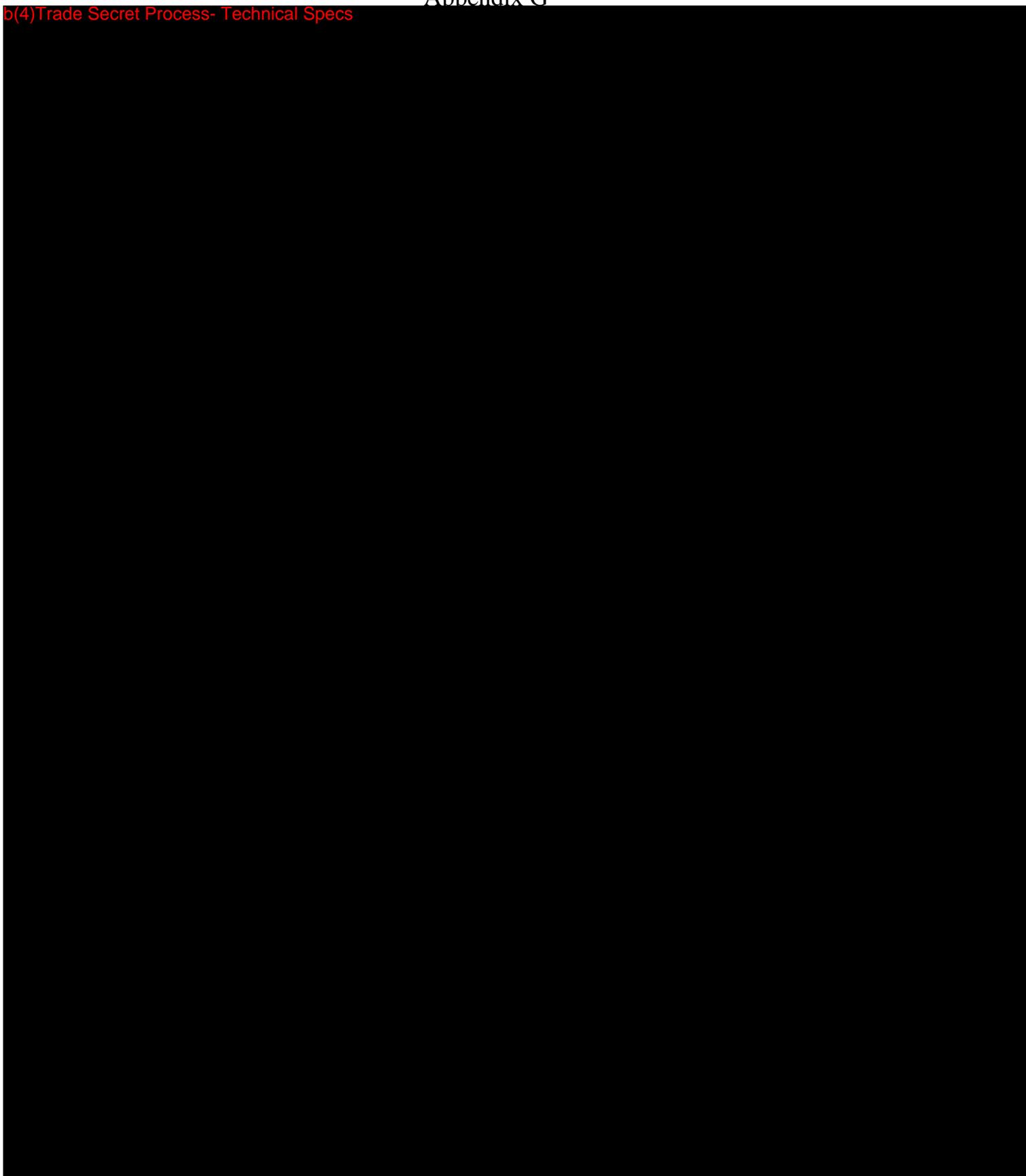
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b(4) Trade Secret Process- Technical Specs



b(4) Trade Secret Process- Technical Specs

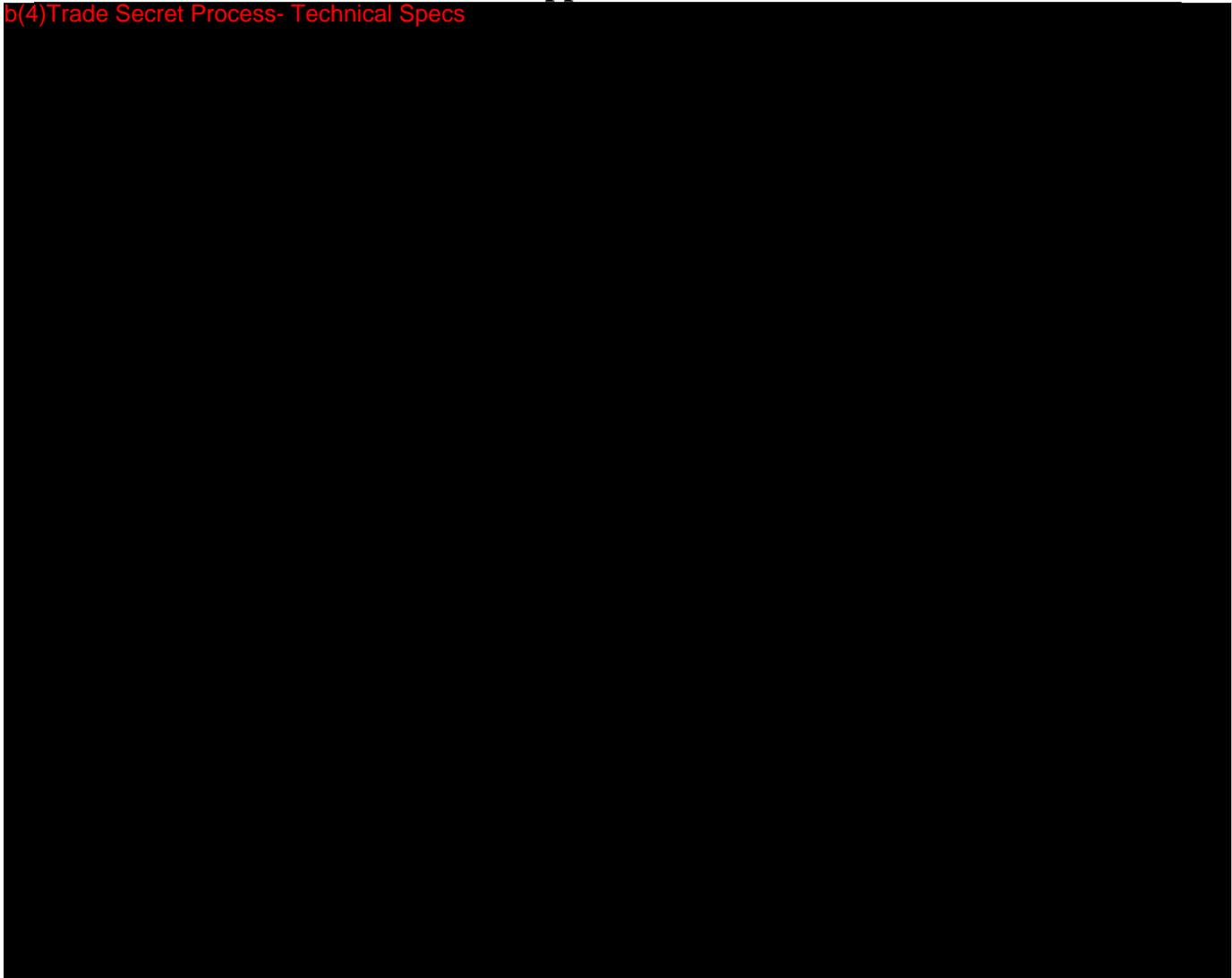


b(4)Trade Secret Process- Technical Specs



Appendix G

b(4) Trade Secret Process- Technical Specs



Appendix G

b(4)Trade Secret Process- Technical Specs



Appendix H1 Clinical Report – Hummingbird™ TTS

1.0 BACKGROUND

1.1 Device Name

The Preceptis Hummingbird™ Tympanostomy Tube System (HTTS)

1.2 Device Description

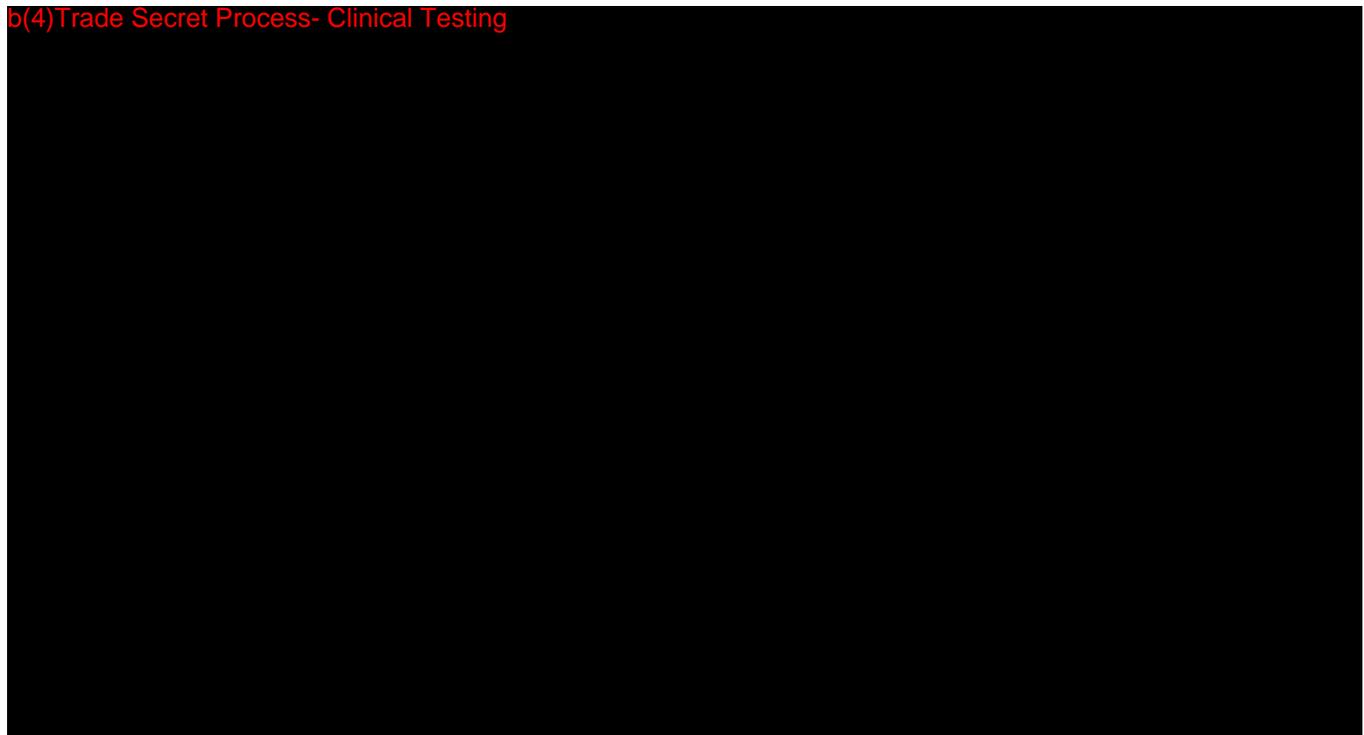
The HTTS is a disposable surgical tool designed to deliver a ventilation tube (VT) across the tympanic membrane of patients during a VT placement procedure.

Preceptis Medical, Inc. has developed the HTTS tool to potentially reduce trauma, pain, and risk to the patient while reducing the overall surgical procedure time. The HTTS device integrates the multiple surgical instruments necessary for the current surgical procedure into a single device. The HTTS device allows the otolaryngologist to create an incision in the tympanic membrane and insert a VT in one pass. The tube used with the HTTS device is a standard, commercially available beveled-flange, grommet style VT manufactured by Summit Medical, Inc. (St. Paul, MN).

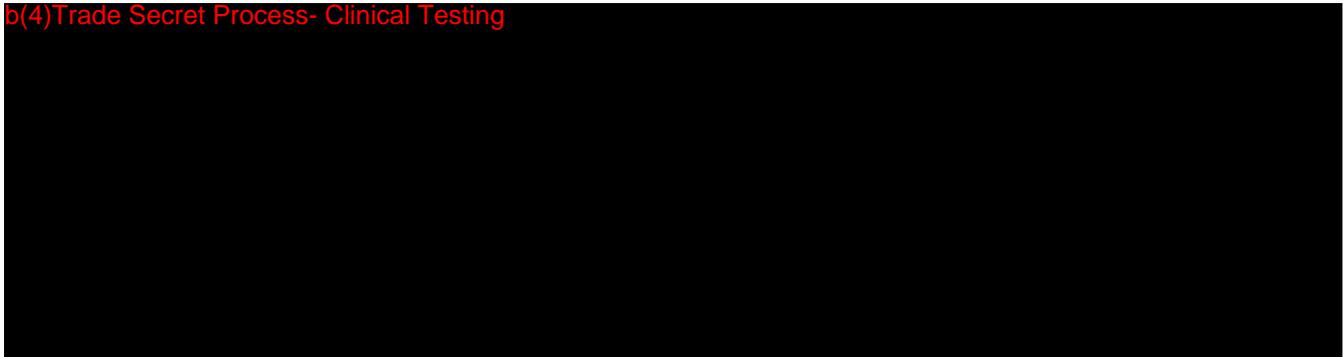
1.3 Indications for Use and Intended Use

The HTTS is indicated for patients undergoing a tympanostomy procedure. The HTTS is intended to create a myringotomy incision and deliver a VT through the tympanic membrane of a patient.

b(4)Trade Secret Process- Clinical Testing



b(4)Trade Secret Process- Clinical Testing



5.0 STUDY ENDPOINTS

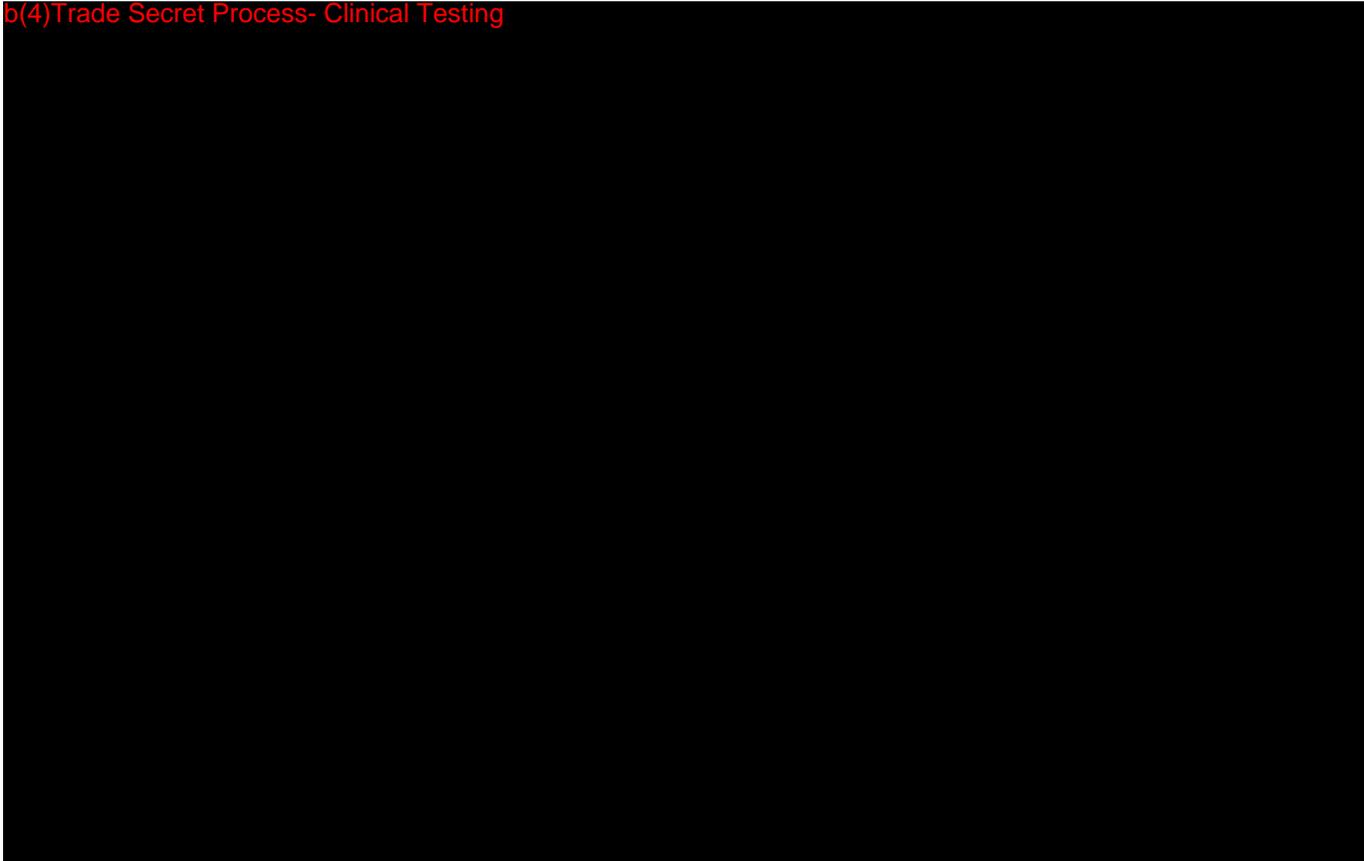
5.1 Safety Endpoint

Evaluation of safety was based on the rate of all adverse events (AE) and the rates for each type of AE.

5.2 Efficacy Endpoint

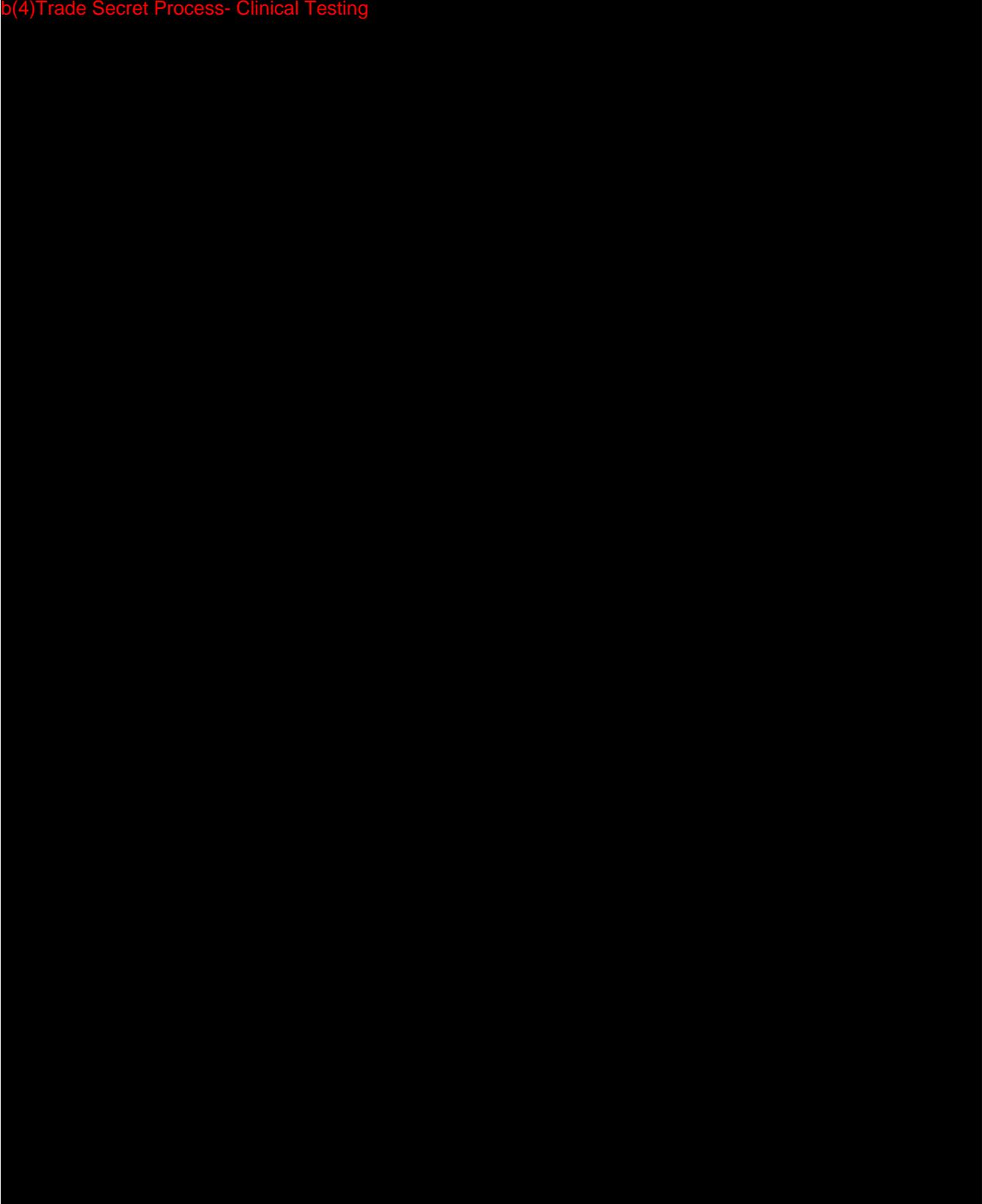
Efficacy evaluation was based on determining whether the HTTS device delivered the VT across the tympanic membrane and whether the tube was still in place and patent at the follow-up visit.

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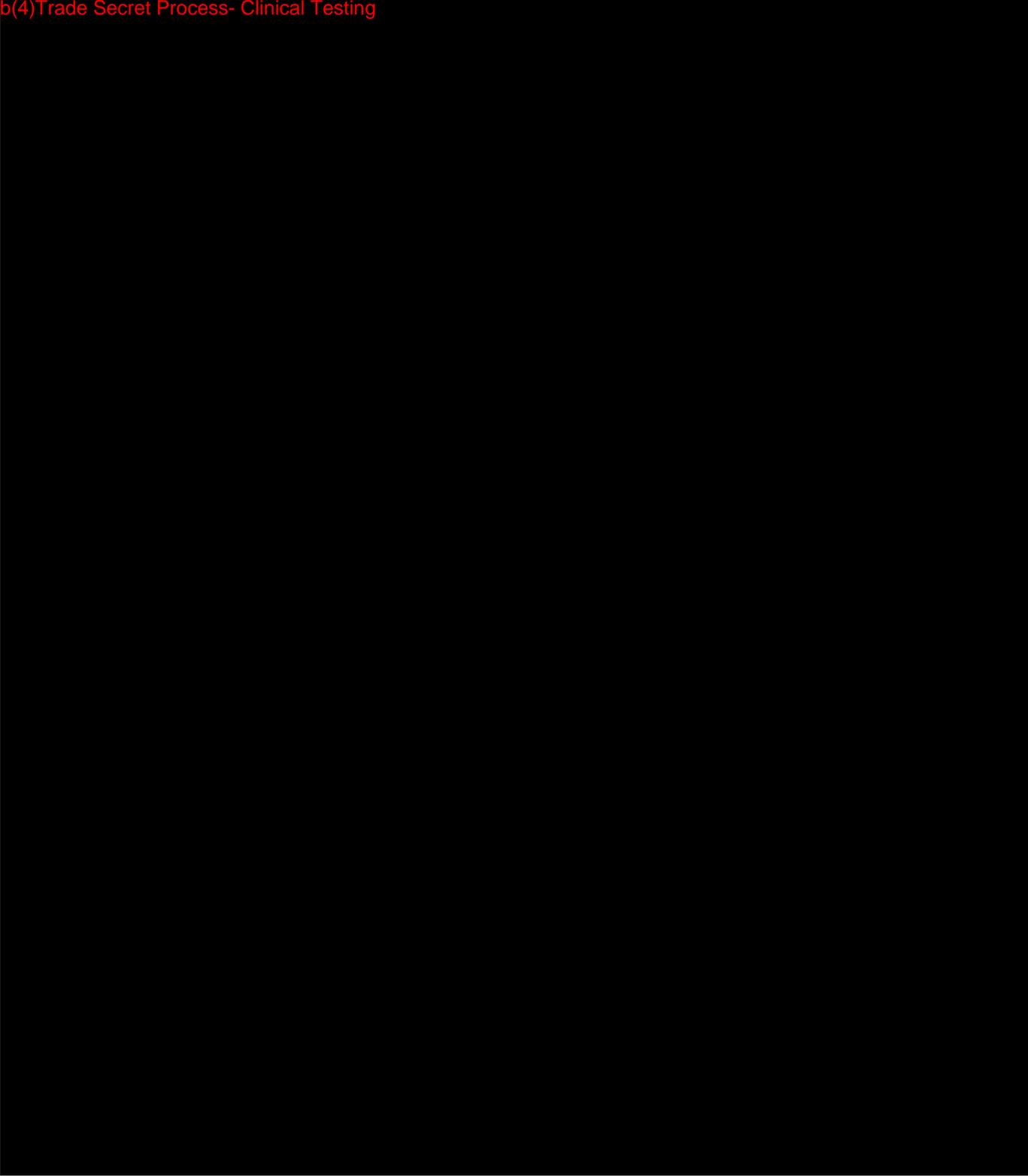
Appendix H1 Clinical Report – Hummingbird™ TTS

b(4)Trade Secret Process- Clinical Testing



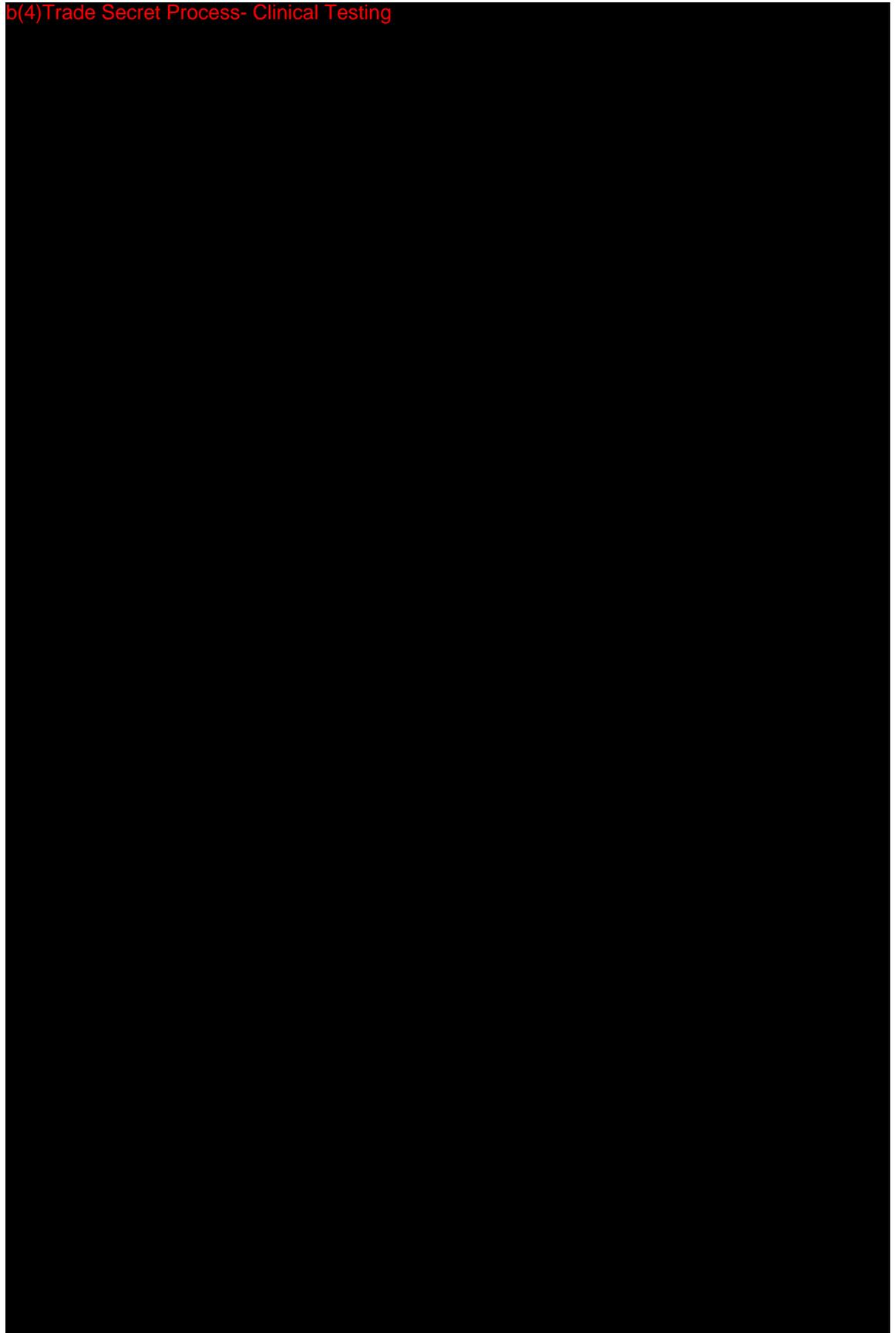
Appendix H1 Clinical Report – Hummingbird™ TTS

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Appendix H1 Clinical Report – Hummingbird™ TTS

b(4)Trade Secret Process- Clinical Testing



b(4)Trade Secret Process- Clinical Testing

12.0 RESULTS

12.1 Patients

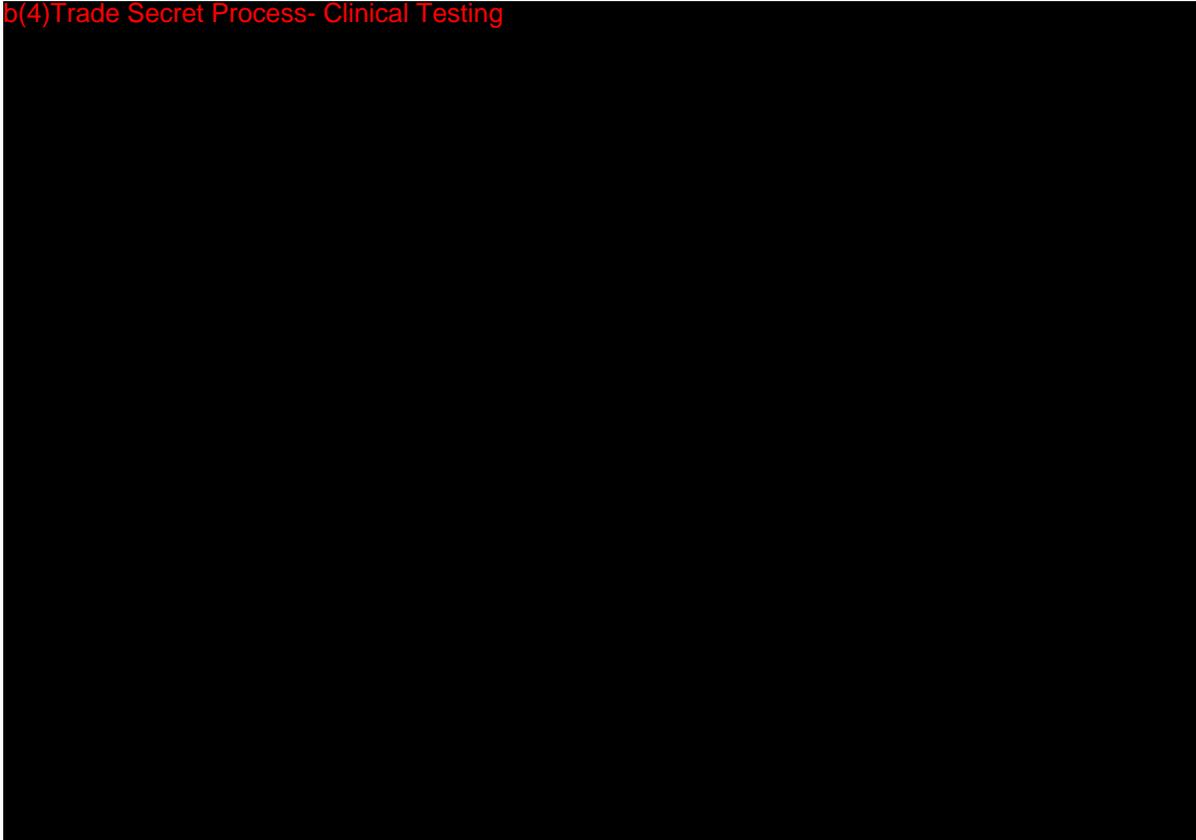
Sixty-nine (69) children from the Beta and Alpha studies who underwent routine myringotomy tympanostomy with the HTTS under moderate sedation between 27 December 2012 and 23 July 2014 are included in this report. Of the 69 patients, 40 patients were from Beta and 29 patients were from Alpha. A total of 136 ears were treated, 78 ears in Beta and 58 ears in Alpha. Patient baseline characteristics from Beta and Alpha were the same based on baseline information collected, with both studies having a patient mean age of 2.4 years.

