Traditional 510k Summary

General Information **Date: 4/29/2015**

1.	**Applicant**	Genadyne Biotechnologies, Inc. 16 Midland Ave, Hicksville, NY 11801 (t) 516.487.8787 (f) 516.977-8974
2.	**Contact Person**	Mr. Chien-Ming GOH (Andrew) Vice President Genadyne Biotechnologies Inc. 16 Midland Ave, Hicksville, NY 11801 (t) 516.217.0101 (f) 516.977.8974
3.	**Trade Name**	Genadyne XLR8 White Foam Dressing Kit (Ref:PVA-FOAM1)
4.	**Common Name**	Foam Dressing
5.	**Classification Name**	Negative Pressure Wound Therapy Powered Suction Pump and Accessories
6.	**Regulation Number**	21 CFR 878.4780
7.	**Product Code**	OMP
8.	**Class in which Device has been placed**	Class II
9.	**Panel**	General & Plastic Surgery
10.	**Reason for Premarket Notification**	New Device
11.	**Identification of Legally Marketed Device Which We Can Claim Substantial Equivalence (Predicate Device)**	A4-XLR8 Foam Dressing K092992
12.	**Brief Description of Device**	The Genadyne XLR8 White Foam Kit consists of a XLR8 Port, XLR8 Transparent Film and a XLR8 White Foam. Each component are packaged, sealed and sterilized individually and then bagged

into a kit.

13. **Indications for use [21 CFR 807.92(a)(5)]**

Genadyne XLR8 White Foam Dressing Kit is intended to be used in conjunction with the Genadyne A4-XLR8 Wound Vacuum System (K090638) to deliver negative pressure wound therapy to the wound. Genadyne A4-XLR8 Wound Vacuum System is indicated for patients who would benefit from a suction device particularly as the device may promote wound healing by the removal of excess exudates, infectious material and tissue debris.

XLR8 White Foam Dressing is appropriate for use on the following wounds:

- Pressure ulcers
- Diabetic/Neuropathic Ulcers
- Venous insufficiency Ulcers
- Traumatic wounds
- Post-operative and dehisced surgical wounds
- Skin flap and grafts

The Genadyne XLR8 White Foam Dressing Kit is a Rx only device.

14**. Technological Characteristics**

No.		Foam	Port Tubing	Film
1.	Materials Used:	Polyvinyl Alcohol Dressing	Silicone	Polyurethane
2.	Size:	20 cm x 15 cm x 1 cm 15 cm x 10 cm x 1 cm 7.5 cm x 10 cm x 1 cm	31 inches	26 x 30 cm

Table of Comparison to Predicate Devices:

	Predicate	New
Parameters	Genadyne A4-XLR8 Foam Dressing	Genadyne XLR8 White Foam Dressing Kit
510(k) Number	K092992	TBD
Indications for Use	Genadyne A4-XLR8 Foam Dressing is intended to be used in conjunction with the Genadyne A4 Wound Vacuum System (K082676) to deliver negative pressure wound therapy to the wound.	Genadyne XLR8 White Foam Dressing Kit is intended to be used in conjunction with the Genadyne A4-XLR8 Wound Vacuum System (K090638) to deliver negative pressure wound therapy to the

	Genadyne A4 Wound Vacuum System is indicated for patients who would benefit from a suction device, particularly as the device may promote wound healing by the removal of excess exudates, infectious material and tissue debris. A4-XLR8 Foam Dressing is appropriate for use on the following wounds:Pressure ulcers • Diabetic/Neuropathic Ulcers • Venous insufficiency ulcers • Traumatic wounds • Post-operative and dehisced surgical wounds • Skin flap and graft	wound. Genadyne A4-XLR8 Wound