Table 1 presents data on the age of the patients.

Table 1: Patient Age

Age (N=69)	Years
Mean	2.4
Median	1.7
Range	0.7 –8.9

b(4)Trade Secret Process- Clinical Testing

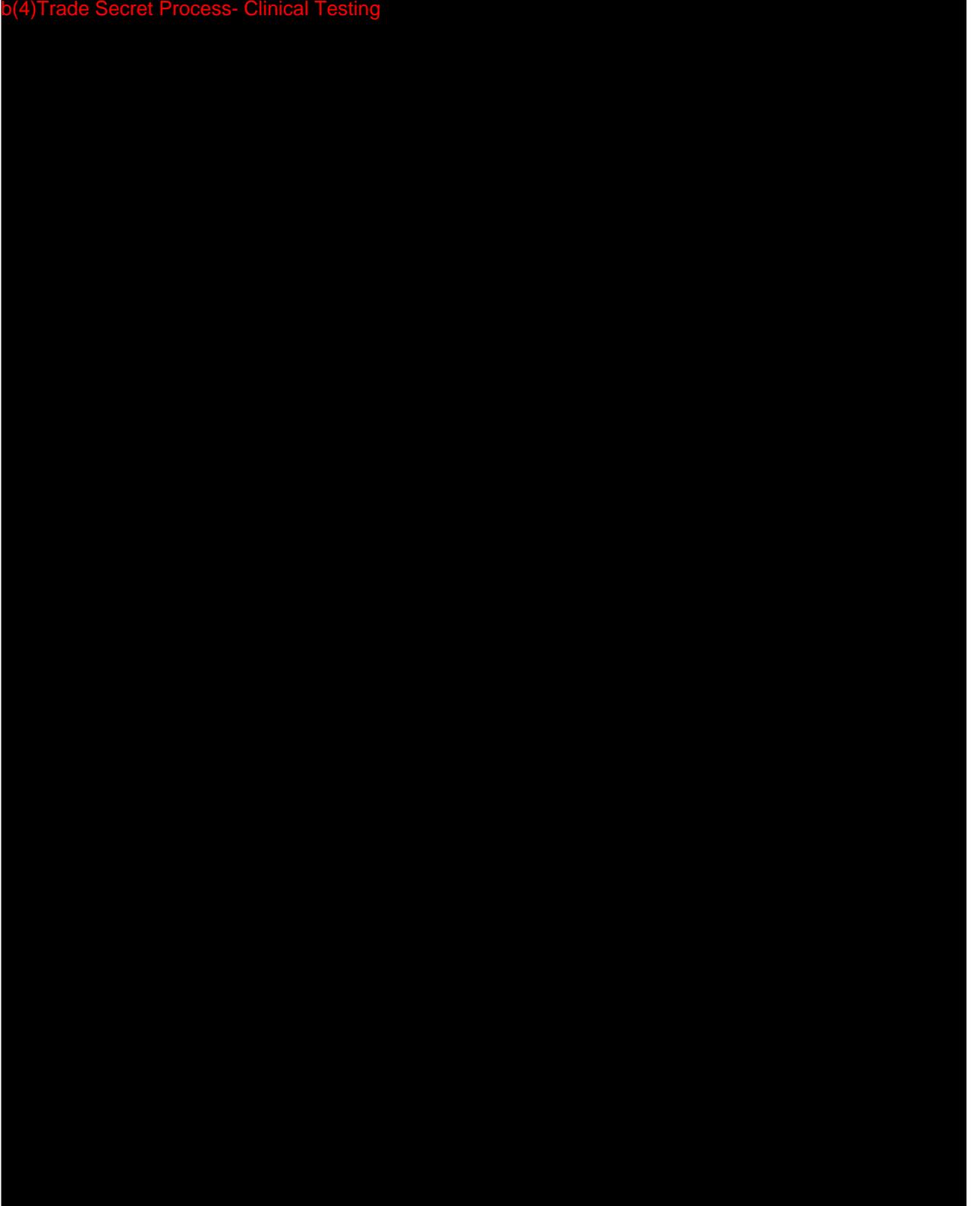


12.3 Outcomes

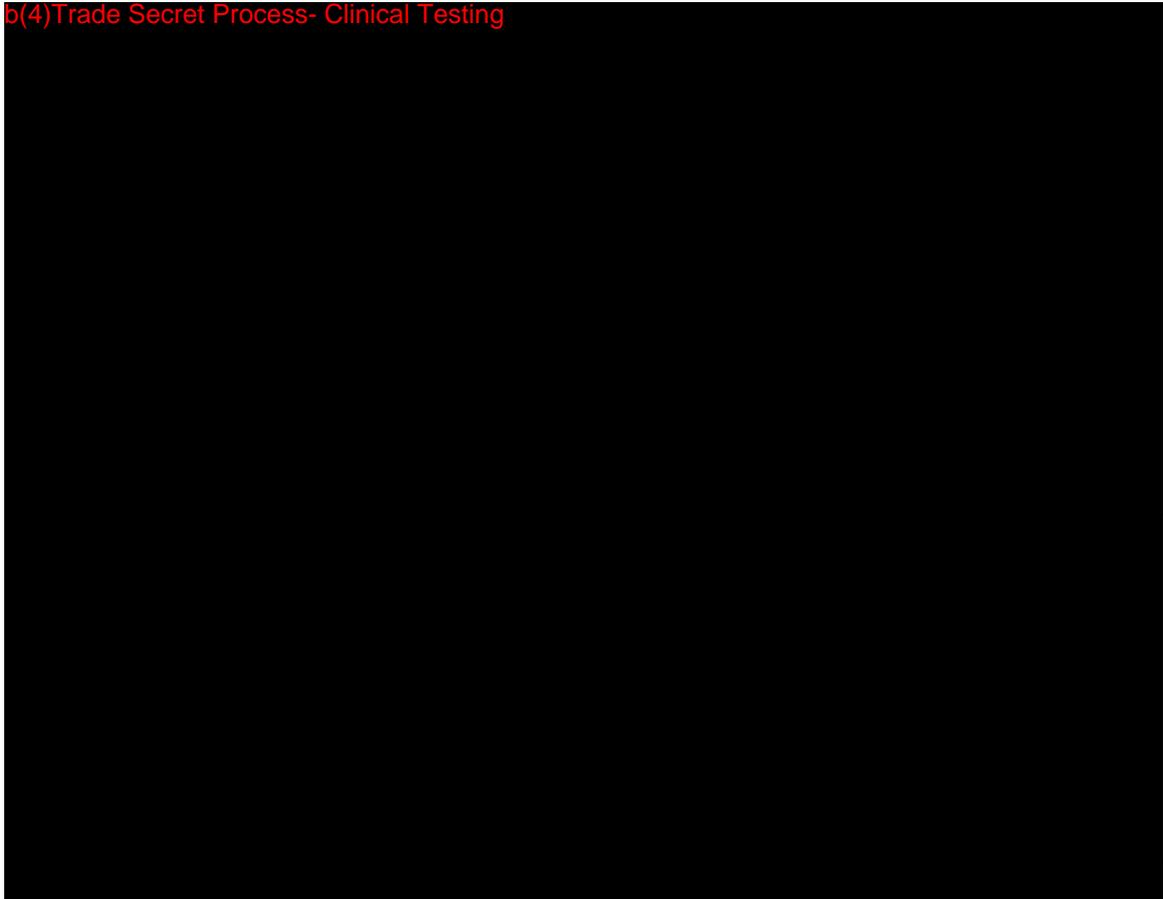
All 69 patients had successful procedures and received tubes as planned. Sixty-seven (67) had bilateral procedures, and two (2) patients had a unilateral procedure for a total of 136 ears treated. Fourteen patients (20% -- 12 Beta patients and 2 Alpha patients) were converted from moderate sedation to general anesthesia during the procedure. Conversion was accomplished by simply turning on the flow of sevoflurane to the mask already in place over a child's nose and mouth. Tables 3A and 3B provide the reasons for conversion.

Appendix H1 Clinical Report – Hummingbird™ TTS

(b)(4) Trade Secret Process- Clinical Testing



b(4)Trade Secret Process- Clinical Testing

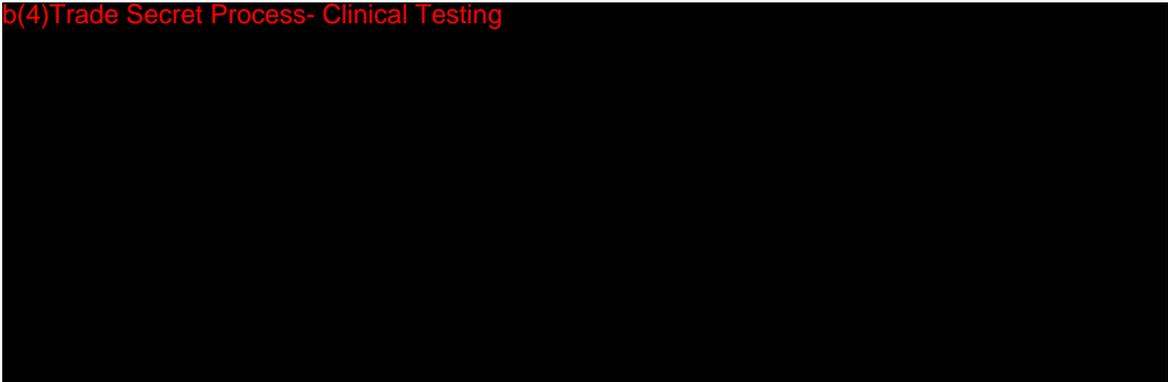


12.5 Adverse Events

Safety issues with using the HTTS to deliver tympanostomy tubes under moderate sedation would be identified intra-operatively. There were no intra-operative AE's.

The anticipated AE's for the study also included outcomes that are considered normal and expected within the standard of care for tympanostomy procedures, including otorrhea, chronic tube extrusion, and tube clogging. Preceptis and its investigators included these outcomes as AE's to be conservative when reporting results.

b(4)Trade Secret Process- Clinical Testing



Appendix H1 Clinical Report – Hummingbird™ TTS

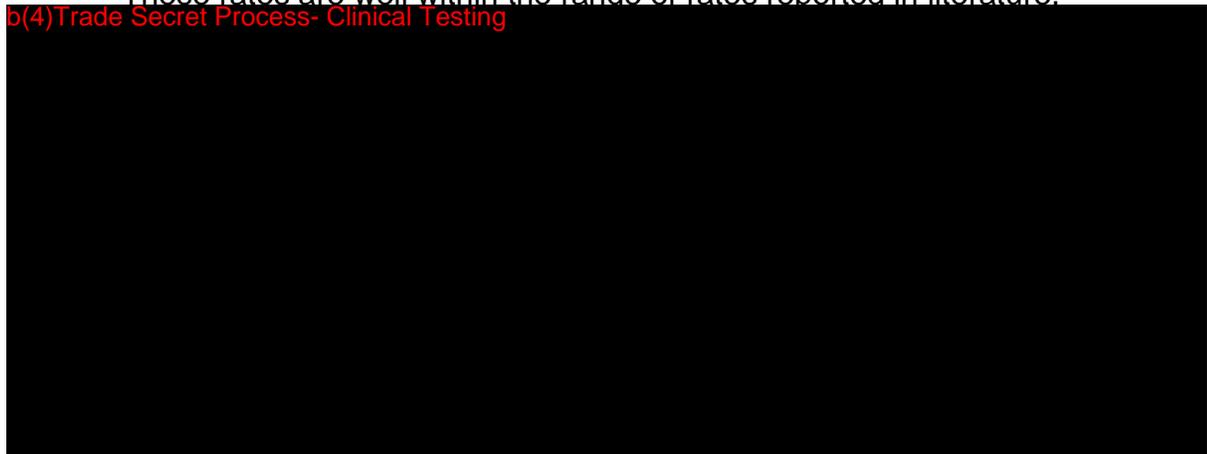
b(4)Trade Secret Process- Clinical Testing



12.5.3 Total AE Rates at 3-10 Weeks Follow-up

The rate of otorrhea was 4/136 ears (2.9%). The rate of occlusion was also 4/136 ears (2.9%). The rate of extrusion was 1/136 ears (0.7%). These rates are well within the range of rates reported in literature.

b(4)Trade Secret Process- Clinical Testing



12.5.5 Conclusion

There were no intra-operative AEs. All AEs were anticipated, and none were serious or device-related. Therefore, these results unequivocally demonstrate that the safety profile of the HTTS when used under moderate sedation in children is safe and acceptable.

13.0 SUMMARY

The Preceptis HTTS is a disposable tool designed to create a myringotomy incision and place a VT across the tympanic membrane in one surgical pass, thereby reducing surgical trauma for the patient. Preceptis Medical, Inc. conducted prospective, treatment-only multicenter clinical studies to evaluate the performance and the safety of the HTTS. A total of 136 ears indicated for VT insertion were treated in 69 patients under moderate sedation by 3 investigators at 3 study sites.

The success rate in performing the tympanostomy procedures was 100% (i.e., all patients received tubes as planned). There were no intra-operative AEs. The rate of AEs at the first follow-up visit was within normal rates. Additionally, an independent otolaryngologist reviewed all Beta results and determined that there were no safety issues associated with the HTTS. The

Appendix H1 Clinical Report – Hummingbird™ TTS

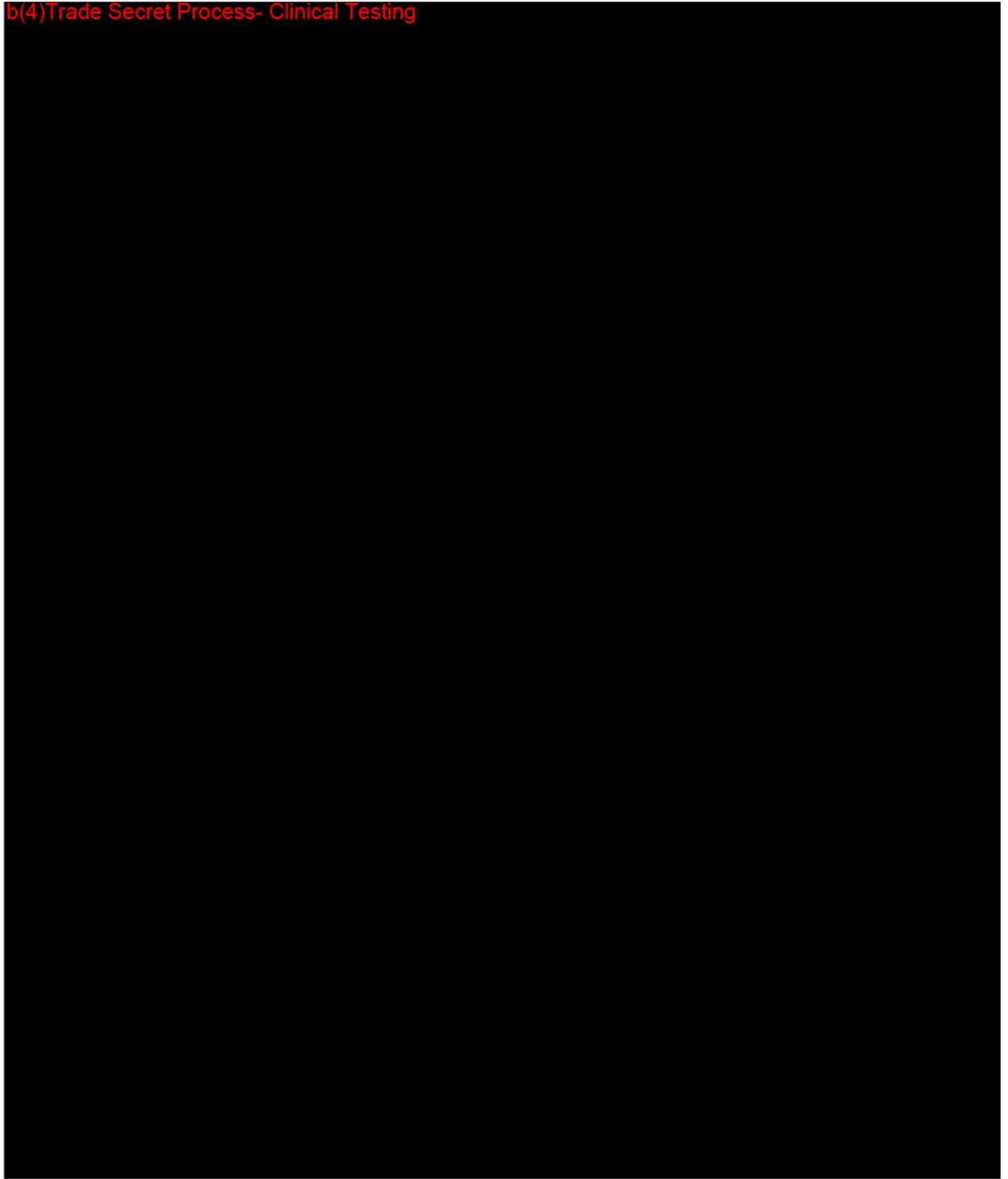
HTTS met the study safety and performance criteria. As a result, the HTTS provides a potential option for otolaryngologists and anesthesiologists to safely perform tympanostomy procedures in children without incurring the risk of general anesthesia.

Appendix H1 Clinical Report – Hummingbird™ TTS

ATTACHMENT A CONSENT DOCUMENTS

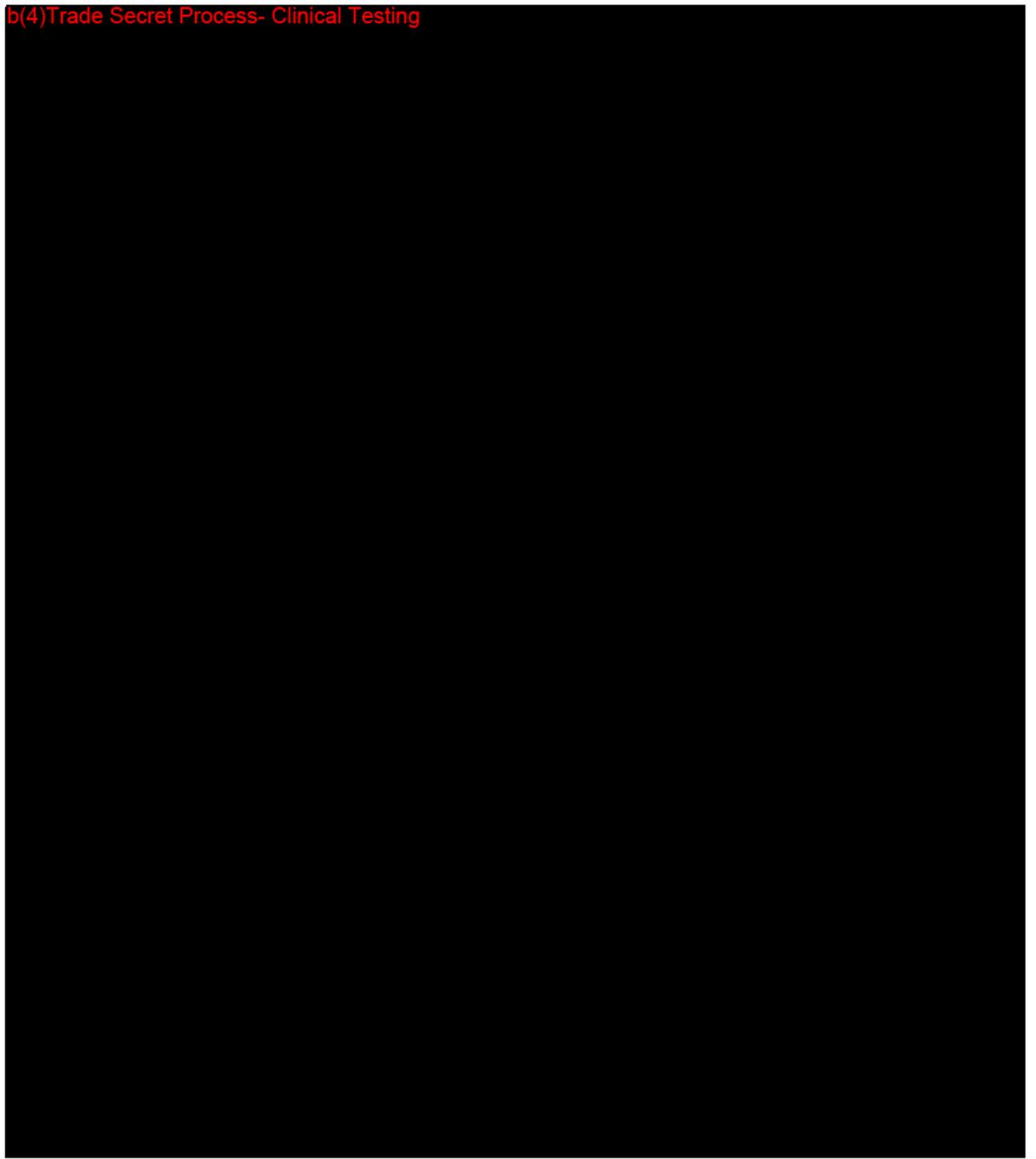
Appendix H1 Clinical Report – Hummingbird™ TTS

b(4)Trade Secret Process- Clinical Testing



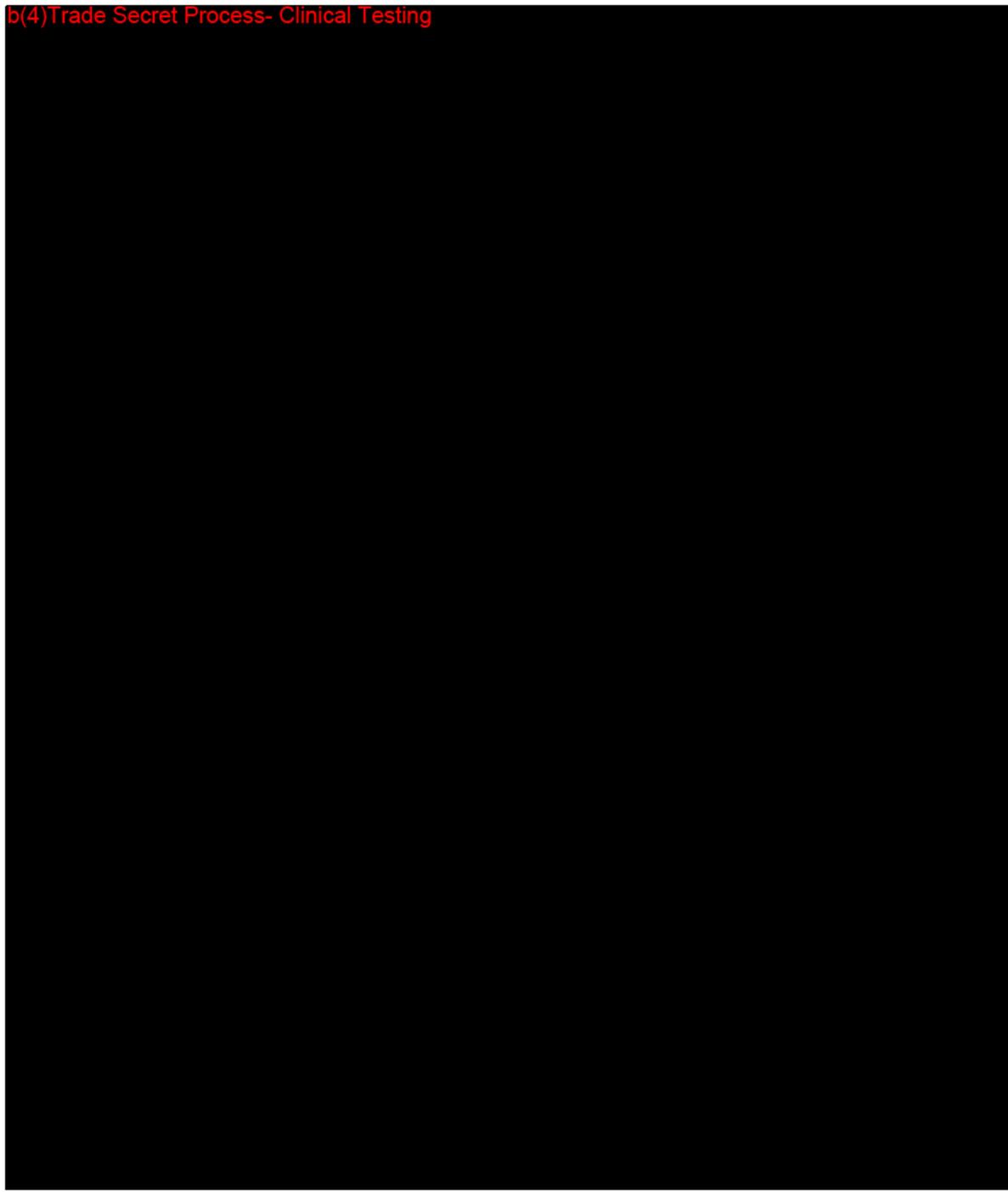
Appendix H1 Clinical Report – Hummingbird™ TTS

b(4)Trade Secret Process- Clinical Testing



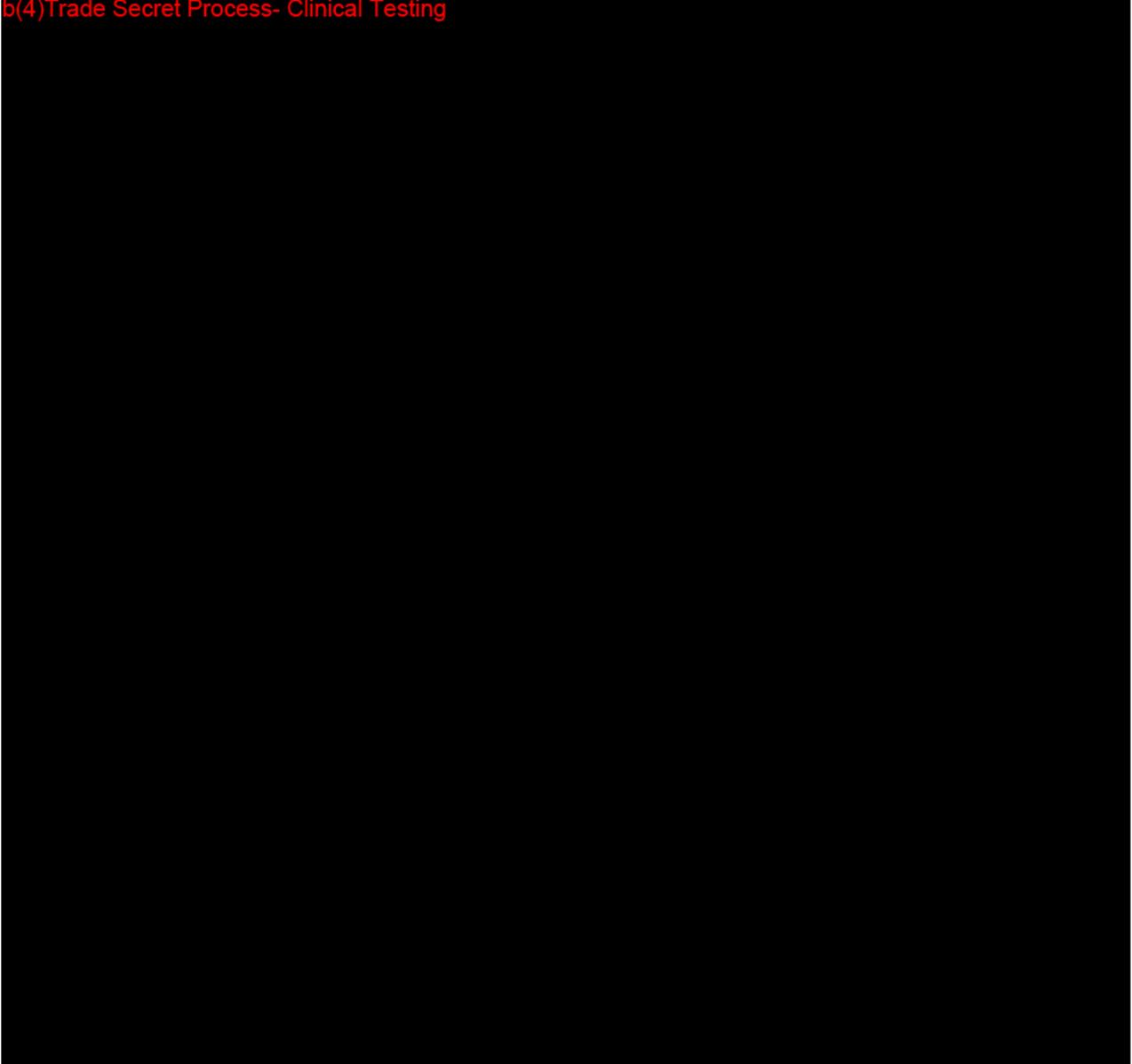
Appendix H1 Clinical Report – Hummingbird™ TTS

b(4)Trade Secret Process- Clinical Testing



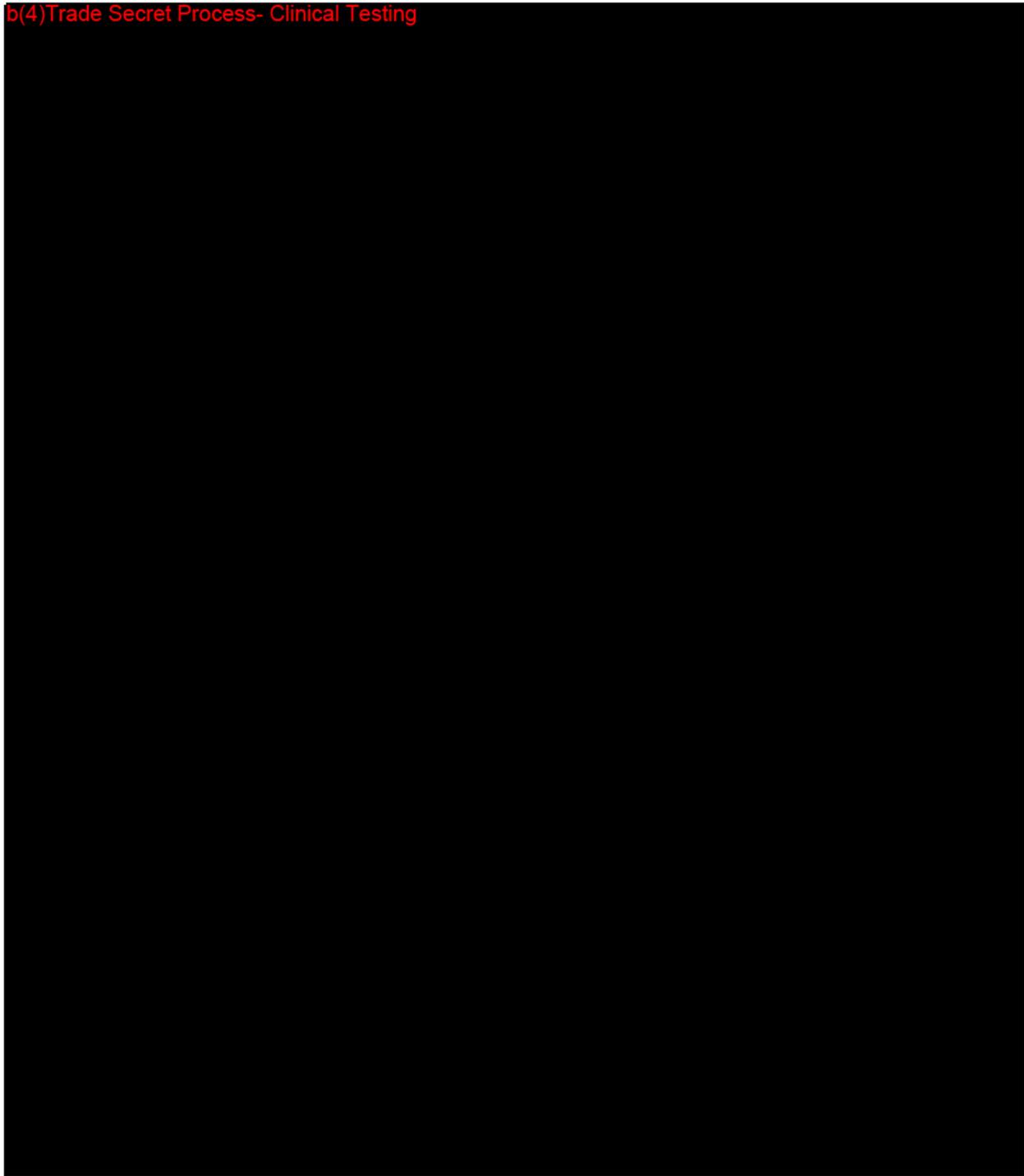
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b(4)Trade Secret Process- Clinical Testing



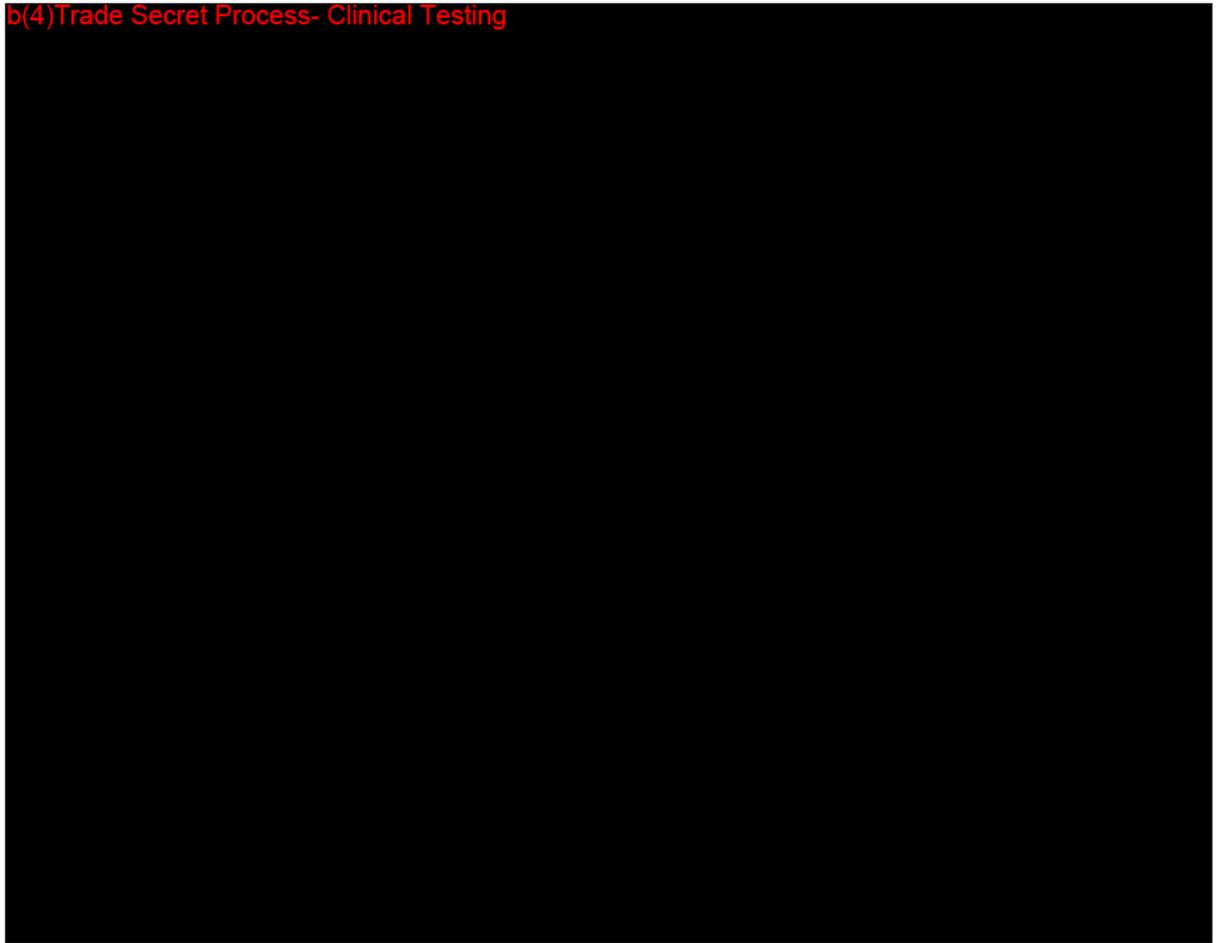
Appendix H1 Clinical Report – Hummingbird™ TTS

b(4)Trade Secret Process- Clinical Testing



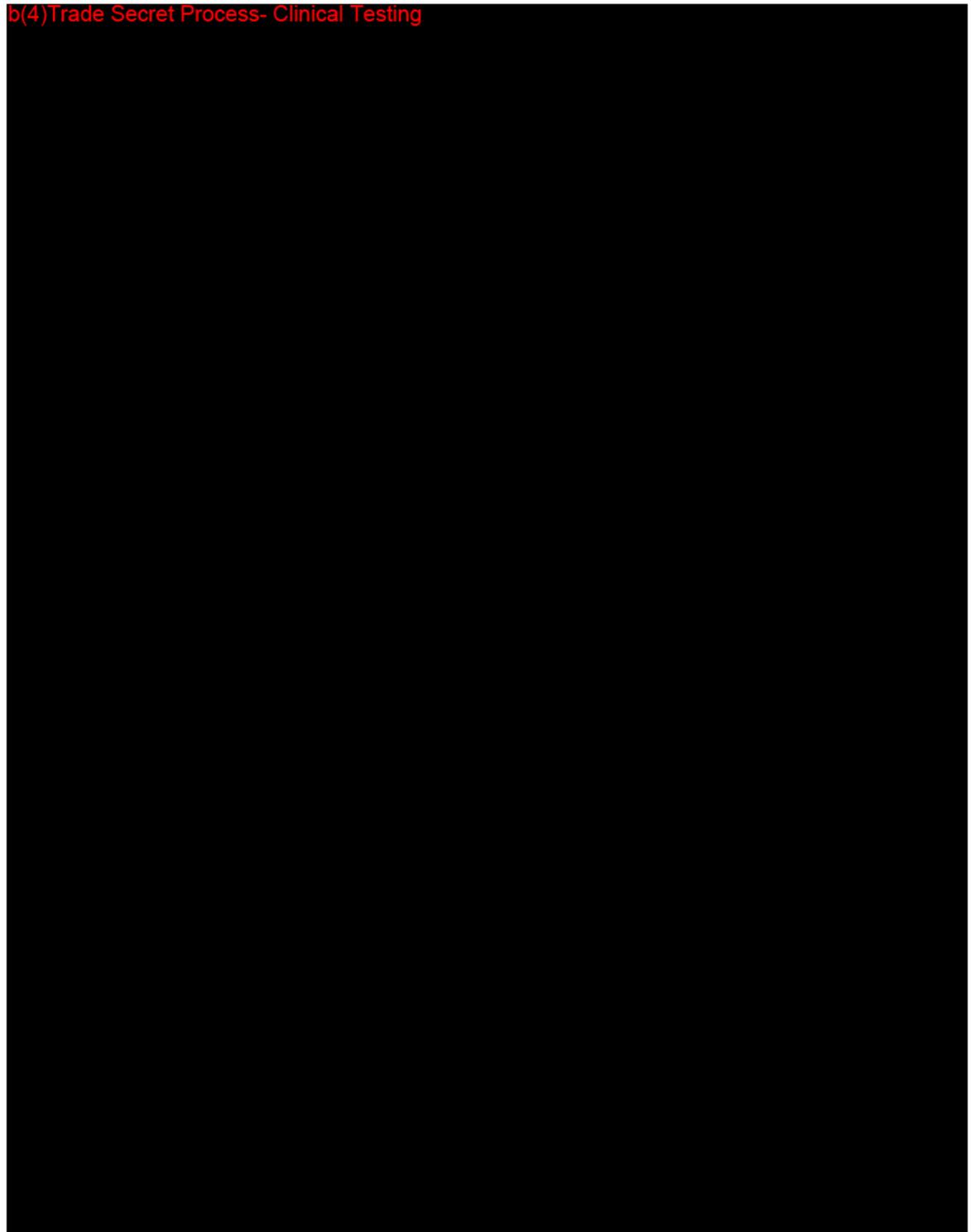
Appendix H1 Clinical Report – Hummingbird™ TTS

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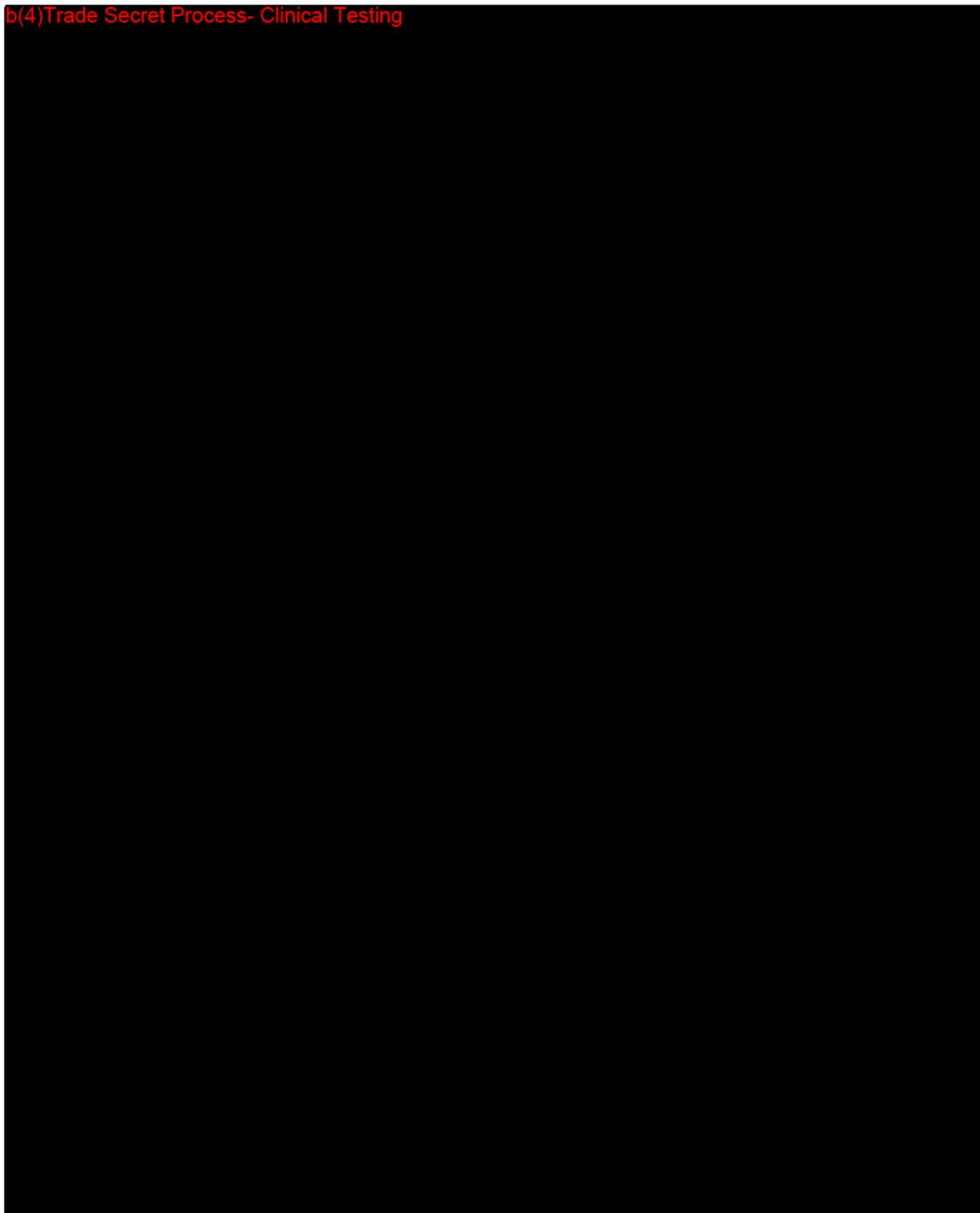
Appendix H1 Clinical Report – Hummingbird™ TTS

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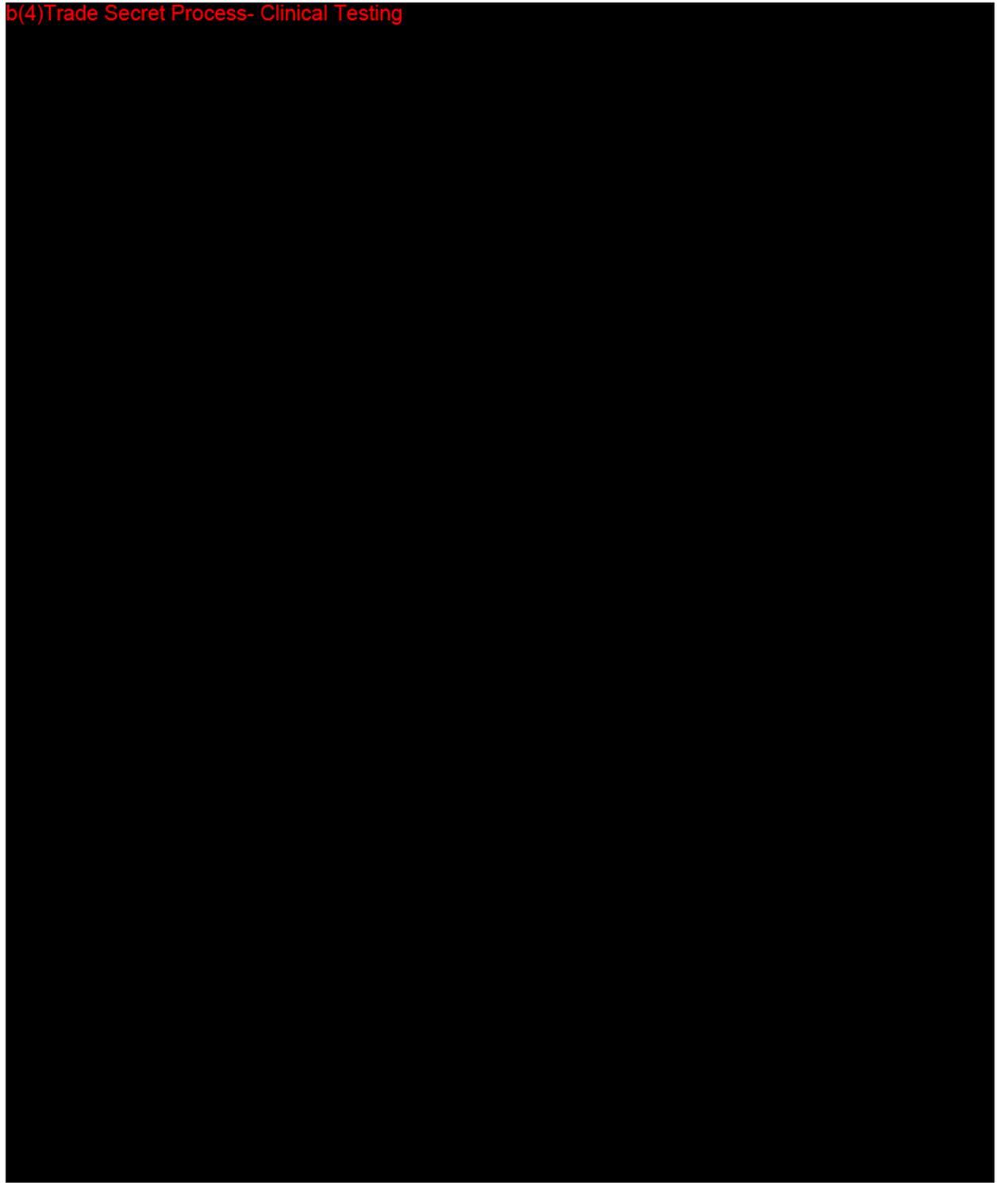
Appendix H1 Clinical Report – Hummingbird™ TTS

(b)(4)Trade Secret Process- Clinical Testing



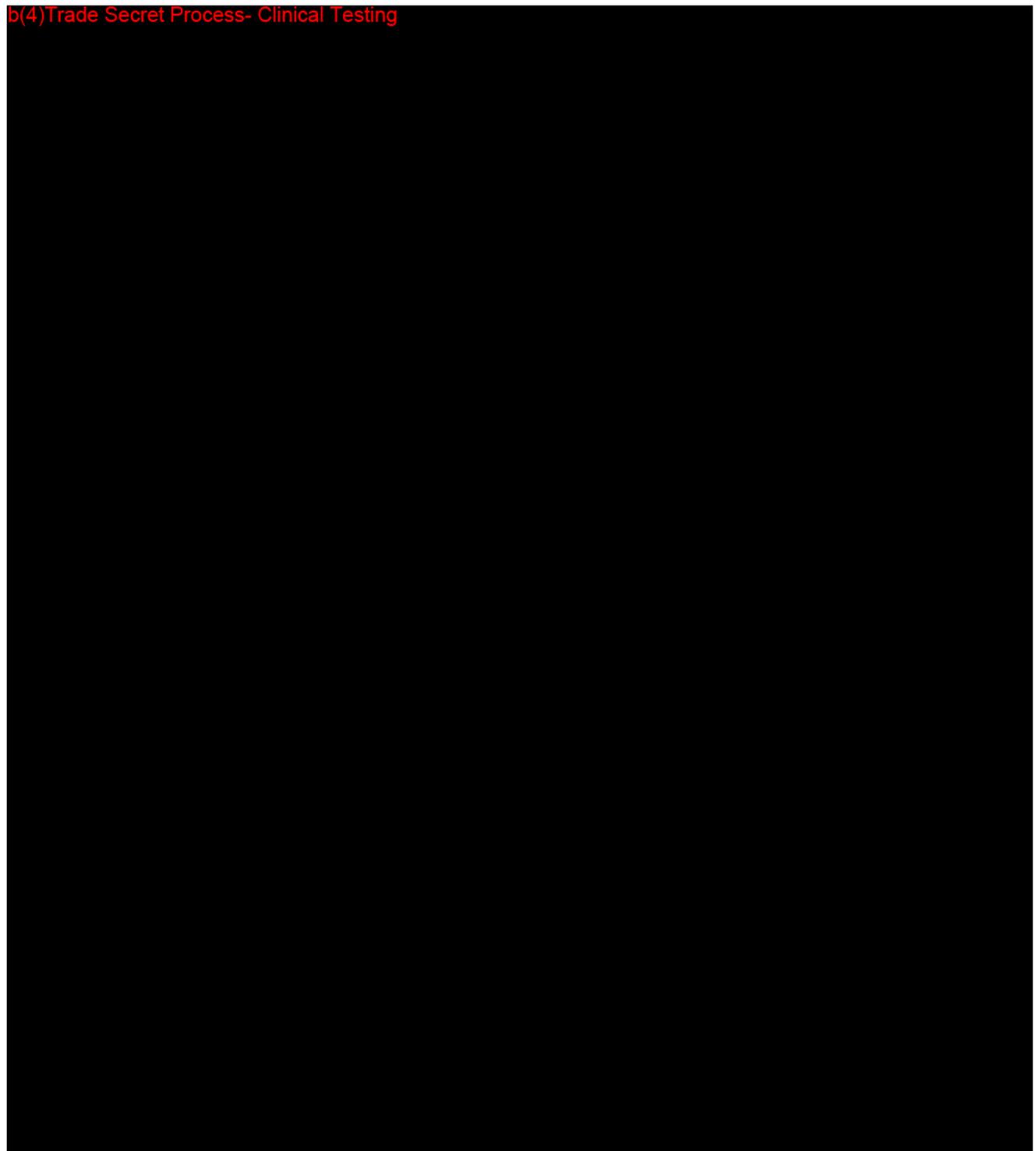
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b(4)Trade Secret Process- Clinical Testing



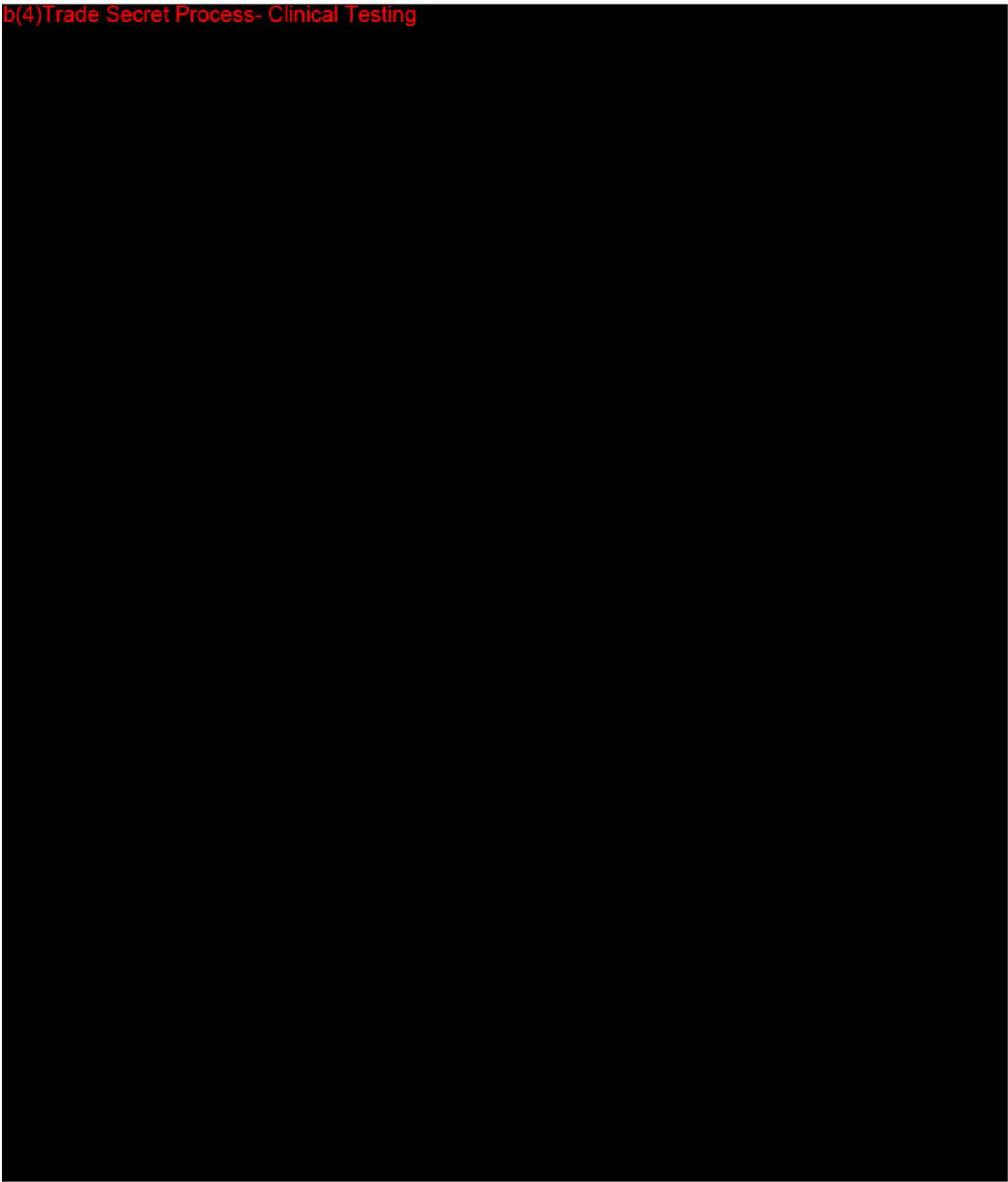
Appendix H1 Clinical Report – Hummingbird™ TTS

b(4)Trade Secret Process- Clinical Testing



Appendix H1 Clinical Report – Hummingbird™ TTS

b(4)Trade Secret Process- Clinical Testing



Appendix H1 Clinical Report – Hummingbird™ TTS

ATTACHMENT B REPORTABLE ANTICIPATED ADVERSE EVENTS

Appendix H1 Clinical Report – Hummingbird™ TTS

REPORTABLE ANTICIPATED ADVERSE EVENTS

Anticipated AE	Definition
Otorrhea	Fluid discharge from the middle ear.
Acute tube extrusion	During the surgical procedure, a myringotomy incision is completed but the TT will not stay in the tympanic membrane.
Chronic tube extrusion	At the follow-up visit, the tube is no longer in place in the tympanic membrane.
Tube dislocating into middle ear space	Tube passes completely through the tympanic membrane and falls into the middle ear cavity.
Tube clogging	Tube becomes clogged and fails to provide ventilation and drainage.
Bleeding	Bleeding in the ear canal, tympanic membrane, or the middle ear.
Vertigo	The patient experiences dizziness beyond 72 hours post-surgically.
Nausea	The patient experiences nausea and/or vomiting beyond 72 hours post-surgically.
Infection	Patient has fever ≥ 101 F beyond 24 hours post-surgically.
Hearing loss	Hearing loss ≥ 15 dB compared to baseline result in Pure Tone Average (PTA).
Facial nerve injury	Any weakness in face or altered perception of taste beyond 24 hours post-surgically.

Appendix H2

Form Approved: OMB No. 0910-0616. Expiration Date: 2/28/2015. See PRA Statement on page 2.



DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Certification of Compliance

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

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

SPONSOR / APPLICANT / SUBMITTER INFORMATION

1. Name of Sponsor/Applicant/Submitter Preceptis Medical, Inc.		2. Date of the Application/Submission Which This Certification Accompanies 14 August 2014	
3. Address Address 1 (Street address, P.O. box, company name c/o) 505 Highway 169 North Address 2 (Apartment, suite, unit, building, floor, etc.) Suite 365 City Plymouth State/Province/Region MN Country USA ZIP or Postal Code 55441		4. Telephone and Fax Numbers (Include country code if applicable and area code) (Tel): 763-568-7819 (Fax): 763-568-7820	

PRODUCT INFORMATION

5. **For Drugs/Biologics:** Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s).
For Devices: Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s)

Common Name: Tympanostomy Tube and Insertion Accessory

Classification: ETD

Trade Name: Hummingbird(TM) Tympanostomy Tube System

Continuation Page for #5

APPLICATION / SUBMISSION INFORMATION

6. Type of Application/Submission Which This Certification Accompanies

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

7. Include IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/ Other Number (If number previously assigned)

If BLA was selected in item 6, provide Supplement Number

8. Serial Number Assigned to Application/Submission Which This Certification Accompanies

CERTIFICATION STATEMENT / INFORMATION

9. Check only one of the following boxes (See instructions for additional information and explanation)

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

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

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

Certification Statement / Information section continued on page 2

Appendix H2

CERTIFICATION STATEMENT / INFORMATION (Continued)

10. If you checked box C, in number 9, provide the National Clinical Trial (NCT) Number(s) for any "applicable clinical trial(s)," under 42 U.S.C. § 282(j)(1)(a)(i), section 402(j)(1)(a)(i) of the Public Health Service Act, referenced in the application/ submission which this Certification accompanies. (Add continuation page as necessary.)

NCT Number(s): NCT02165384

Continuation Page for #10

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

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

11. Name and Title of the Person who Signs Number 15

<p>Name Steve Anderson</p>	<p>Title President and CEO</p>	
<p>12. Address</p> <p>Address 1 (Street address, P.O. box, company name c/o) 505 Highway 169 North</p> <p>Address 2 (Apartment, suite, unit, building, floor, etc.) Suite 365</p> <p>City: Plymouth State/Province/Region: MN</p> <p>Country: USA ZIP or Postal Code: 55441</p>		<p>13. Telephone and Fax Numbers (Include country code if applicable and area code)</p> <p>(Tel): 763-568-7809</p> <p>(Fax): 763-568-7820</p>
<p>14. Date of Certification 14 Aug 2019</p>	<p>15. Signature of Sponsor/Applicant/Submitter or an Authorized Representative (Sign)</p> <div style="text-align: right;">  <div style="border: 1px solid black; padding: 2px; display: inline-block; margin-left: 10px;">Sign</div> </div>	

This section applies only to requirements of the Paperwork Reduction Act of 1995.

*****DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.*****

The burden time for this collection of information is estimated to average 15 minutes and 45 minutes (depending on the type of application/ submission) per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

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



Preceptis
MEDICAL

K142282/501

FDA CDRH DMC

SEP 08 2014

Received

4 September 2014

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – W066-G609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

**RE: Traditional 510(k) Premarket Notification K142282 – 21 CFR 807.90(e)
Preceptis Medical, Inc.**

To Whom It May Concern:

Please find included an eCopy of the response to support the traditional 510(k)
#K142282 being submitted by Preceptis Medical, Inc.

The eCopy is an exact duplicate of the paper copy.

Sincerely,

Keith Leland

1-CD
70

Section 3
Cover Letter and Acceptance Checklist



14 August 2014

FDA CDRH DMC

SEP 08 2014

Received

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

RE: Traditional 510(k) Premarket Notification - 21 CFR 807.90(e)

Preceptis Medical, Inc.

To Whom It May Concern:

The enclosed Traditional 510(k) Pre-Market Notification requests clearance for the Hummingbird™ Tympanostomy Tube System (TTS). This product is preceded by the following predicate:

- Preceptis Tympanostomy Tube System [cleared under 510(k) #K133921].

The Hummingbird™ Tympanostomy Tube System consists of the identical device cleared under K133921, with the only difference being a modification of the instructions for use to expand the cleared anesthesia indications for pediatric patients to include moderate sedation in addition to general anesthesia. Within this submission, the sponsor will demonstrate that the TTS safely and effectively inserts tympanostomy tubes into pediatric patients under moderate sedation or general anesthesia provided in a hospital or ASC setting by an anesthesia provider.

The abbreviations MTI (Myringotomy Tube Inserter), TTI (Tympanostomy Tube Inserter), TTS (Tympanostomy Tube System), and HTTS (Hummingbird™ Tympanostomy Tube System) used in this submission all refer to the candidate device.

Preceptis Medical, Inc • 505 Hwy 169 North, #365 • Plymouth, MN 55441

Section 3
Cover Letter and Acceptance Checklist

General information for the subject device is provided in the table below.

General Information	
Trade Name	Hummingbird™ Tympanostomy Tube System (TTS)
Common Name	Tympanostomy Tube Inserter with pre-loaded ventilation tube
Predicate 510(k)	Preceptis Tympanostomy Tube System (TTS), K133921
Product Code	ETD
Classification	Ear Nose & Throat
Review Panel	Ear Nose & Throat
Manufacturer	Preceptis Medical, Inc.
Registration #	3010610937

This premarket notification is organized following the recommendations contained in the CDRH guidance titled *Format for Traditional and Abbreviated 510(k)s* (August 12, 2005). As recommended in the FDA guidance, a table summarizing the device design and use is provided on the following page.

Section 3
Cover Letter and Acceptance Checklist

Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?	X	
Is the device intended for single use?	X	
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?		NA
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?		X
Does the submission include clinical information?	X	
Is the device implanted?	X	

Contact Information	
Primary contact person	Alternate contact person
Keith Leland VP of R&D Tel: 763.568.7819; Fax: 763.568.7820 Email: keith@preceptismedical.com	Steve Anderson President and CEO Tel: 763.568.7809; Fax: 763.568.7820 Email: steve@preceptismedical.com

This 510(k) submission, and the information it contains, is considered confidential; Preceptis Medical, Inc. respectfully requests that the FDA give it the maximum protection provided by law per 21 CFR 807.95.

In accordance with Section 510(k) of the Federal Food, Drug and Cosmetic Act and in conformance with 21 CFR 807, one (1) complete original paper submission and one (1) eCopy on CD-ROM, which is a complete and exact copy of the paper submission, are provided. If you require further information, please contact me.

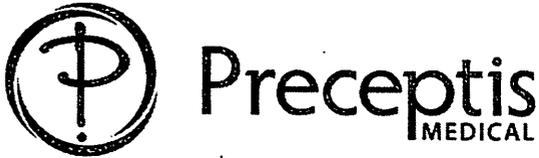
Sincerely,
Keith Leland



VP of R&D
Preceptis Medical, Inc.
505 Highway 169 N, #365
Plymouth, Minnesota 55441

Preceptis Medical, Inc • 505 Hwy 169 North, #365 • Plymouth, MN 55441

Section 3
Cover Letter and Acceptance Checklist



K 142282/5001

14 August 2014

FDA/CDRH/DCC

SEP 05 2014

RECEIVED

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

RE: Traditional 510(k) Premarket Notification - 21 CFR 807.90(e)

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Sincerely,
Keith Leland



VP of R&D
Preceptis Medical, Inc.
505 Highway 169 N, #365
Plymouth, Minnesota 55441

Preceptis Medical, Inc • 505 Hwy 169 North, #365 • Plymouth, MN 55441



Preceptis
MEDICAL

K142282/S001

4 September 2014

Food and Drug Administration
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Silver Spring, Maryland 20993-0002

FDA/CDRH/DCC
SEP 05 2014
RECEIVED

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Keith Leland

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Section 3
Cover Letter and Acceptance Checklist



14 August 2014

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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Section 3
Cover Letter and Acceptance Checklist

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Common Name	Tympanostomy Tube Inserter with pre-loaded ventilation tube
Predicate 510(k)	Preceptis Tympanostomy Tube System (TTS), K133921
Product Code	ETD
Classification	Ear Nose & Throat
Review Panel	Ear Nose & Throat
Manufacturer	Preceptis Medical, Inc.
Registration #	3010610937

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Section 3 Cover Letter and Acceptance Checklist

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Sincerely,
Keith Leland



VP of R&D
Preceptis Medical, Inc.
505 Highway 169 N, #365
Plymouth, Minnesota 55441

Section 4
Indications For Use Statement

Indications for Use

510(k) Number (if known):

Device Name: Hummingbird™ Tympanostomy Tube System

Indications For Use:

The Hummingbird™ Tympanostomy Tube System is intended to deliver a tympanostomy tube in tympanostomy procedures in which the patient is receiving a tympanostomy tube.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Section 5 510k Summary

Submitter Information:	Preceptis Medical, Inc. 505 Highway 169 North, #365 Plymouth, MN 55441 763.568.7819
Contact:	Keith Leland, VP of R&D
Date Prepared:	12 August 2014
Trade Name	Hummingbird™ Tympanostomy Tube System (TTS)
Product Code	ETD (21 CFR Part 874.3880)
Common Name	Tympanostomy Tube Inserter with pre-loaded ventilation tube
Predicate Devices	Preceptis Tympanostomy Tube System, 510(k) K133921
Device Description	<p>The Hummingbird™ Tympanostomy Tube System (TTS) which includes a tympanostomy tube inserter (TTI) with a preloaded ventilation tube, is a single-use, sterile manual surgical instrument which is used to create a myringotomy in the tympanic membrane and place a ventilation tube. The TTS includes a handle with one or more tip assemblies which contain a sterile tympanostomy tube.</p> <p>Each tip assembly can be removably attached to the handle and includes a positioning rod and a ventilation tube pre-loaded inside the distal end of a sharpened sheath. Attaching the tip assembly to the handle also connects the sheath and actuator, allowing the user to retract the sheath by manually scrolling an actuator located on the handle.</p> <p>The user manually advances the sharpened sheath to create a myringotomy and simultaneously positions the ventilation tube within the myringotomy, always under direct visualization. The user then manually retracts the sharpened sheath away from the myringotomy using the manual actuator located on the handle. The retraction of the sheath releases the tube within the myringotomy.</p> <p>A first tip assembly can then be removed from the handle and replaced with a second preloaded tip assembly for bilateral procedures.</p>
Indications For Use	The Hummingbird™ Tympanostomy Tube System is intended to deliver a tympanostomy tube in tympanostomy procedures in which the patient is receiving a tympanostomy tube.

Section 5 510k Summary

<p>Technological Characteristics</p>	<p>The TTS is intended to deliver a tympanostomy tube (also referred to as a ventilation tube) through the tympanic membrane (TM) of the patient. It combines the separate functions of creating a myringotomy, positioning and placing a ventilation tube across the TM, and suctioning.</p> <p>The TTI is a manual surgical instrument. The actions of creating the myringotomy, positioning the ventilation tube, and retracting the sheath surrounding the ventilation tube are all performed manually by the user.</p> <p>A comparison between the TTS and predicate device shows that the devices are identical.</p>
<p>Performance Data</p>	<p>In two non-significant risk studies, a total of 69 children (mean age of 2.4 years, ranging from 8 months to 8.9 years) underwent tympanostomy procedures under moderate sedation using the Preceptis TTS to reduce surgical trauma for the patients. Results:</p> <ul style="list-style-type: none"> • The IRBs at each institution designated the studies as Non-Significant Risk due to the low risk profile of the TTS and the fact that anesthetic regimen is determined and delivered by an anesthesia professional within the hospital. • This approach is presented as an additional option to the current standard of care under general anesthesia.. It is also an extension of current tympanostomy medical practice in which children 12 and above are treated in the office with only topical anesthetic. • 100% of the children received ventilation tubes as planned. • There were <u>no intra-operative adverse events</u>, no unanticipated adverse events, and adverse event rates were well within normal reported rates. • There is no additional risk in converting cases from moderate sedation to general anesthesia since the conversion process simply involves turning off the nitrous oxide and turning on the flow of sevoflurane to the mask already in place over a child’s nose and mouth. <p>Performing tympanostomy procedures in young children under moderate sedation in a hospital setting with anesthesia delivered by an anesthesia professional is safe and a well-reasoned alternative to the use of general anesthesia for caregivers and clinicians who are comfortable with this choice.</p>

Section 10 Executive Summary

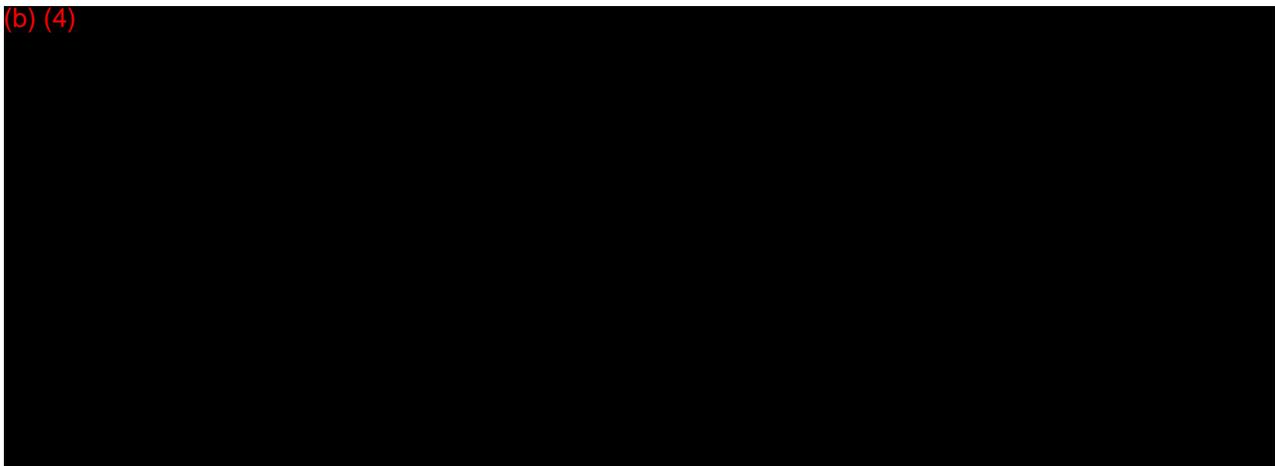
Executive Summary

Overview of Device

The Hummingbird™ Tympanostomy Tube System (TTS) is a manual surgical instrument that places a standard ventilation tube across the tympanic membrane of a patient. It combines the separate functions of creating a myringotomy, positioning and placing the ventilation tube, and suctioning.

The TTS is intended to place a ventilation tube to provide ventilation to the middle ear space through the tympanic membrane.

(b) (4)



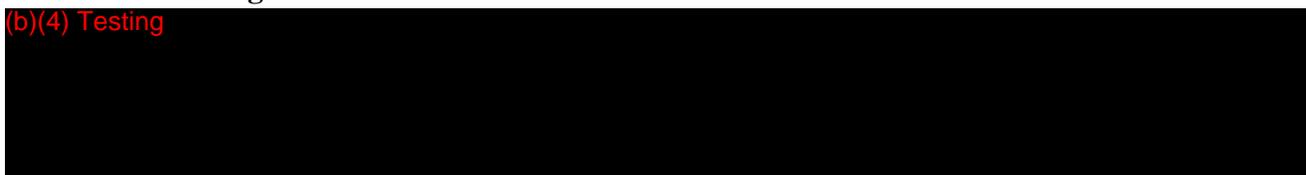
The Hummingbird TTS is preceded by the previous, identical predicate:

1. The Preceptis Tympanostomy Tube System cleared under 510(k) #K133921

(b) (4) [redacted] (b) (4) [redacted]
ventilation tube is now packaged pre-loaded into the TTS for ease of use for the ENT surgeon. Within this submission, the sponsor will demonstrate that the TTI delivers the (b) (4) [redacted] ventilation tube as designed, that the TTS safely and effectively inserts tympanostomy tubes into pediatric patients under moderate sedation or general anesthesia provided in a hospital or ASC setting by an anesthesia provider, (b) (4) [redacted]
(b) (4) [redacted]
(b) (4) [redacted]

Bench Testing

(b)(4) Testing



Section 10

Executive Summary

(b)(4) Testing

Clinical Testing

In two non-significant risk studies, a total of 69 children (mean age of 2.4 years, ranging from 8 months to 8.9 years) underwent tympanostomy procedures under moderate sedation using the Preceptis TTS to reduce surgical trauma for the patients. Results:

- The IRBs at each institution designated the studies as Non-Significant Risk due to the low risk profile of the TTS and the fact that anesthetic regimen is determined and delivered by an anesthesia professional within the hospital.
- This approach is presented as an additional option to the current standard of care under general anesthesia.. It is also an extension of current tympanostomy medical practice in which children 12 and above are treated in the office with only topical anesthetic.
- 100% of the children received ventilation tubes as planned.
- There were no intra-operative adverse events, no unanticipated adverse events, and adverse event rates were well within normal reported rates.
- There is no additional risk in converting cases from moderate sedation to general anesthesia since the conversion process simply involves turning off the nitrous oxide and turning on the flow of sevoflurane to the mask already in place over a child's nose and mouth.

Performing tympanostomy procedures in young children under moderate sedation in a hospital setting with anesthesia delivered by an anesthesia professional is safe and a well-reasoned alternative to the use of general anesthesia for caregivers and clinicians who are comfortable with this choice.

Substantial Equivalence Analysis

The key performance, safety and design characteristics of the predicate device are identified and are listed in the substantial equivalence table. The device comparison table shows that the Hummingbird™ Tympanostomy Tube System is identical to the predicate device. The indications for use for the devices are the same. An analysis of the differences between the devices showed that none exist and that the devices are identical.

Section 12 Substantial Equivalence Discussion

Substantial Equivalence

The Hummingbird™ TTS is identical to the Preceptis TTS with preloaded tube cleared under 510(k) K133921.

The device comparison table shows the similarities and differences between the Hummingbird™ Tympanostomy Tube System and the predicate devices. The indications for use, physical characteristics, materials, and safety testing requirements are all the same.

Device Comparison Table

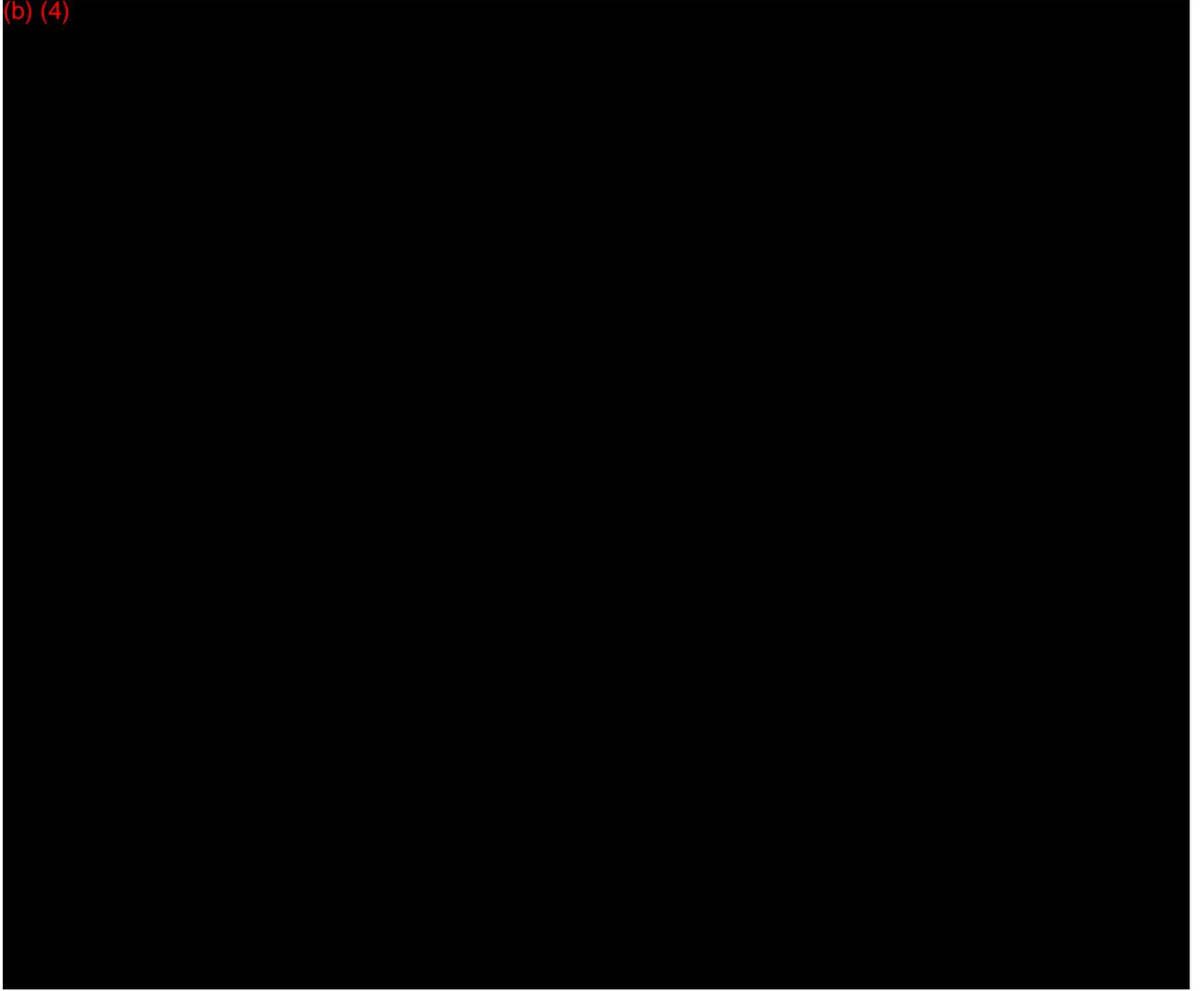
Parameter	Hummingbird™ Tympanostomy Tube System w/ pre-loaded ventilation tube (TTS - PN 05-1001-50X)	Preceptis Tympanostomy Tube System w/ pre-loaded ventilation tube (510k #133921)	Comparison
Indications for Use	The Hummingbird Tympanostomy Tube System (TTS) is intended to deliver a tympanostomy tube in tympanostomy procedures in which the patient is receiving a tympanostomy tube.	The Hummingbird Tympanostomy Tube System (TTS) is intended to deliver a tympanostomy tube in tympanostomy procedures in which the patient is receiving a tympanostomy tube.	Same
Intended use	The TTS is intended to deliver a tympanostomy tube through the tympanic membrane (TM) of the patient. It combines the separate functions of creating a myringotomy, positioning and placing a ventilation tube across the TM, and suctioning.	The TTS is intended to deliver a tympanostomy tube through the tympanic membrane (TM) of the patient. It combines the separate functions of creating a myringotomy, positioning and placing a ventilation tube across the TM, and suctioning.	Same
Design	<u>Manual Surgical Instrument</u> 1. Vent tube provided pre-loaded inside of a cutting sheath (hollow trocar). 2. Incision of the tympanic membrane using the cutting sheath, and insertion of the tube is performed manually by user. 3. Hollow cutting sheath manually retracted from around vent tube after placement by sliding actuation wheel.	<u>Manual Surgical Instrument</u> 1. Vent tube provided pre-loaded inside of a cutting sheath (hollow trocar). 2. Incision of the tympanic membrane using the cutting sheath, and insertion of the tube is performed manually by user. 3. Hollow cutting sheath manually retracted from around vent tube after placement by sliding actuation wheel.	Same
Technological Characteristics	<u>Manual operation</u> 1. Manual myringotomy creation controlled by surgeon. 2. Depth of penetration controlled manually by surgeon. 3. Vent tube positioned manually in myringotomy under direct visualization. 4. Manual retraction of cutting element by surgeon.	<u>Manual operation</u> 1. Manual myringotomy creation controlled by surgeon. 2. Depth of penetration controlled manually by surgeon. 3. Vent tube positioned manually in myringotomy under direct visualization. 4. Manual retraction of cutting element by surgeon.	Same
Dimensions (vent tube)	1 mm lumen diameter	1 mm lumen diameter	Same
Materials	Medical Grade Silicone, Stainless Steel, Plastic	Medical Grade Silicone, Stainless Steel, Plastic	Same
Sterile	Sterile (EO)	Sterile (EO)	Same

Summary of Similarities and Differences.

- The two devices are identical, no differences exist.

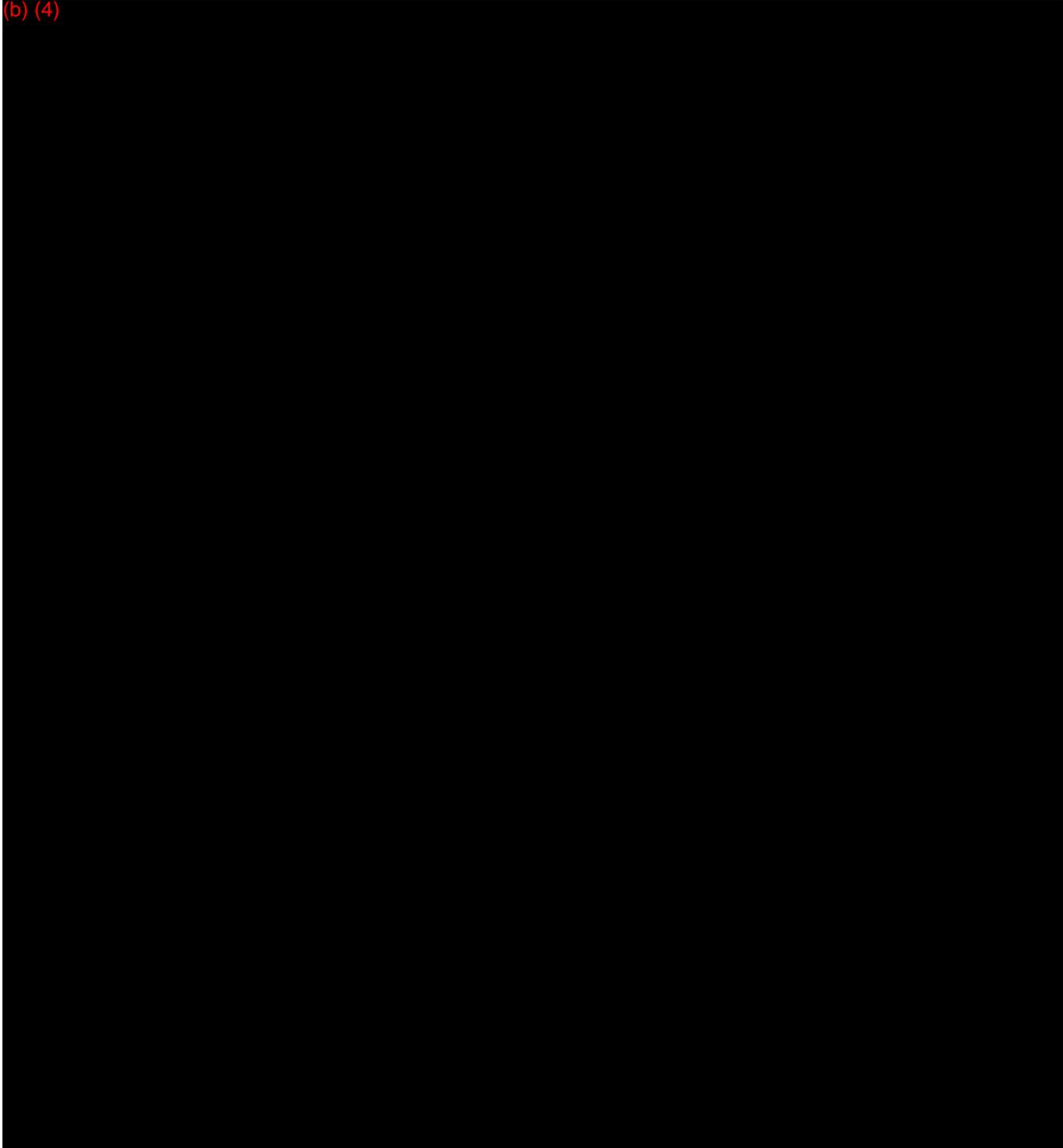
Section 14
Sterilization and Shelf Life

(b) (4)



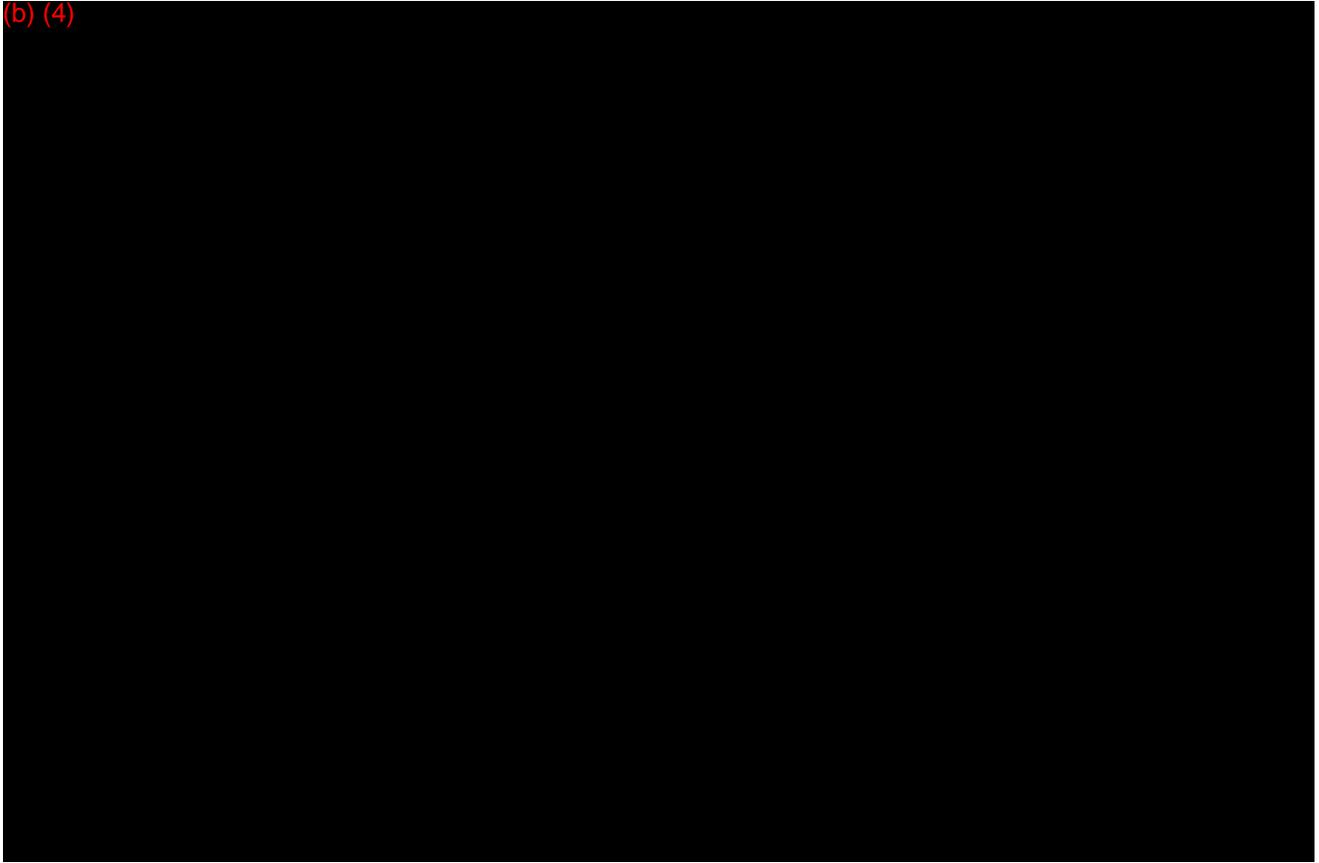
Section 14
Sterilization and Shelf Life

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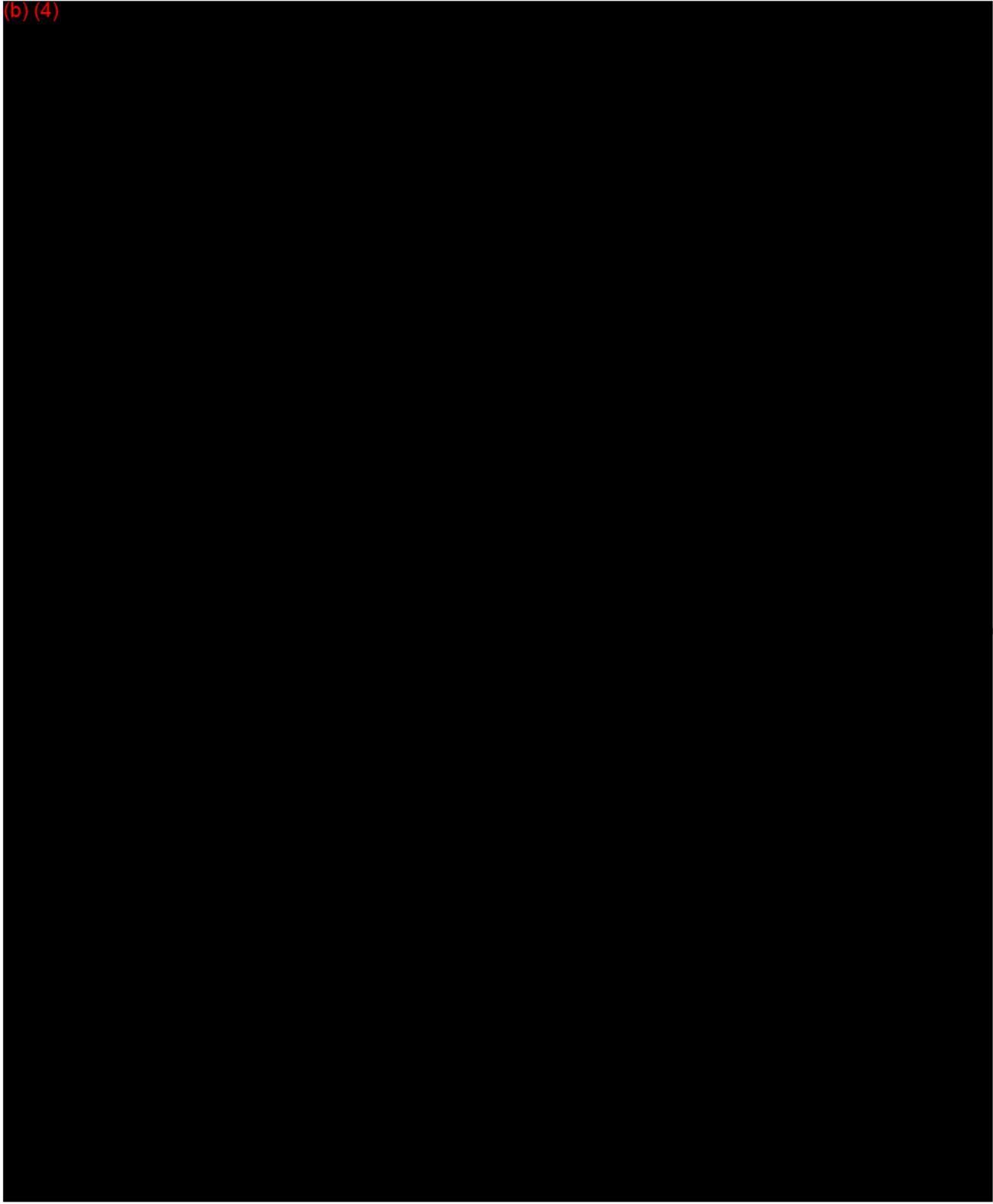
Section 14
Sterilization and Shelf Life

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Section 15
Biocompatibility

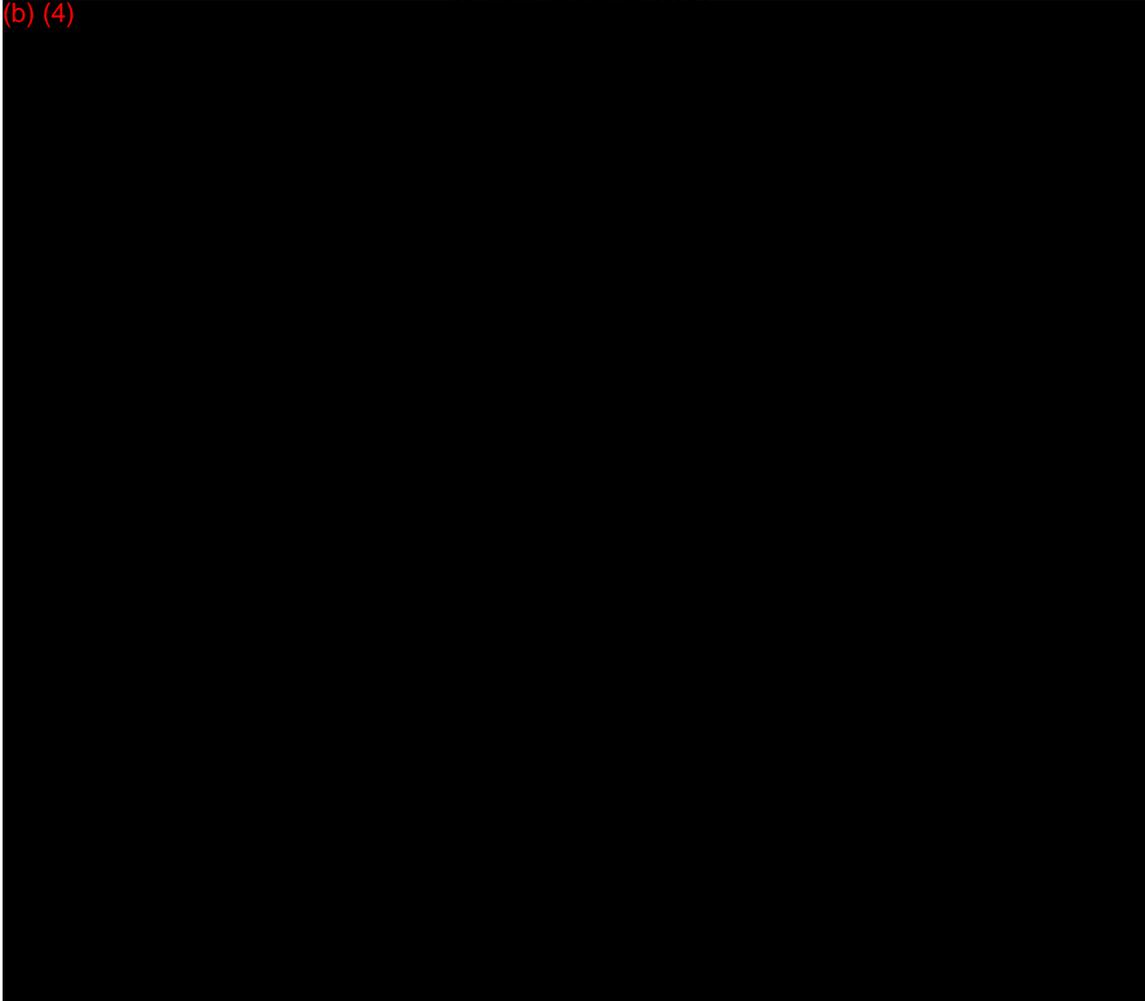
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e

Section 15
Biocompatibility

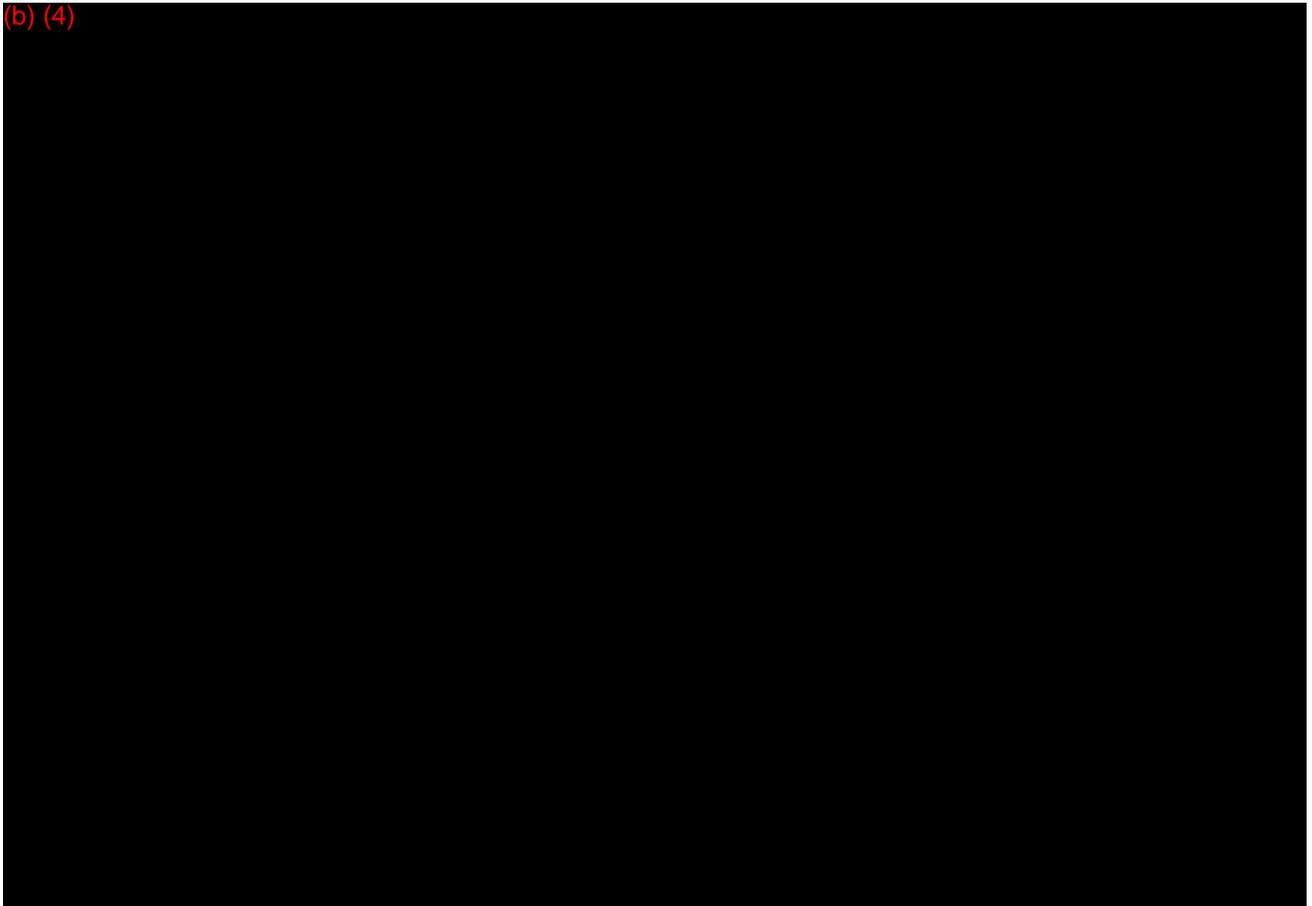
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Section 18

Performance Testing - Bench

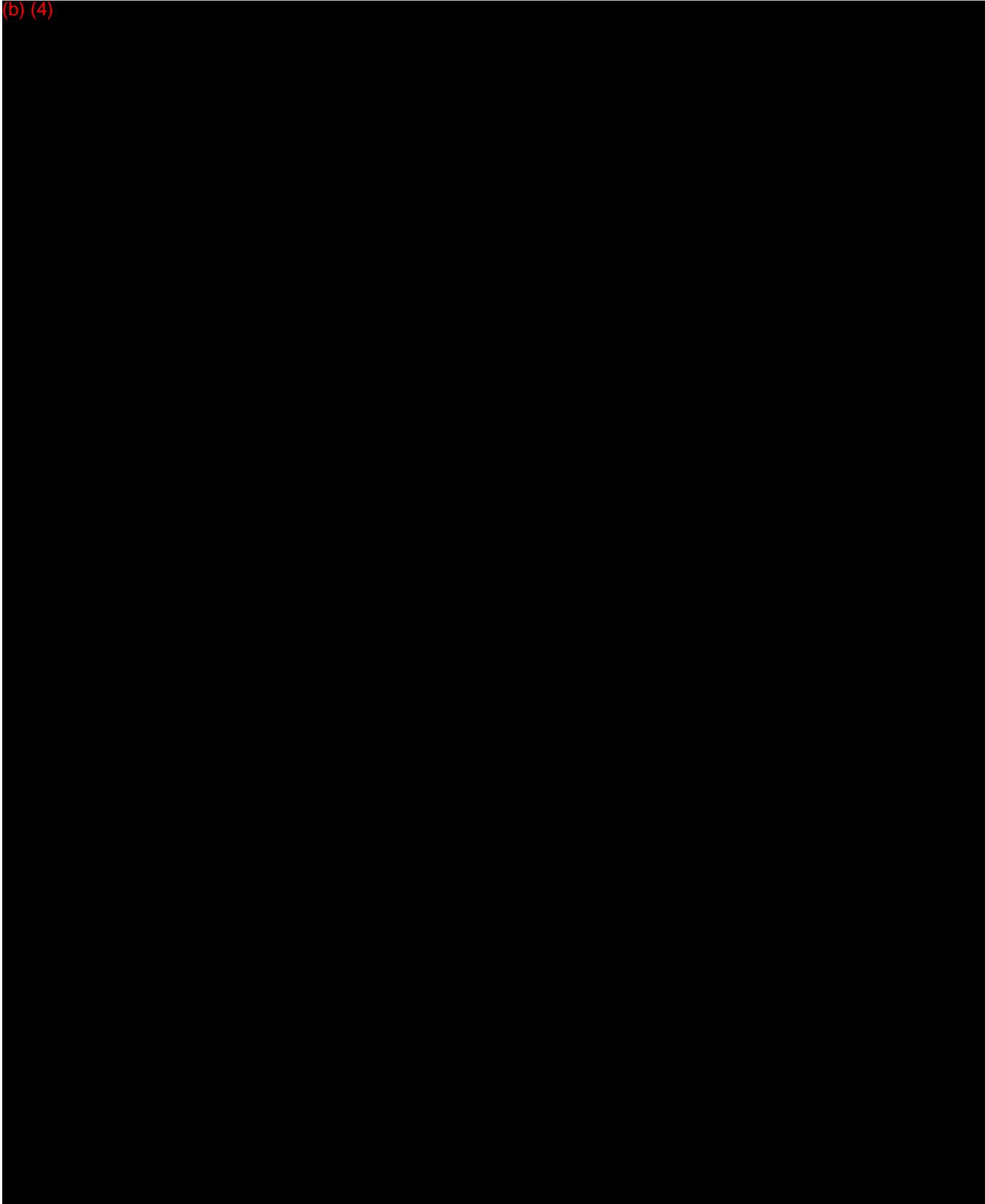
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Section 18

Performance Testing - Bench

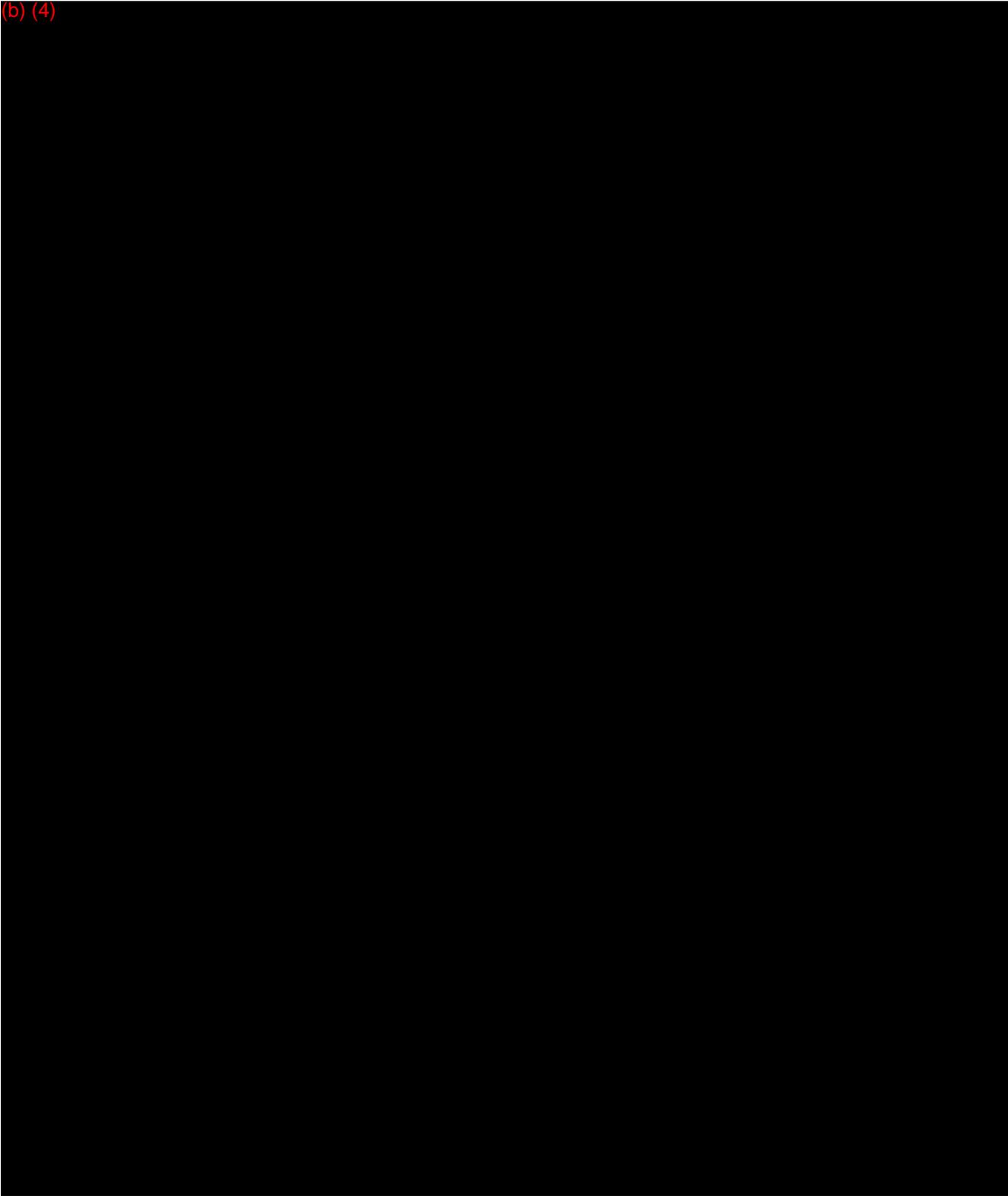
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Section 18

Performance Testing - Bench

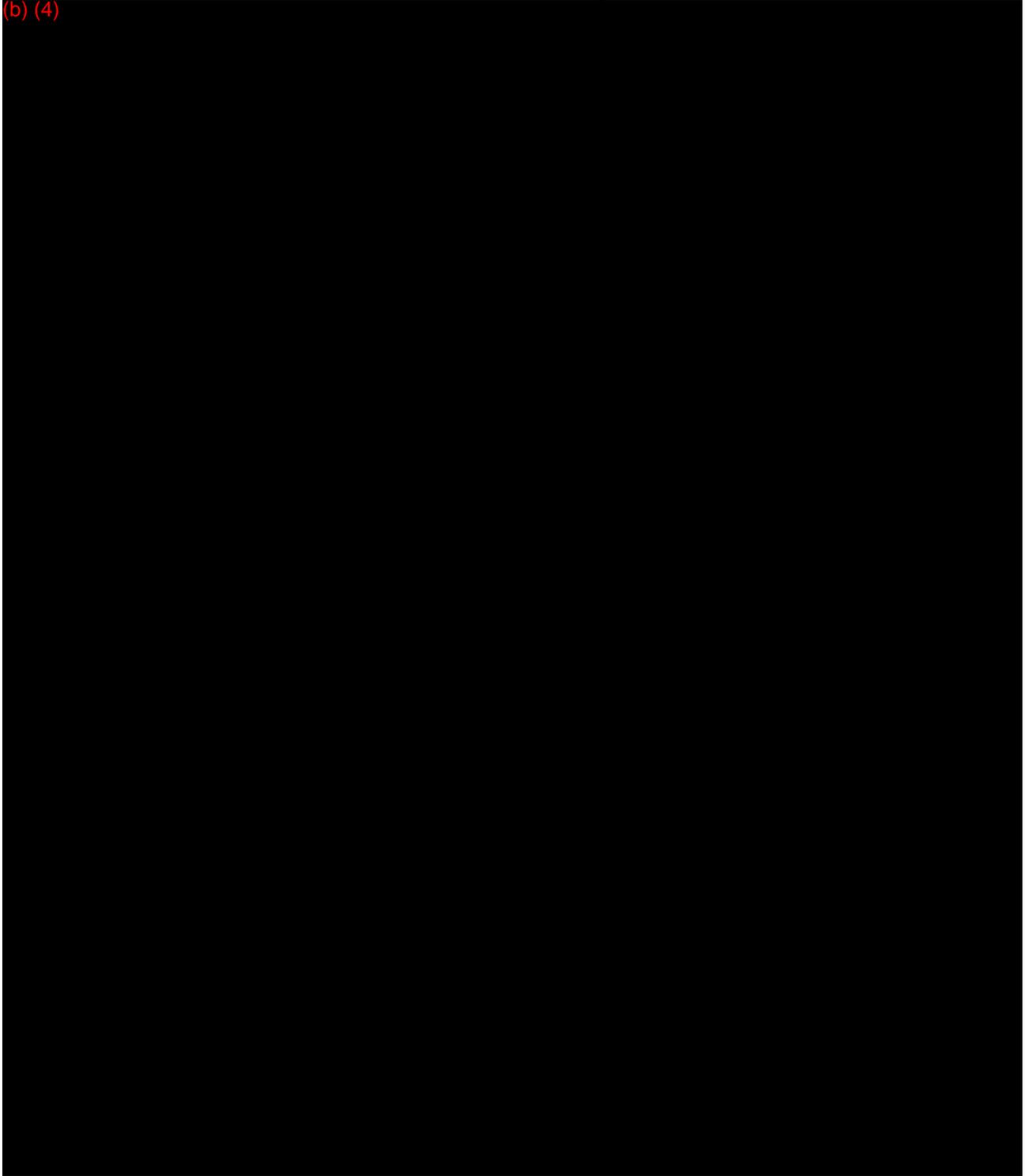
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Section 18

Performance Testing - Bench

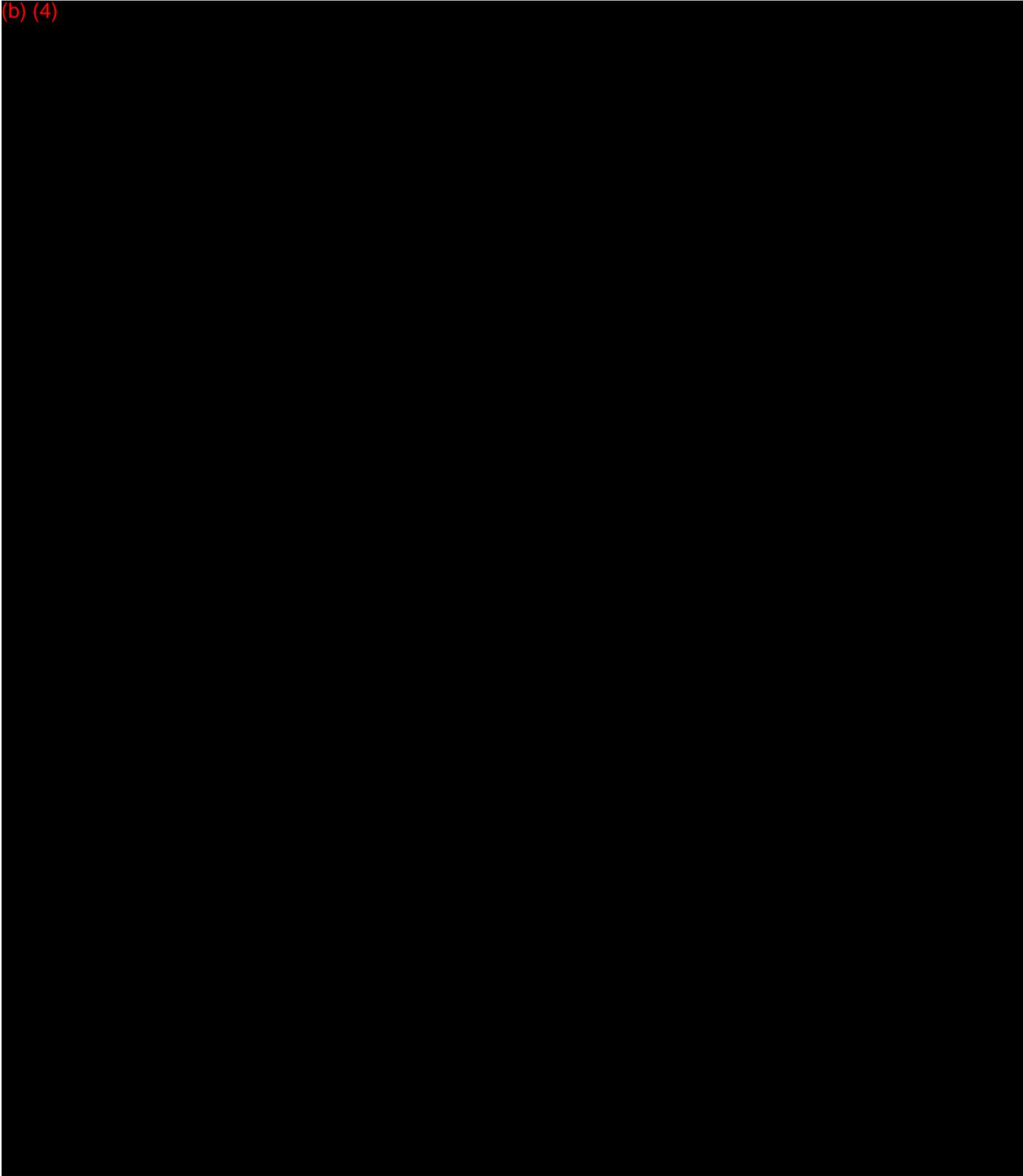
(b) (4)



Section 18

Performance Testing - Bench

(b) (4)



Appendix B – Draft Labeling & Instructions for Use

The Hummingbird TTS instructions for use are unchanged from the Preceptis TTS predicate device cleared in 510(k) #133921, except for the modification to the warning related to general anesthesia. The changes are highlighted in yellow under the warnings section.

HUMMINGBIRD™ TYMPANOSTOMY TUBE SYSTEM With PRE-LOADED VENTILATION TUBE (TTS) INSTRUCTIONS FOR USE (DRAFT)

CAREFULLY READ ALL INSTRUCTIONS PRIOR TO USE.

CAUTION: Federal law restricts this device to sale by or on the order of a physician.

Indications for Use

The Hummingbird™ Tympanostomy Tube System (TTS) is intended to deliver a tympanostomy tube in tympanostomy procedures in which the patient is receiving a tympanostomy tube.

Intended Use

The TTS is intended to deliver a tympanostomy tube through the tympanic membrane (TM) of the patient. It combines the separate functions of creating a myringotomy, positioning and placing a ventilation tube across the TM, and suctioning.

Warnings

- The TTS is intended for single patient use. DO NOT REUSE.
- Use the TTS with an ear speculum to avoid injury to the auditory canal.
- Do not use the TTS device if the visual depth markers provided (a visual tab located on the lateral end of the ventilation tube, and/or a marker band located on the cutting sheath) cannot be seen during use within the ear canal.
- Do not advance the visual depth markers past the tympanic membrane to avoid damage to the middle or inner ear.
- Do not attempt to re-load a deployed myringotomy tube or to load a new myringotomy tube into the TTS device.
- Do not bend or shape the device. This may cause device damage.
- Do not apply suction through the tip of the device while it is located behind the TM.
- When using the TTS for tympanostomy tube placement in children:
 - Either general anesthesia or moderate sedation is recommended.
 - The anesthetic regimen should be determined by the attending otolaryngologist and anesthesia professional.
 - The tympanostomy procedure should only be performed in a hospital or ambulatory surgical center setting, with the anesthesia delivered by an anesthesia professional.

Appendix B – Draft Labeling & Instructions for Use

Precautions

- Follow standard hospital/clinic policies and procedures.
- Ensure the auditory canal is sufficiently clean to allow direct visualization of the TM and of the TTS device during tube placement.
- Insertion location of the TTS on the tympanic membrane should be chosen to avoid damage to the malleus and the ossicular chain.
- Avoid excessive penetration depths with the TTS device to reduce the risk of injury to vasculature or nerves in the case of abnormal anatomy.
- Completely retract the cutting sheath after tube insertion and prior to applying suction through the TTS device.
- When applying suction through the TTS device after tube insertion, ensure that the tube is not inadvertently pulled out of the myringotomy.
- Suction cannot be applied through the TTS device prior to tube deployment. Attempts to apply suction prior to tube insertion or to clear a perceived blockage prior to insertion may cause the ventilation tube to deploy erratically.
- Inspect the packages and devices carefully. Do not use if the package or device is damaged.
- Do not use if the expiration dates are exceeded.
- Use caution in opening the packaging and removing the devices to insure the devices are not damaged.

Potential Complications

Possible risks associated with the device may include but are not limited to:

- Otorrhea,
- Acute tube extrusion,
- Chronic tube extrusion,
- Tube dislocating into middle ear,
- Tube clogging,
- Bleeding,
- Vertigo,
- Nausea,
- Infection,
- Hearing loss,
- Facial nerve injury.

Restrictions

The TTS should be only operated by physicians experienced in tympanostomy procedures, which have reviewed this Instruction for Use and understood the use of the TTS.

Maintenance

The device is a single patient-use disposable product. No maintenance is required.

Appendix B – Draft Labeling & Instructions for Use

TTS Components

Disposable Components (provided EO Treated):

- TTS (Tympanostomy Tube System with Tip Assembly)
- TTS Tip Assembly
- Ventilation tubes (PN 05-1026-009)

Other Recommended Components (not provided)

- Ear speculum
- Vacuum system and appropriate suction tubing

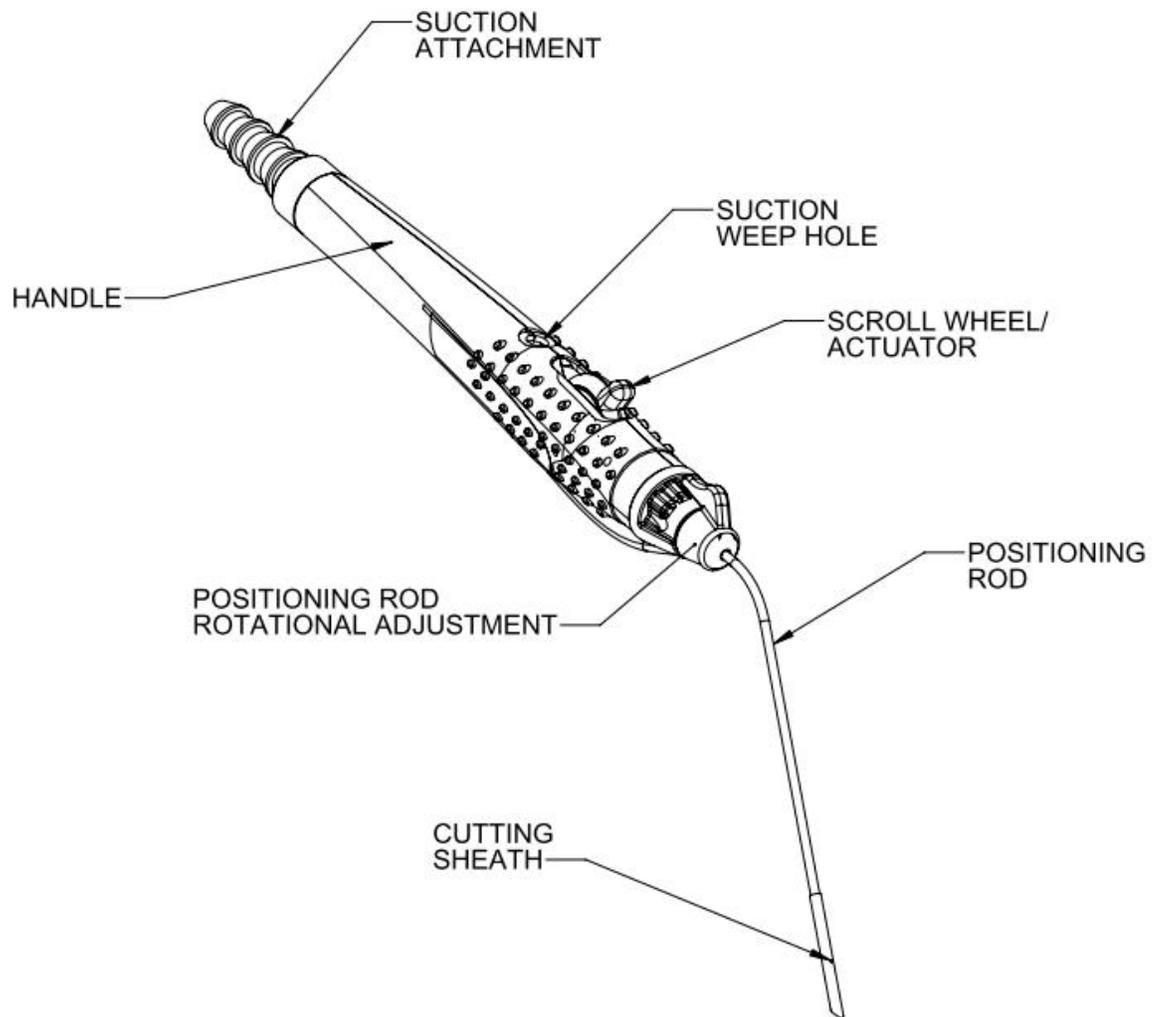


Figure 1. Tympanostomy Tube Inserter

Appendix B – Draft Labeling & Instructions for Use

Setup

- Carefully remove the TTS from the packaging.
- Inspect the TTS upon removal from packaging to make sure the device is not damaged.
- Verify that the ventilation tube is properly loaded within the device and that the depth indicator is visible (see figure 2).

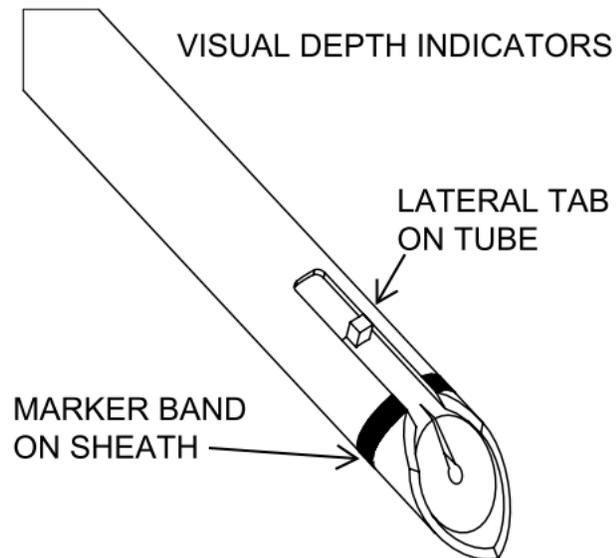


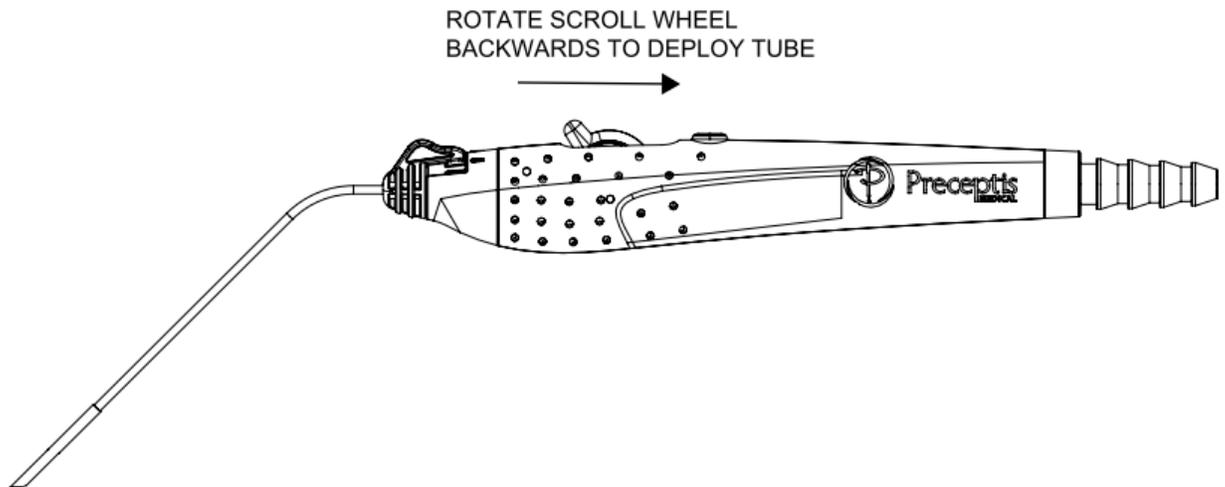
Figure 2. Close up of loaded ventilation tube showing correct placement within device and depth indicators.

Procedural steps:

1. If suction is to be used, attach suction tubing to the barbed fitting located on the TTS handle.
2. Insert an ear speculum into the outer ear canal following routine preparation. The ear canal and area around the tympanic membrane must be cleaned sufficiently to allow for good visualization of the tympanic membrane and the visual depth indicator located on the TTS.
3. Under visualization, for example through an operating microscope, manually advance the TTS through the speculum and down the ear canal such that the cutting component pierces the tympanic membrane in the location indicated for ventilation tube insertion.

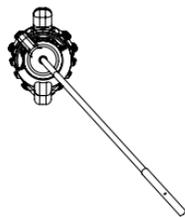
Appendix B – Draft Labeling & Instructions for Use

4. Advance the TTS until the beveled portion of the cutting sheath is completely through the TM and the visual depth indicator (visualization tab on the tube or visualization marker band on the cutting sheath) is visible proximal to the TM.
5. Rotate the scroll wheel located on the device handle BACKWARDS (see figure below) to retract the cutting sheath and position the ventilation tube across the TM. Continue to rotate the scroll wheel through its full range of motion to fully retract the cutting sheath.
6. Apply suction if desired by covering the suction weep hole located on the handle.
7. Retract the TTS from the ear canal and dispose of appropriately.



The tip assembly is user adjustable to three different angular orientations to provide improved ergonomics for the user (see figures below). The following three figures show the three tip orientations possible. The tip is adjusted by grasping the tip adjustment tab and twisting it while holding the handle. Do not adjust the tip by grasping the positioning rod as this may damage the tip assembly.

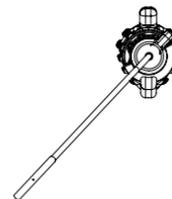
TIP ENGAGEMENT POSITION 1



TIP ENGAGEMENT POSITION 2

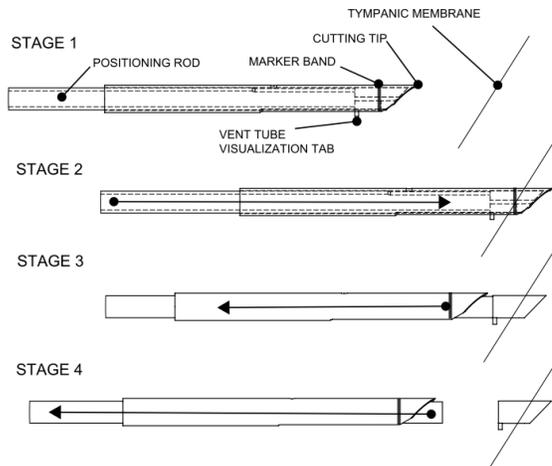


TIP ENGAGEMENT POSITION 3



Appendix B – Draft Labeling & Instructions for Use

The following schematic illustrates the steps taken with the device to perform ventilation tube placement. A close up of the front of the device is shown illustrating the tympanic membrane, the stainless steel positioning/suction tube, the cutting component, and the ventilation tube. The ventilation tube is constrained within the cutting component and is held in place by friction. A slot in the cutting component allows direct visualization of the vent tube throughout the procedure. The cutting component retracts axially along the positioning tube when the scroll wheel on the handle is turned.



Stage 1 – The device is manually advanced down the ear canal.

Stage 2 – The entire device is manually advanced so that the cutting tip pierces the tympanic membrane. A slot in the cutting component allows visualization of the vent tube, ensuring it is positioned correctly in relation to the TM.

Stage 3 – Using the scroll wheel on the handle, the clinician retracts the cutting component. The positioning rod tube remains stationary and pushes the vent tube out of the cutting component, leaving it correctly positioned across the TM.

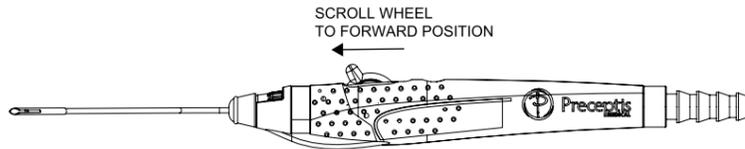
Stage 4 - The sharp edge of the cutting component is protected after retraction.

Appendix B – Draft Labeling & Instructions for Use

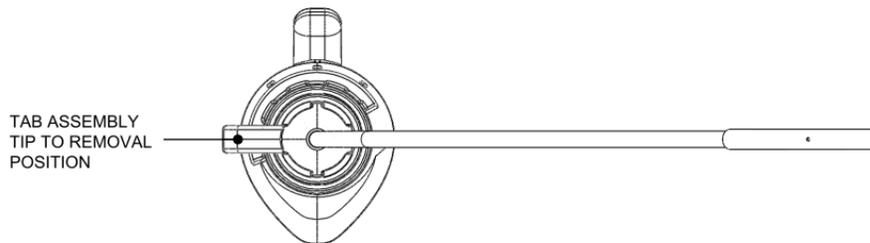
Tip Assembly Replacement:

Tip Assembly Removal

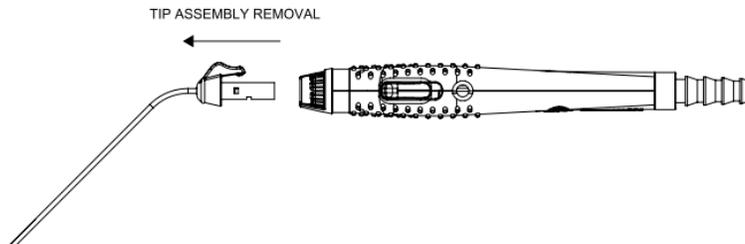
1. Return scroll wheel to the fully forward position.



2. Rotate Tip Assembly counterclockwise as far as it will turn, until the tab on rotating nosepiece is aligned with the insertion groove on the handle nosepiece.



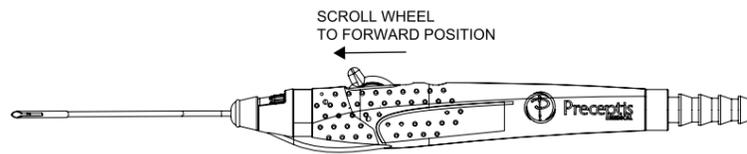
3. Grasping the plastic rotating nosepiece, firmly pull straight out on the tip assembly until it is fully disengaged from the handle.



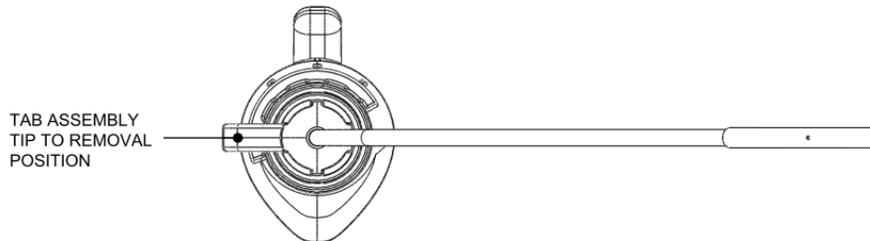
Appendix B – Draft Labeling & Instructions for Use

Tip Assembly Insertion:

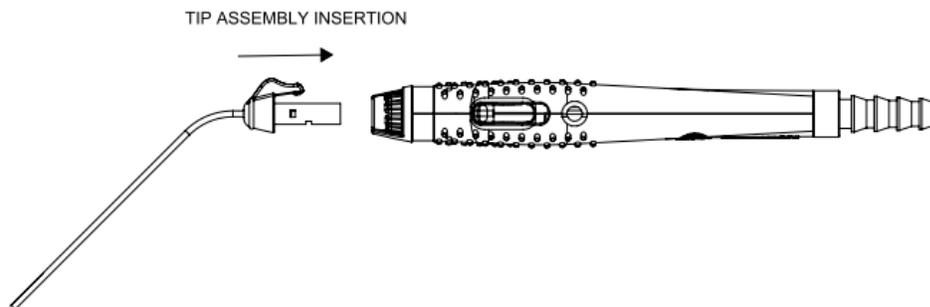
1. Position scroll wheel in the fully forward position.



2. Align tab on rotating nosepiece with insertion groove on handle nosepiece.

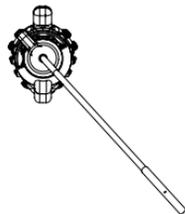


3. Insert rotating nosepiece into handle, ensuring that scroll wheel remains in fully forward position



4. Once the tip assembly is fully inserted, rotate clockwise to desired orientation to engage with the handle.

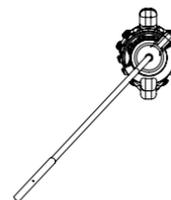
TIP ENGAGEMENT POSITION 1



TIP ENGAGEMENT POSITION 2



TIP ENGAGEMENT POSITION 3



Appendix B – Draft Labeling & Instructions for Use

Operating and Storage Conditions

Disposal

All components of the TTS are single patient-use.

Functional Life

All components of the TTS are single patient-use devices and must be used prior to the stated expiration date.

Definitions of Symbols

	DO NOT REUSE		Date of Manufacture
	Batch/Lot Code		Catalog Number
	Serial Number		Sterilized Using Ethylene Oxide
	Use by		

Appendix B – Draft Labeling & Instructions for Use

Specifications Table

System Component	Specification	
Tympanostomy Tube Inserter – Replaceable Tip <i>PN 05-1008-005</i> <i>PN 05-1008-006</i>	Cutting Sheath Diameter	0.072" (1.8 mm)
	Positioning Rod	0.060" (1.5 mm)
	Working Length	2.6" (65 mm)
Tympanostomy Tube Introducer - Handle <i>PN 05-1001-007</i> <i>PN 05-1001-008</i>	Length	5.125 in. (13 cm)
Ventilation Tube	05-1026-009	Inside Diameter 0.039" (1.0 mm)
05-1001-501	-90 Handle Assembly, 05-1001-007 +90 Tip Assembly, 05-1008-005 Two tubes, 05-1029-009	
05-1001-502	+90 Handle Assembly, 05-1001-008 +90 Tip Assembly, 05-1008-006 Two tubes, 05-1029-009	
05-1001-503	-90 Handle Assembly, 05-1001-007 -90 Tip Assembly, 05-1008-005 Two tubes, 05-1029-009	

Contact Information:

Preceptis Medical, Inc.
505 Highway 169 N
Suite #365
Plymouth, MN 55441
Telephone: (952) 568-7819



Preceptis
MEDICAL

K142282 | 5002
FDA CDRH DMC

NOV 14 2014

Received

13 November 2014

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – W066-G609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

**RE: Traditional 510(k) Premarket Notification K142282 – 21 CFR 807.90(e)
Preceptis Medical, Inc.**

To Whom It May Concern:

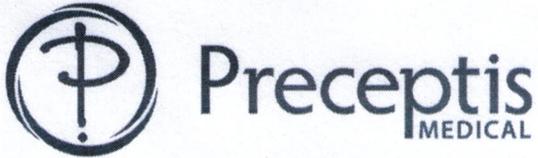
Please find included an eCopy of the response to support the traditional 510(k)
#K142282 being submitted by Preceptis Medical, Inc.

The eCopy is an exact duplicate of the paper copy.

Sincerely,

Keith Leland

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November 13, 2014

Sageev George, Ph.D.
US Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center – WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

RE: Preceptis response to the Agency's request for additional information on K142282:
Preceptis Tympanostomy Tube Inserter with preloaded ventilation tube.

Dear Dr. George:

Thank you for reviewing our traditional 510(k) submission for Preceptis' Tympanostomy Tube Inserter with preloaded ventilation tube. We hereby submit two copies of our response along with an electronic copy, which is an exact copy.

We hope that this response addresses all of your questions. If you have any additional questions regarding this submission, please contact Keith Leland by email at keith@preceptismedical.com or by phone at (763) 568-7819.

Sincerely,

A handwritten signature in black ink, appearing to be "SA", with a long horizontal line extending to the right.

Steve Anderson
Chief Executive Officer

Enclosure & 2 copies

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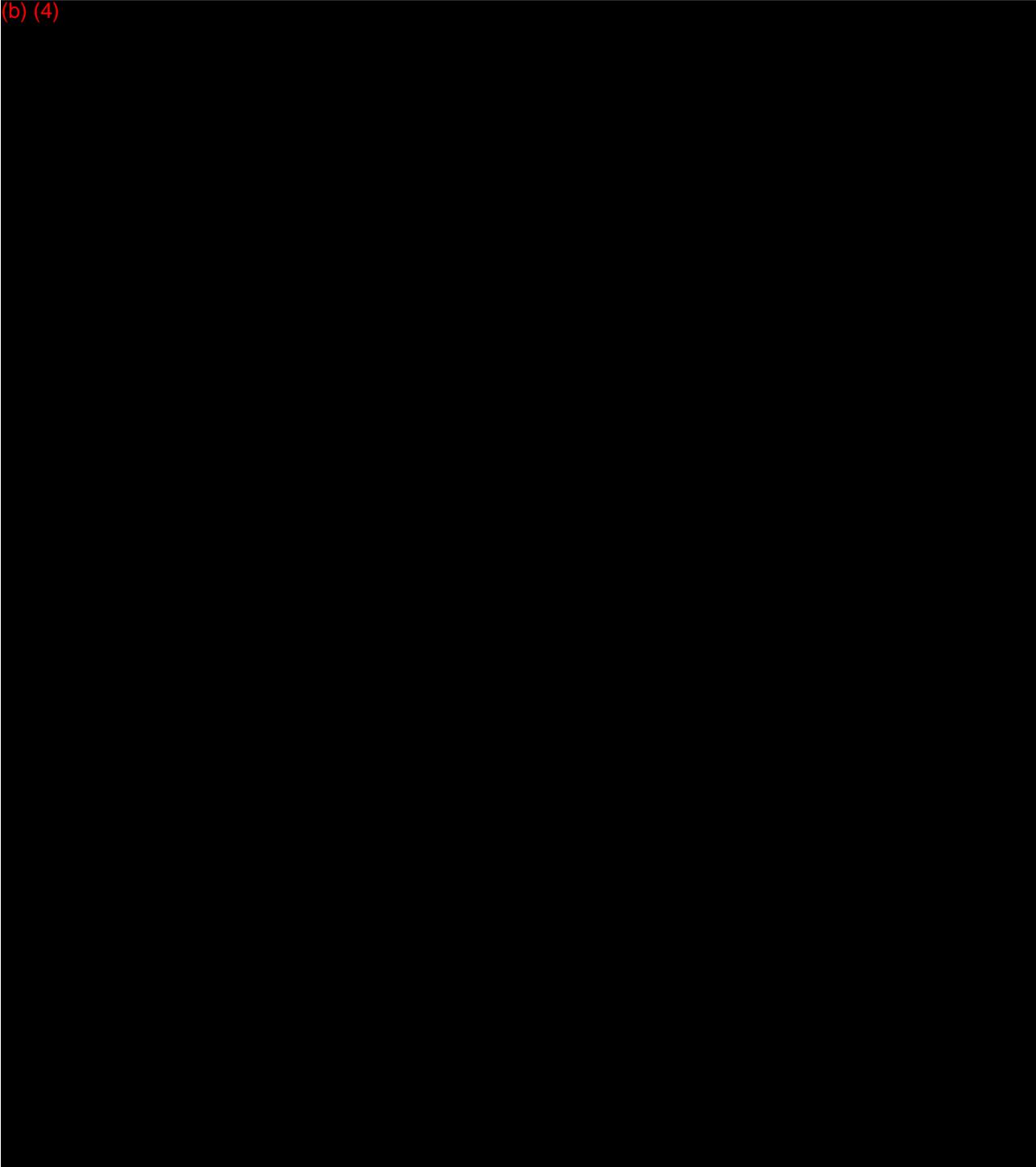
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b(4)Trade Secret Process- Product Specs

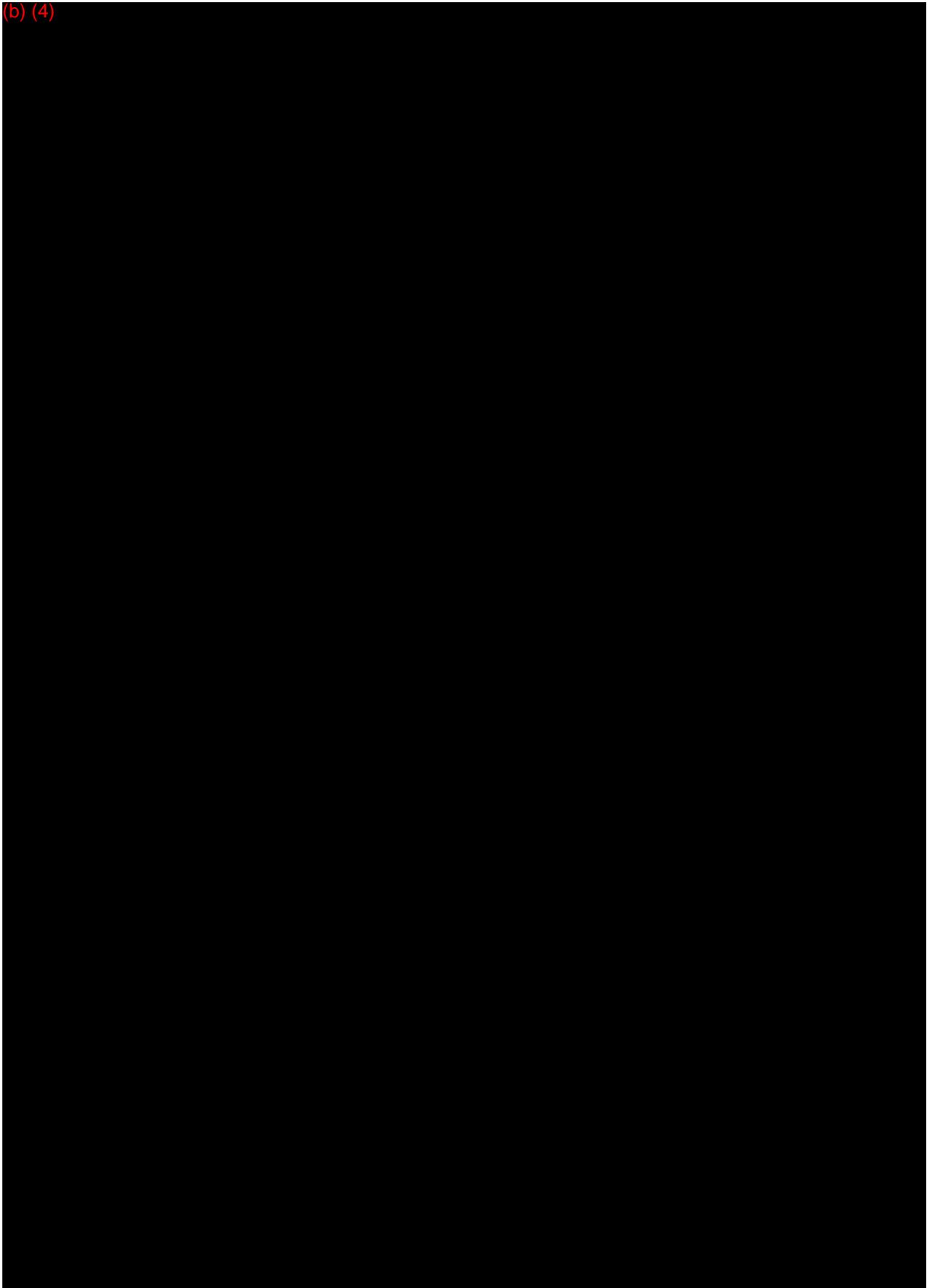
Re: K142282
Hummingbird™ Tympanostomy Tube System (TTS)

Clinical

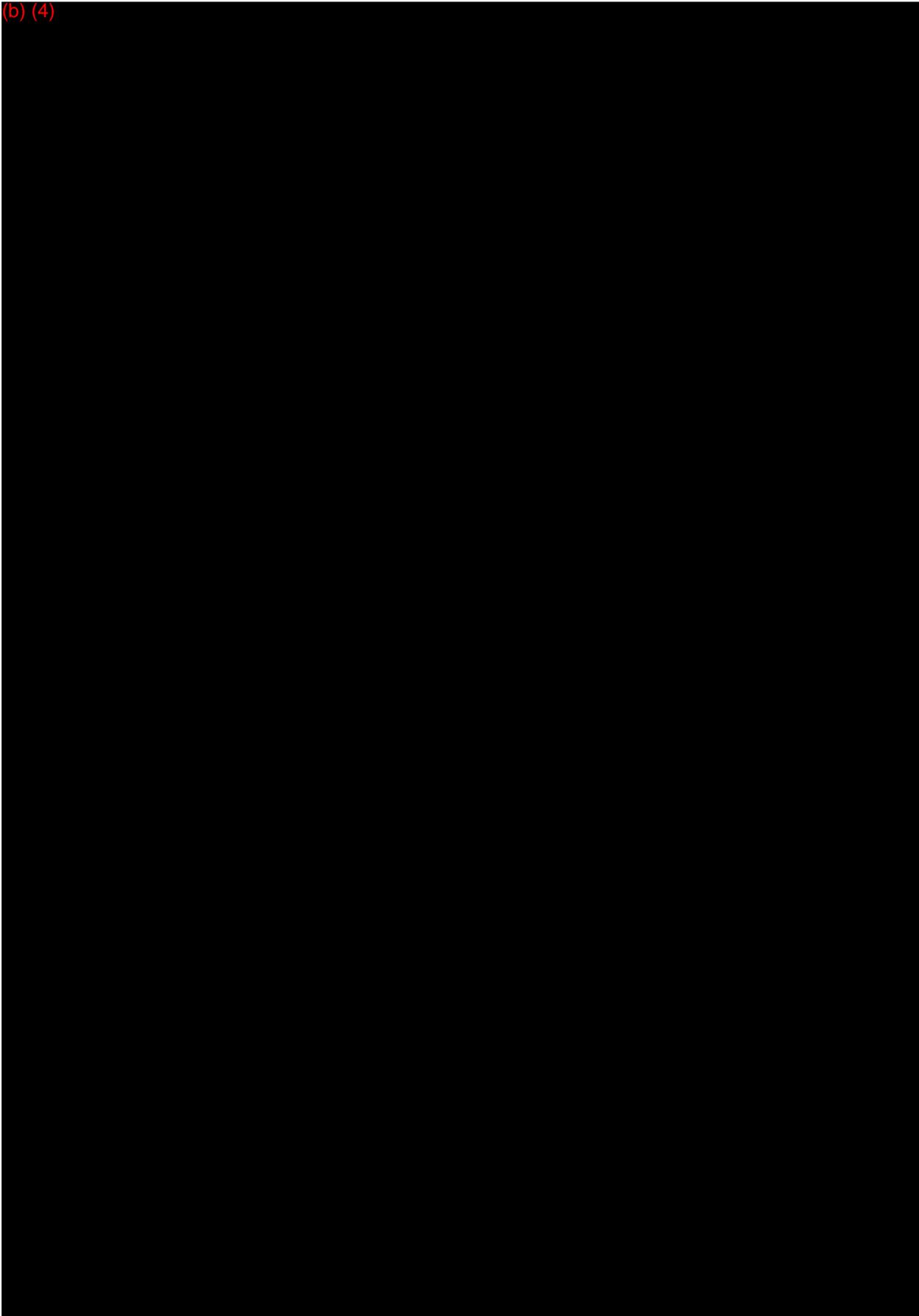
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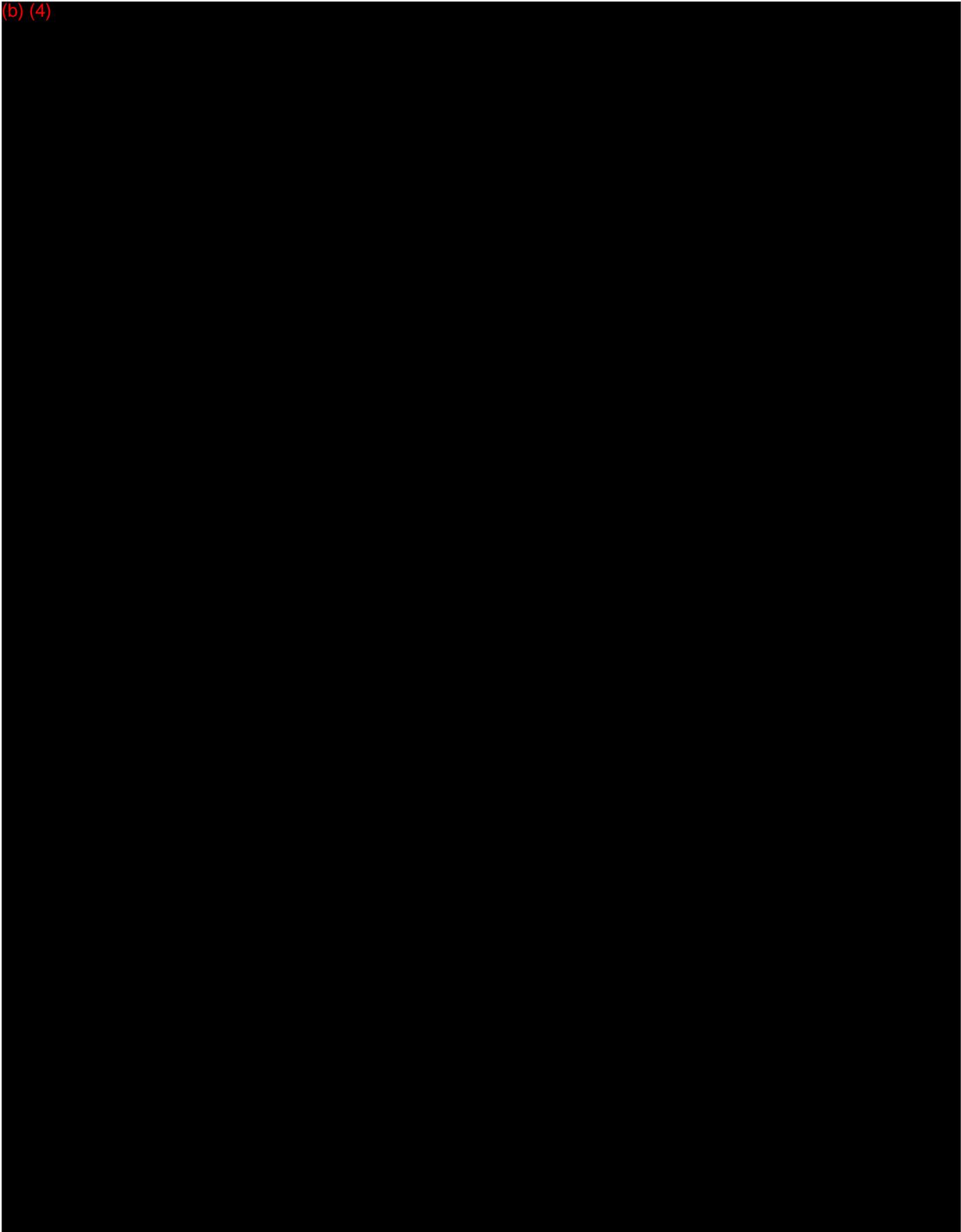
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(b) (4)



Section 5 510k Summary

Submitter Information:	Preceptis Medical, Inc. 505 Highway 169 North, #365 Plymouth, MN 55441 763.568.7819
Contact:	Keith Leland, VP of R&D
Date Prepared:	12 November 2014
Trade Name	Hummingbird™ Tympanostomy Tube System (TTS)
Product Code	ETD (21 CFR Part 874.3880)
Common Name	Tympanostomy Tube Inserter with pre-loaded ventilation tube
Predicate Devices	Preceptis Tympanostomy Tube System, 510(k) K133921
Device Description	<p>The Hummingbird™ Tympanostomy Tube System (TTS) which includes a tympanostomy tube inserter (TTI) with a preloaded ventilation tube, is a single-use, sterile manual surgical instrument which is used to create a myringotomy in the tympanic membrane and place a ventilation tube. The TTS includes a handle with one or more tip assemblies which contain a sterile tympanostomy tube.</p> <p>Each tip assembly can be removably attached to the handle and includes a positioning rod and a ventilation tube pre-loaded inside the distal end of a sharpened sheath. Attaching the tip assembly to the handle also connects the sheath and actuator, allowing the user to retract the sheath by manually scrolling an actuator located on the handle.</p> <p>The user manually advances the sharpened sheath to create a myringotomy and simultaneously positions the ventilation tube within the myringotomy, always under direct visualization. The user then manually retracts the sharpened sheath away from the myringotomy using the manual actuator located on the handle. The retraction of the sheath releases the tube within the myringotomy.</p> <p>A first tip assembly can then be removed from the handle and replaced with a second preloaded tip assembly for bilateral procedures.</p>
Indications For Use	The Hummingbird™ Tympanostomy Tube System is intended to deliver a tympanostomy tube in tympanostomy procedures in which the patient is receiving a tympanostomy tube.

Section 5
510k Summary

Technical Characteristics	<p>The TTS is intended to deliver a tympanostomy tube (also referred to as a ventilation tube) through the tympanic membrane (TM) of the patient. It combines the separate functions of creating a myringotomy, positioning and placing a ventilation tube across the TM, and suctioning.</p> <p>The TTI is a manual surgical instrument. The actions of creating the myringotomy, positioning the ventilation tube, and retracting the sheath surrounding the ventilation tube are all performed manually by the user.</p> <p>A comparison between the TTS and predicate device shows that the devices are identical.</p>
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Section 5 510k Summary

Performance Data	<p>In two non-significant risk studies (an initial feasibility study followed by a multi-site study), a total of 69 children (136 ears) underwent tympanostomy procedures under moderate sedation using the Preceptis TTS. The mean age of the patients was 2.4 years (range of 8 months to 8.9 years). Results:</p> <ul style="list-style-type: none">• The IRBs at each institution designated the studies as Non-Significant Risk due to the low risk profile of the TTS and the fact that anesthetic regimen is determined and delivered by an anesthesia professional within the hospital.• 100% of the children received ventilation tubes as planned.• There were no intra-operative adverse events, no unanticipated adverse events, and adverse event rates were well within peer-reviewed literature reported rates.• Moderate sedation was per definition from the ASA guidelines, Continuum of Depth of Sedation: Definition of General Anesthesia and Levels of Sedation/Analgesia.• The moderate sedation regimen was determined by the surgeon and anesthesiologist. In these two studies, the surgeon and anesthesiologist chose to use nitrous oxide (50-70%) in all cases.• In the 1st study, there were 12 conversions (30%) from moderate sedation to general anesthesia due to surgical challenges. In the 2nd study, 2 cases (7%) were converted. The reduction in the conversion rate was likely due to increased surgical experience and design improvements to the TTS to improve visibility and repeatability.• There is no additional risk in converting cases from moderate sedation to general anesthesia since the conversion process simply involves turning off the nitrous oxide and turning on the flow of sevoflurane to the mask already in place over a child's nose and mouth. <u>However, general anesthesia needs to be available as back-up in all moderate sedation cases.</u>• Performing tympanostomy procedures in young children under moderate sedation in a hospital setting with anesthesia delivered by an anesthesia professional is safe and a well-reasoned alternative to the use of general anesthesia for caregivers and clinicians who are comfortable with this choice.
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Section 10 Executive Summary

Executive Summary

Overview of Device

The Hummingbird™ Tympanostomy Tube System (TTS) is a manual surgical instrument that places a standard ventilation tube across the tympanic membrane of a patient. It combines the separate functions of creating a myringotomy, positioning and placing the ventilation tube, and suctioning.

The TTS is intended to place a ventilation tube to provide ventilation to the middle ear space through the tympanic membrane.

(b) (4)



The Hummingbird TTS is preceded by the previous, identical predicate:

1. The Preceptis Tympanostomy Tube System cleared under 510(k) #K133921

This 510k submission for the Hummingbird™ TTS thereby consists of the predicate above with the only difference being that labeling now includes instructions for use under moderate sedation in addition to general anesthesia.

Clinical Testing

In two non-significant risk studies (an initial feasibility study followed by a multi-site study), a total of 69 children (136 ears) underwent tympanostomy procedures under moderate sedation using the Preceptis TTS. The mean age of the patients was 2.4 years (range of 8 months to 8.9 years). Results:

- The IRBs at each institution designated the studies as Non-Significant Risk due to the low risk profile of the TTS and the fact that anesthetic regimen is determined and delivered by an anesthesia professional within the hospital.
- 100% of the children received ventilation tubes as planned.

Section 10

Executive Summary

- There were no intra-operative adverse events, no unanticipated adverse events, and adverse event rates were well within peer-reviewed literature reported rates.
- Moderate sedation was per definition from the ASA guidelines, Continuum of Depth of Sedation: Definition of General Anesthesia and Levels of Sedation/Analgesia.
- The moderate sedation regimen was determined by the surgeon and anesthesiologist. In these two studies, the surgeon and anesthesiologist chose to use nitrous oxide (50-70%) in all cases.
- In the 1st study, there were 12 conversions (30%) from moderate sedation to general anesthesia due to surgical challenges. In the 2nd study, 2 cases (7%) were converted. The reduction in the conversion rate was likely due to increased surgical experience and design improvements to the TTS to improve visibility and repeatability.
- There is no additional risk in converting cases from moderate sedation to general anesthesia since the conversion process simply involves turning off the nitrous oxide and turning on the flow of sevoflurane to the mask already in place over a child's nose and mouth. However, general anesthesia needs to be available as back-up in all moderate sedation cases.

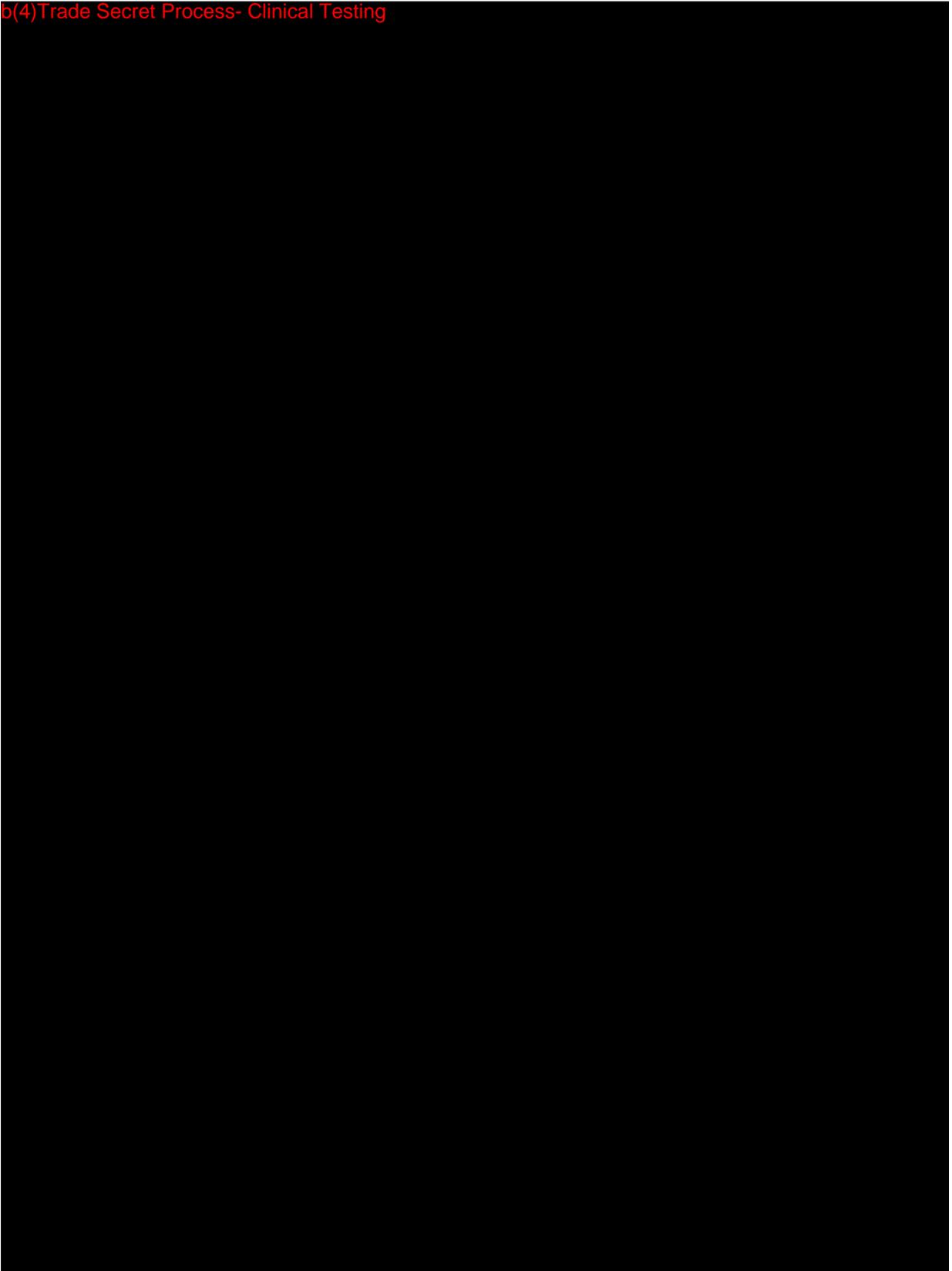
Performing tympanostomy procedures in young children under moderate sedation in a hospital setting with anesthesia delivered by an anesthesia professional is safe and a well-reasoned alternative to the use of general anesthesia for caregivers and clinicians who are comfortable with this choice.

Substantial Equivalence Analysis

The key performance, safety and design characteristics of the predicate device are identified and are listed in the substantial equivalence table. The device comparison table shows that the Hummingbird™ Tympanostomy Tube System is identical to the predicate device. The indications for use for the devices are the same. An analysis of the differences between the devices showed that none exist and that the devices are identical.

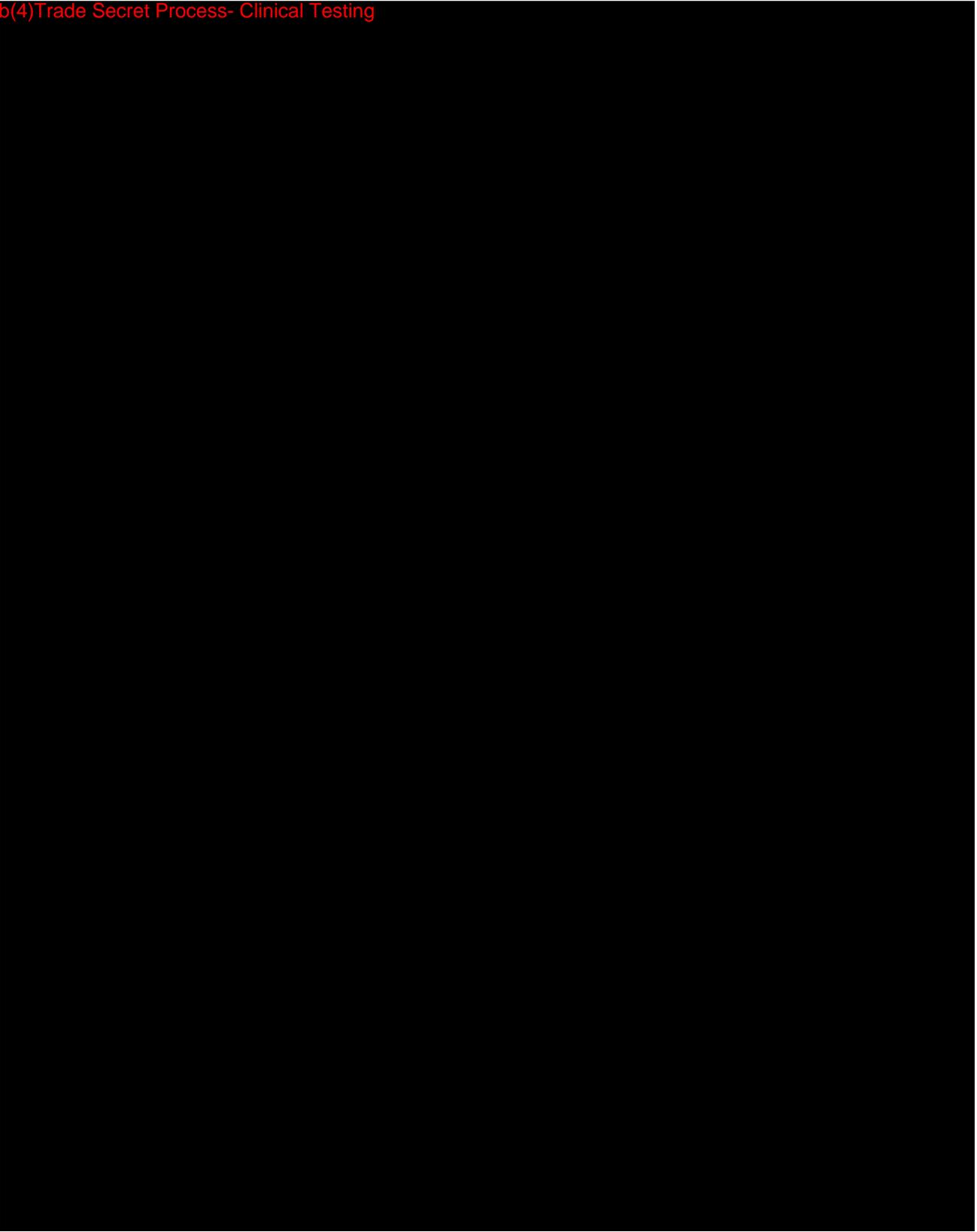
Section 20
Performance Testing – Clinical

b(4) Trade Secret Process- Clinical Testing



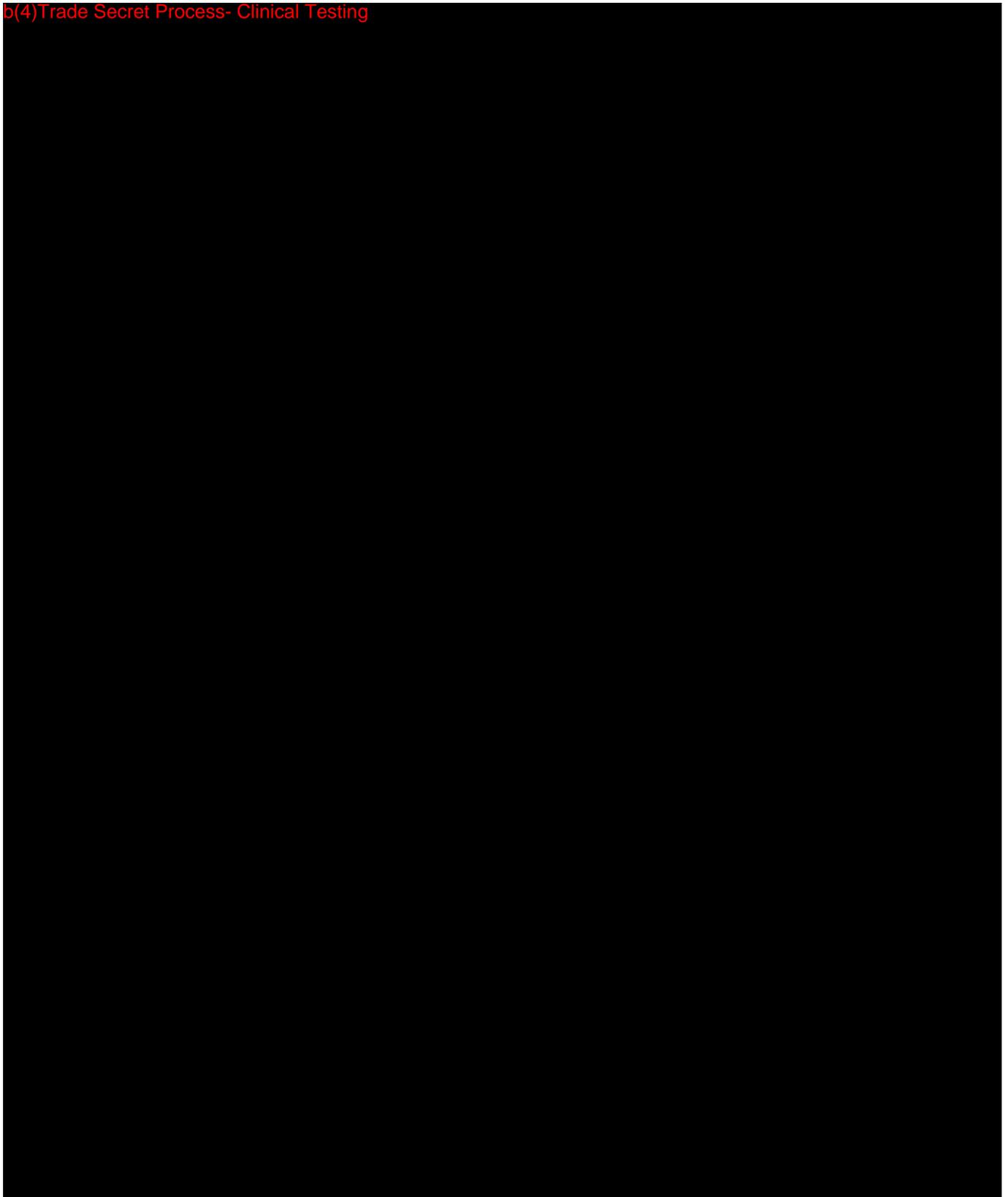
Section 20
Performance Testing – Clinical

b(4)Trade Secret Process- Clinical Testing



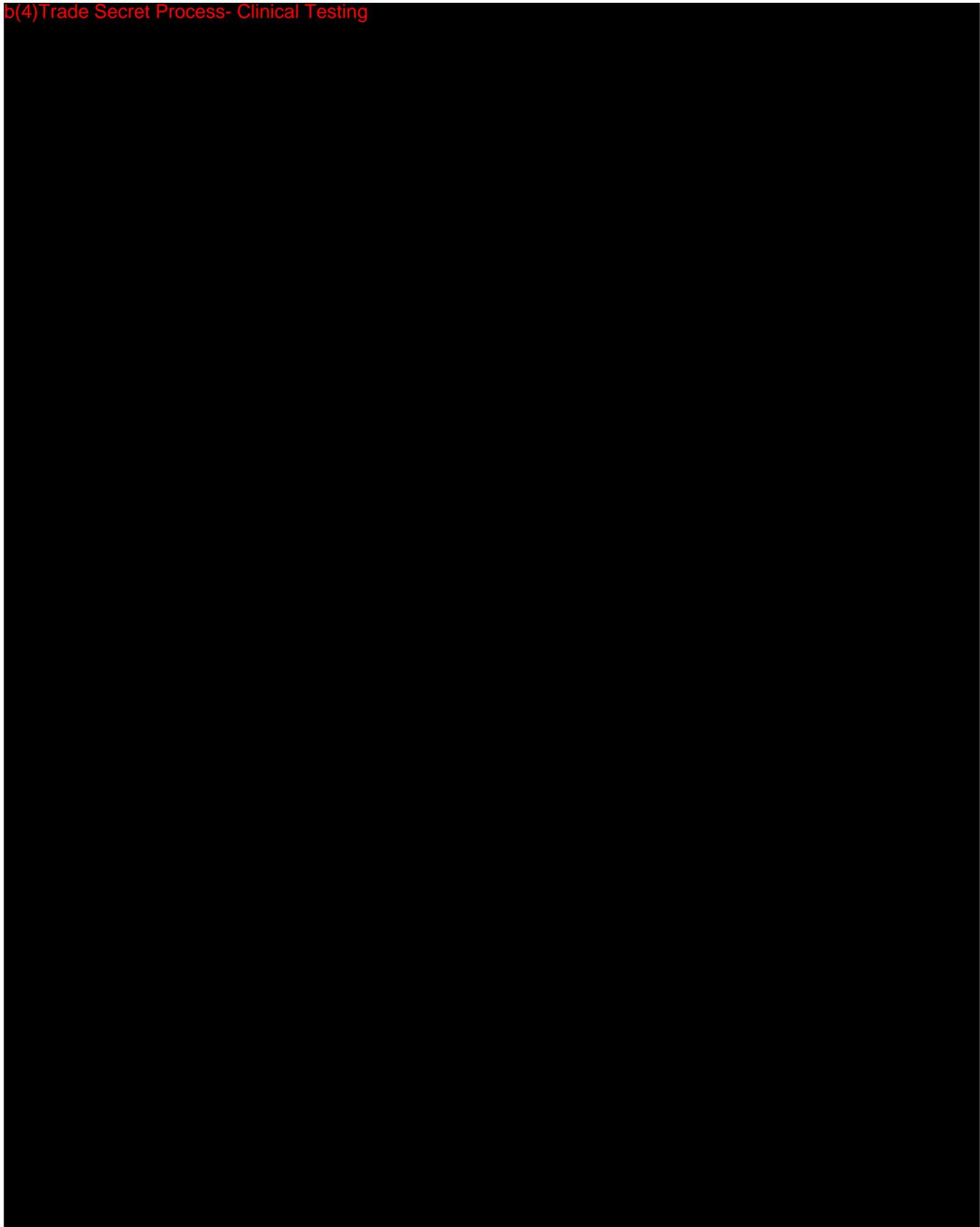
Section 20
Performance Testing – Clinical

b(4)Trade Secret Process- Clinical Testing



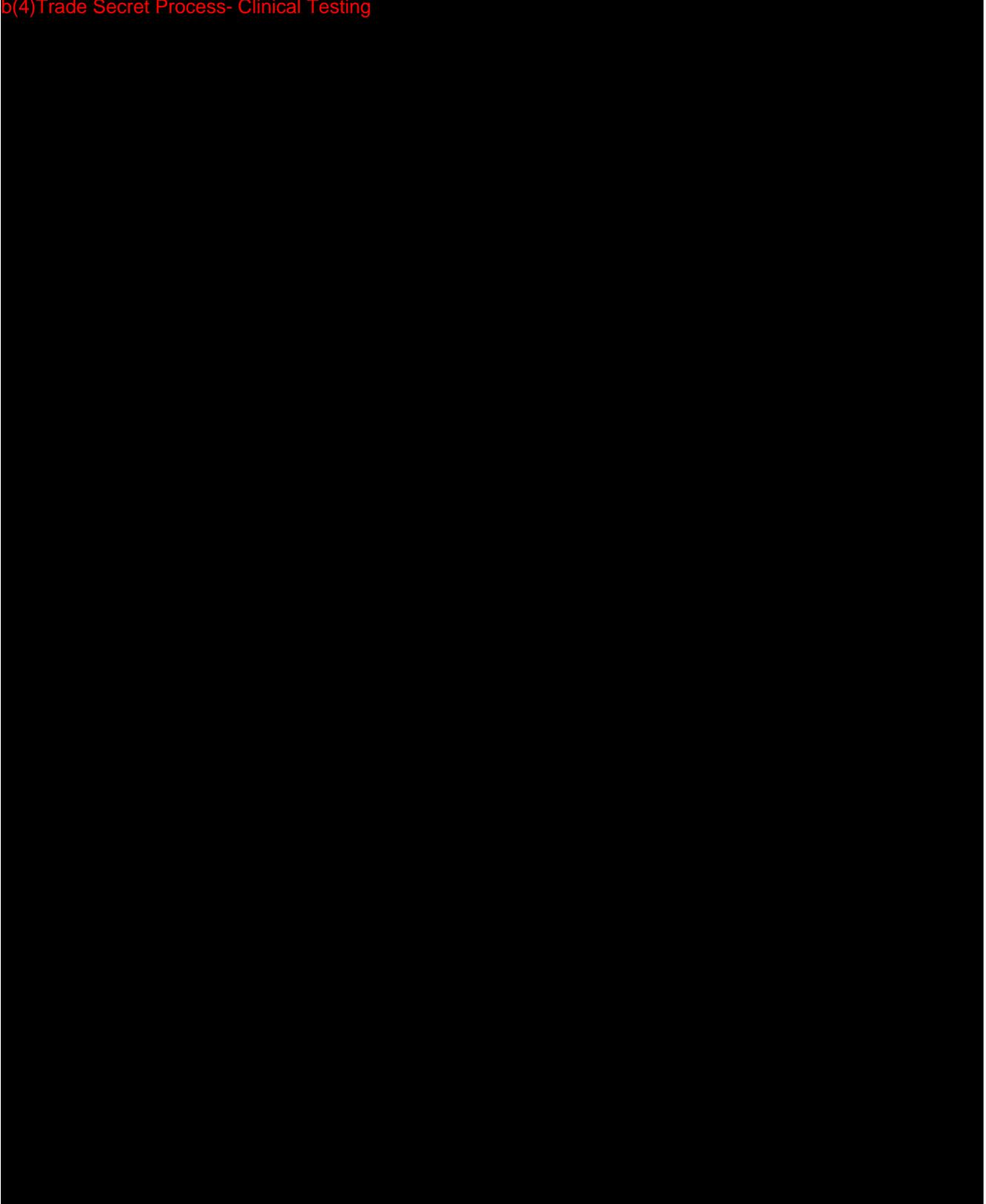
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Performance Testing – Clinical

b(4)Trade Secret Process- Clinical Testing



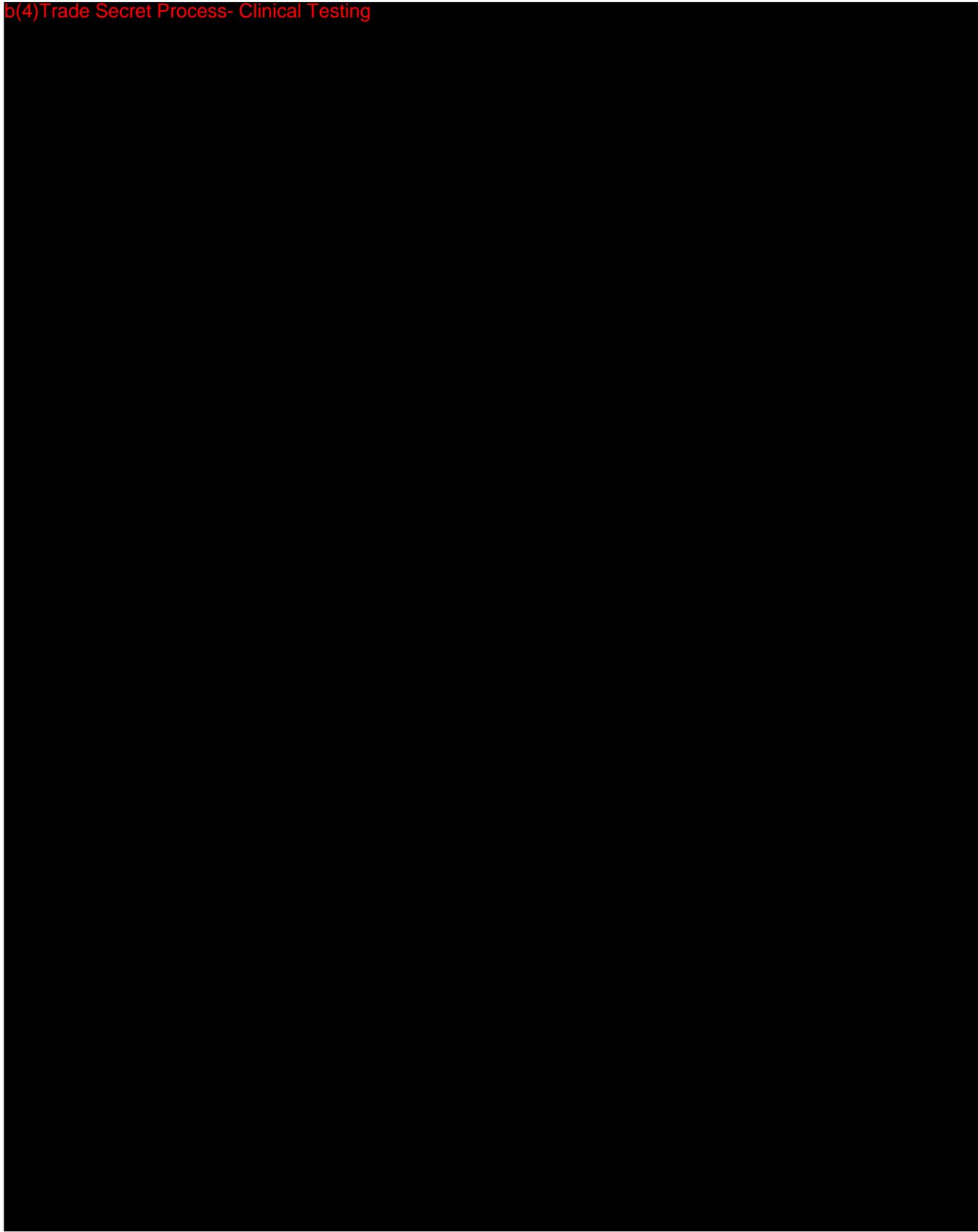
Section 20
Performance Testing – Clinical

b(4)Trade Secret Process- Clinical Testing



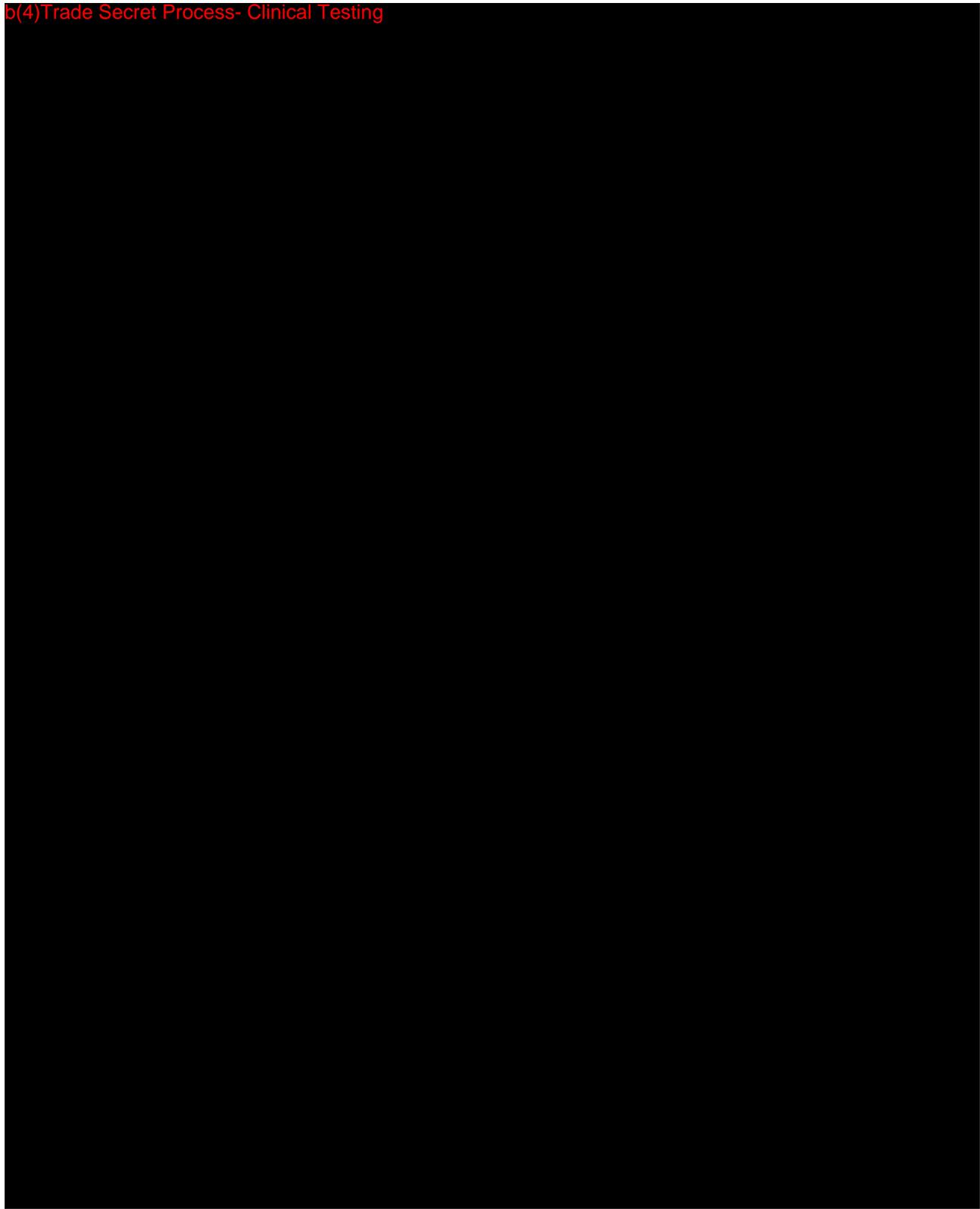
Section 20
Performance Testing – Clinical

b(4)Trade Secret Process- Clinical Testing



Section 20
Performance Testing – Clinical

b(4)Trade Secret Process- Clinical Testing



Section 20

Performance Testing – Clinical

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9. Thijs M.A., et al., A Trial of Treatment for Acute Otorrhea in Children with Tympanostomy Tubes. *New England Journal of Medicine*, 2014; 370; 723-33.
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Draft Instructions For Use

HUMMINGBIRD™ TYMPANOSTOMY TUBE SYSTEM With PRE-LOADED VENTILATION TUBE (TTS) INSTRUCTIONS FOR USE (DRAFT)

CAREFULLY READ ALL INSTRUCTIONS PRIOR TO USE.

CAUTION: Federal law restricts this device to sale by or on the order of a physician.

Indications for Use

The Hummingbird™ Tympanostomy Tube System (TTS) is intended to deliver a tympanostomy tube in tympanostomy procedures in which the patient is receiving a tympanostomy tube.

Intended Use

The TTS is intended to deliver a tympanostomy tube through the tympanic membrane (TM) of the patient. It combines the separate functions of creating a myringotomy, positioning and placing a ventilation tube across the TM, and suctioning.

Clinical Data

In two non-significant risk studies (an initial feasibility study followed by a multi-site study), a total of 69 children (136 ears) underwent tympanostomy procedures under moderate sedation using the Preceptis TTS. The mean age of the patients was 2.4 years (range of 8 months to 8.9 years). Results:

- The IRBs at each institution designated the studies as Non-Significant Risk due to the low risk profile of the TTS and the fact that anesthetic regimen is determined and delivered by an anesthesia professional within the hospital.
- 100% of the children received ventilation tubes as planned.
- There were no intra-operative adverse events, no unanticipated adverse events, and adverse event rates were well within peer-reviewed literature reported rates.
- Moderate sedation was per definition from the ASA guidelines, Continuum of Depth of Sedation: Definition of General Anesthesia and Levels of Sedation/Analgesia.
- The moderate sedation regimen was determined by the surgeon and anesthesiologist. In these two studies, the surgeon and anesthesiologist chose to use nitrous oxide (50-70%) in all cases.
- In the 1st study, there were 12 conversions (30%) from moderate sedation to general anesthesia due to surgical challenges. In the 2nd study, 2 cases (7%) were converted. The reduction in the conversion rate was likely due to increased surgical experience and design improvements to the TTS to improve visibility and repeatability.

Draft Instructions For Use

- There is no additional risk in converting cases from moderate sedation to general anesthesia since the conversion process simply involves turning off the nitrous oxide and turning on the flow of sevoflurane to the mask already in place over a child's nose and mouth. However, general anesthesia needs to be available as back-up in all moderate sedation cases.

Performing tympanostomy procedures in young children under moderate sedation in a hospital setting with anesthesia delivered by an anesthesia professional is safe and a well-reasoned alternative to the use of general anesthesia for caregivers and clinicians who are comfortable with this choice.

Warnings

- The TTS is intended for single patient use. DO NOT REUSE.
- Use the TTS with an ear speculum to avoid injury to the auditory canal.
- Do not use the TTS device if the visual depth markers provided (a visual tab located on the lateral end of the ventilation tube, and/or a marker band located on the cutting sheath) cannot be seen during use within the ear canal.
- Do not advance the visual depth markers past the tympanic membrane to avoid damage to the middle or inner ear.
- Do not attempt to re-load a deployed myringotomy tube or to load a new myringotomy tube into the TTS device.
- Do not bend or shape the device. This may cause device damage.
- Do not apply suction through the tip of the device while it is located behind the TM.
- When using the TTS for tympanostomy tube placement in children:
 - Either general anesthesia or moderate sedation is recommended.
 - The anesthetic regimen should be determined by the attending otolaryngologist and anesthesia professional.
 - The tympanostomy procedure should only be performed in a hospital or ambulatory surgical center setting, with the anesthesia delivered by an anesthesia professional.

Draft Instructions For Use

Precautions

- Follow standard hospital/clinic policies and procedures.
- Ensure the auditory canal is sufficiently clean to allow direct visualization of the TM and of the TTS device during tube placement.
- Insertion location of the TTS on the tympanic membrane should be chosen to avoid damage to the malleus and the ossicular chain.
- Avoid excessive penetration depths with the TTS device to reduce the risk of injury to vasculature or nerves in the case of abnormal anatomy.
- Completely retract the cutting sheath after tube insertion and prior to applying suction through the TTS device.
- When applying suction through the TTS device after tube insertion, ensure that the tube is not inadvertently pulled out of the myringotomy.
- Suction cannot be applied through the TTS device prior to tube deployment. Attempts to apply suction prior to tube insertion or to clear a perceived blockage prior to insertion may cause the ventilation tube to deploy erratically.
- Inspect the packages and devices carefully. Do not use if the package or device is damaged.
- Do not use if the expiration dates are exceeded.
- Use caution in opening the packaging and removing the devices to insure the devices are not damaged.

Contraindications

- Known allergy to implant materials.
- Patient not indicated for a tympanostomy procedure.
- Anatomy precludes visualization and access to the tympanic membrane.

Potential Complications

Possible risks associated with the device may include but are not limited to:

- Otorrhea,
- Acute tube extrusion,
- Chronic tube extrusion,
- Tube dislocating into middle ear,
- Tube clogging,
- Bleeding,
- Vertigo,
- Nausea,
- Infection,
- Hearing loss,
- Facial nerve injury.

Draft Instructions For Use

Restrictions

The TTS should be only operated by physicians experienced in tympanostomy procedures, which have reviewed this Instruction for Use and understood the use of the TTS.

Maintenance

The device is a single patient-use disposable product. No maintenance is required.

TTS Components

Disposable Components (provided EO Treated):

- TTS (Tympanostomy Tube System with Tip Assembly)
- TTS Tip Assembly
- Ventilation tubes (PN 05-1026-009)

Other Recommended Components (not provided)

- Ear speculum
- Vacuum system and appropriate suction tubing

Draft Instructions For Use

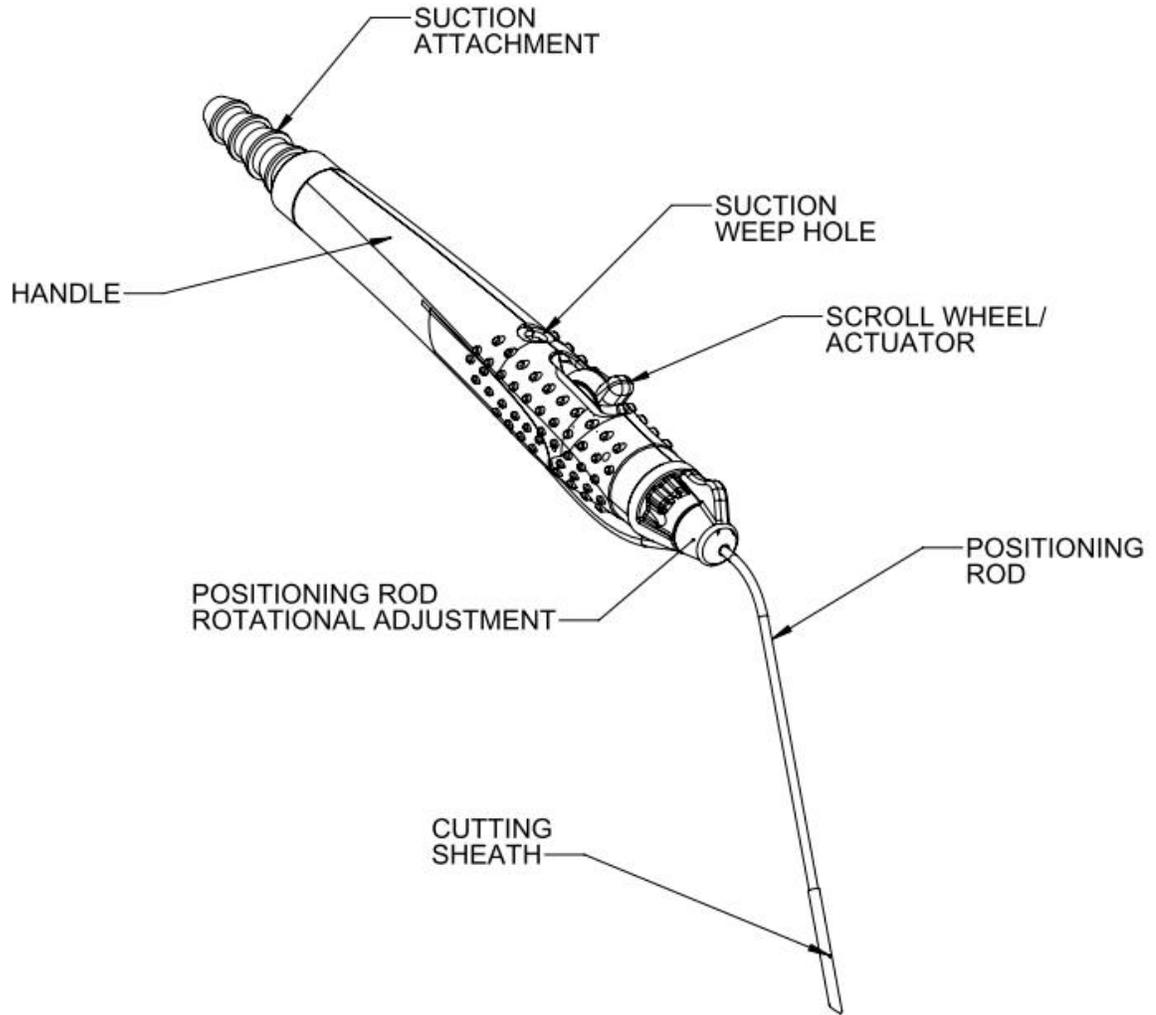


Figure 1. Tympanostomy Tube Inserter

Draft Instructions For Use

Setup

- Carefully remove the TTS from the packaging.
- Inspect the TTS upon removal from packaging to make sure the device is not damaged.
- Verify that the ventilation tube is properly loaded within the device and that the depth indicator is visible (see figure 2).

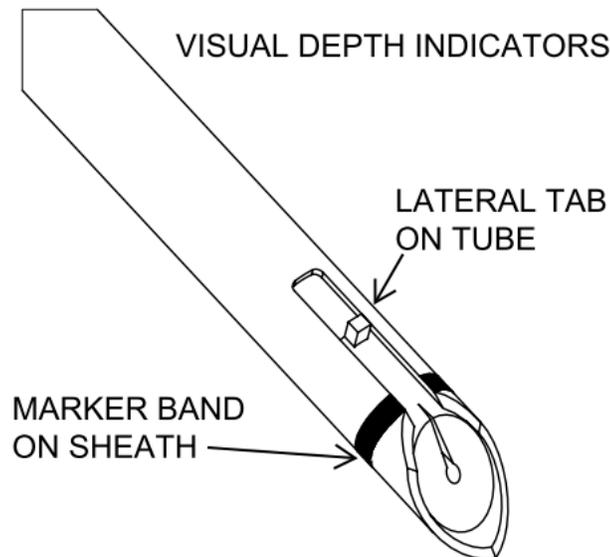


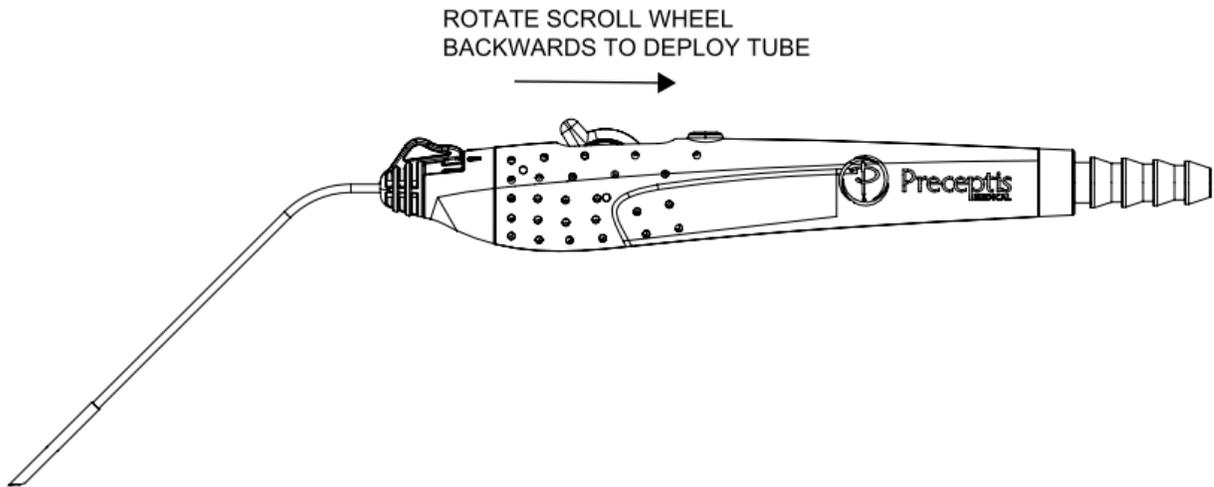
Figure 2. Close up of loaded ventilation tube showing correct placement within device and depth indicators.

Procedural steps:

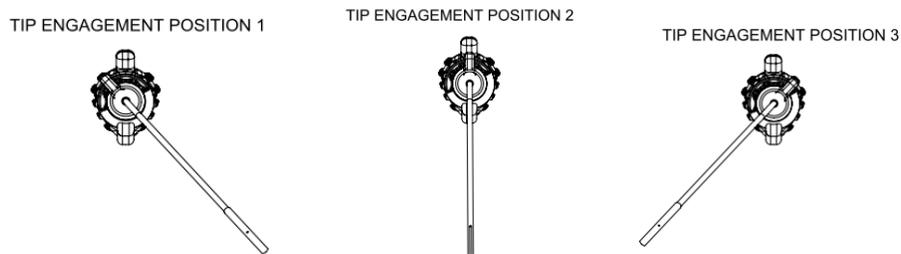
1. If suction is to be used, attach suction tubing to the barbed fitting located on the TTS handle.
2. Insert an ear speculum into the outer ear canal following routine preparation. The ear canal and area around the tympanic membrane must be cleaned sufficiently to allow for good visualization of the tympanic membrane and the visual depth indicator located on the TTS.
3. Under visualization, for example through an operating microscope, manually advance the TTS through the speculum and down the ear canal such that the cutting component pierces the tympanic membrane in the location indicated for ventilation tube insertion.

Draft Instructions For Use

4. Advance the TTS until the beveled portion of the cutting sheath is completely through the TM and the visual depth indicator (visualization tab on the tube or visualization marker band on the cutting sheath) is visible proximal to the TM.
5. Rotate the scroll wheel located on the device handle BACKWARDS (see figure below) to retract the cutting sheath and position the ventilation tube across the TM. Continue to rotate the scroll wheel through its full range of motion to fully retract the cutting sheath.
6. Apply suction if desired by covering the suction weep hole located on the handle.
7. Retract the TTS from the ear canal and dispose of appropriately.

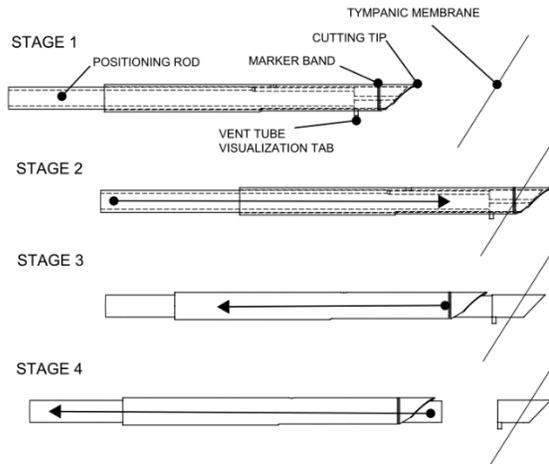


The tip assembly is user adjustable to three different angular orientations to provide improved ergonomics for the user (see figures below). The following three figures show the three tip orientations possible. The tip is adjusted by grasping the tip adjustment tab and twisting it while holding the handle. Do not adjust the tip by grasping the positioning rod as this may damage the tip assembly.



Draft Instructions For Use

The following schematic illustrates the steps taken with the device to perform ventilation tube placement. A close up of the front of the device is shown illustrating the tympanic membrane, the stainless steel positioning/suction tube, the cutting component, and the ventilation tube. The ventilation tube is constrained within the cutting component and is held in place by friction. A slot in the cutting component allows direct visualization of the vent tube throughout the procedure. The cutting component retracts axially along the positioning tube when the scroll wheel on the handle is turned.



Stage 1 – The device is manually advanced down the ear canal.

Stage 2 – The entire device is manually advanced so that the cutting tip pierces the tympanic membrane. A slot in the cutting component allows visualization of the vent tube, ensuring it is positioned correctly in relation to the TM.

Stage 3 – Using the scroll wheel on the handle, the clinician retracts the cutting component. The positioning rod tube remains stationary and pushes the vent tube out of the cutting component, leaving it correctly positioned across the TM.

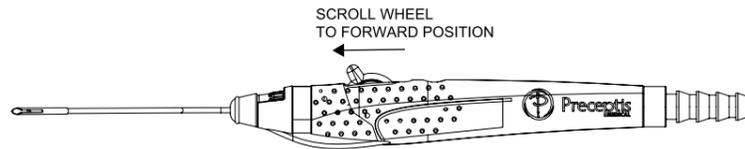
Stage 4 - The sharp edge of the cutting component is protected after retraction.

Draft Instructions For Use

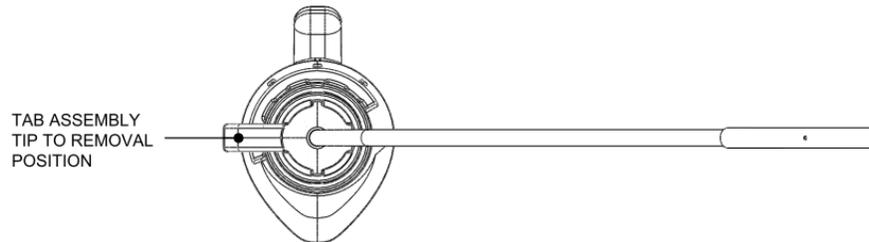
Tip Assembly Replacement:

Tip Assembly Removal

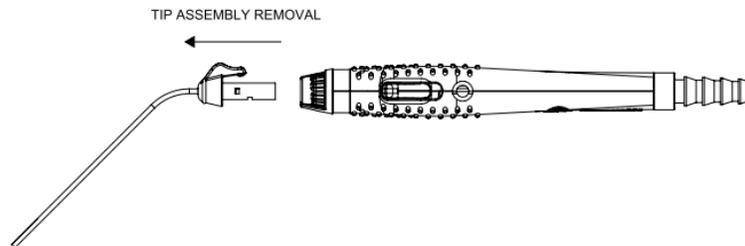
1. Return scroll wheel to the fully forward position.



2. Rotate Tip Assembly counterclockwise as far as it will turn, until the tab on rotating nosepiece is aligned with the insertion groove on the handle nosepiece.



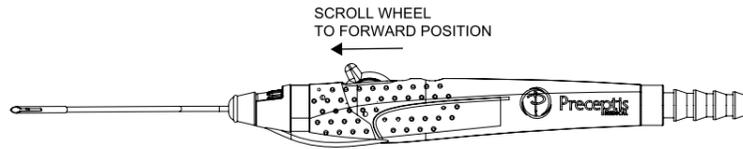
3. Grasping the plastic rotating nosepiece, firmly pull straight out on the tip assembly until it is fully disengaged from the handle.



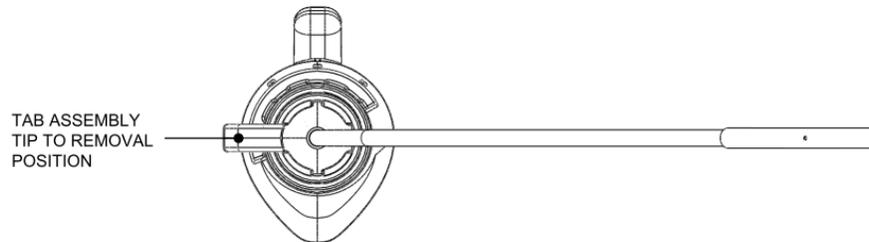
Draft Instructions For Use

Tip Assembly Insertion:

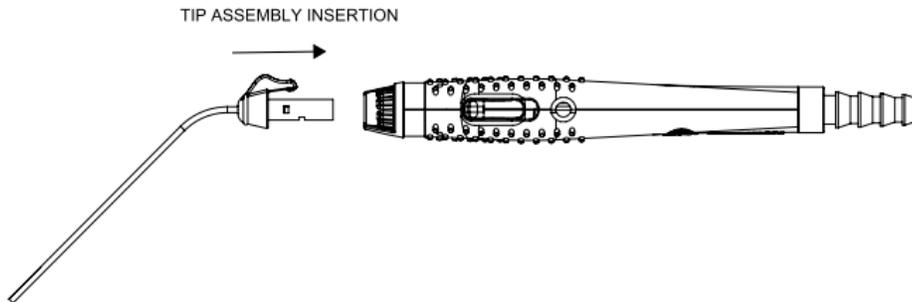
1. Position scroll wheel in the fully forward position.



2. Align tab on rotating nosepiece with insertion groove on handle nosepiece.

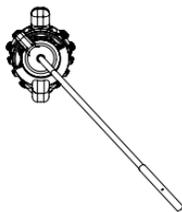


3. Insert rotating nosepiece into handle, ensuring that scroll wheel remains in fully forward position



4. Once the tip assembly is fully inserted, rotate clockwise to desired orientation to engage with the handle.

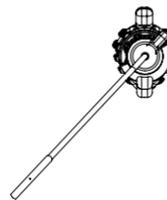
TIP ENGAGEMENT POSITION 1



TIP ENGAGEMENT POSITION 2



TIP ENGAGEMENT POSITION 3



Draft Instructions For Use

Operating and Storage Conditions

Disposal

All components of the TTS are single patient-use.

Functional Life

All components of the TTS are single patient-use devices and must be used prior to the stated expiration date.

Definitions of Symbols

	DO NOT REUSE		Date of Manufacture
	Batch/Lot Code		Catalog Number
	Serial Number		Sterilized Using Ethylene Oxide
	Use by		

Draft Instructions For Use

Specifications Table

System Component	Specification	
Tympanostomy Tube Inserter – Replaceable Tip <i>PN 05-1008-005</i> <i>PN 05-1008-006</i>	Cutting Sheath Diameter	0.072" (1.8 mm)
	Positioning Rod	0.060" (1.5 mm)
	Working Length	2.6" (65 mm)
Tympanostomy Tube Introducer - Handle <i>PN 05-1001-007</i> <i>PN 05-1001-008</i>	Length	5.125 in. (13 cm)
Ventilation Tube	05-1026-009	Inside Diameter 0.039" (1.0 mm)
05-1001-501	-90 Handle Assembly, 05-1001-007 +90 Tip Assembly, 05-1008-005 Two tubes, 05-1029-009	
05-1001-502	+90 Handle Assembly, 05-1001-008 +90 Tip Assembly, 05-1008-006 Two tubes, 05-1029-009	
05-1001-503	-90 Handle Assembly, 05-1001-007 -90 Tip Assembly, 05-1008-005 Two tubes, 05-1029-009	

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60-1075-001 Revision 01

ASA Definition: Continuum of Depth of Sedation

CONTINUUM OF DEPTH OF SEDATION: DEFINITION OF GENERAL ANESTHESIA AND LEVELS OF SEDATION/ANALGESIA*

Committee of Origin: Quality Management and Departmental Administration

**(Approved by the ASA House of Delegates on October 27, 2004, and amended on
October 21, 2009)**

	<i>Minimal Sedation Anxiolysis</i>	<i>Moderate Sedation/ Analgesia</i> <i>(“Conscious Sedation”)</i>	<i>Deep Sedation/ Analgesia</i>	<i>General Anesthesia</i>
<i>Responsiveness</i>	Normal response to verbal stimulation	Purposeful** response to verbal or tactile stimulation	Purposeful** response following repeated or painful stimulation	Unarousable even with painful stimulus
<i>Airway</i>	Unaffected	No intervention required	Intervention may be required	Intervention often required
<i>Spontaneous Ventilation</i>	Unaffected	Adequate	May be inadequate	Frequently inadequate
<i>Cardiovascular Function</i>	Unaffected	Usually maintained	Usually maintained	May be impaired

Minimal Sedation (Anxiolysis) is a drug-induced state during which patients respond normally to verbal commands. Although cognitive function and physical coordination may be impaired, airway reflexes, and ventilatory and cardiovascular functions are unaffected.

Moderate Sedation/Analgesia (“Conscious Sedation”) is a drug-induced depression of consciousness during which patients respond purposefully** to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.

* Monitored Anesthesia Care does not describe the continuum of depth of sedation, rather it describes “a specific anesthesia service in which an anesthesiologist has been requested to participate in the care of a patient undergoing a diagnostic or therapeutic procedure.”

** Reflex withdrawal from a painful stimulus is NOT considered a purposeful response.

ASA Definition: Continuum of Depth of Sedation

CONTINUUM OF DEPTH OF SEDATION: DEFINITION OF GENERAL ANESTHESIA AND LEVELS OF SEDATION/ANALGESIA

Deep Sedation/Analgesia is a drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully** following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained.

General Anesthesia is a drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired.

Because sedation is a continuum, it is not always possible to predict how an individual patient will respond. Hence, practitioners intending to produce a given level of sedation should be able to rescue*** patients whose level of sedation becomes deeper than initially intended. Individuals administering Moderate Sedation/Analgesia (“Conscious Sedation”) should be able to rescue*** patients who enter a state of Deep Sedation/Analgesia, while those administering Deep Sedation/Analgesia should be able to rescue*** patients who enter a state of General Anesthesia.

** Reflex withdrawal from a painful stimulus is NOT considered a purposeful response.

*** Rescue of a patient from a deeper level of sedation than intended is an intervention by a practitioner proficient in airway management and advanced life support. The qualified practitioner corrects adverse physiologic consequences of the deeper-than-intended level of sedation (such as hypoventilation, hypoxia and hypotension) and returns the patient to the originally intended level of sedation. It is not appropriate to continue the procedure at an unintended level of sedation.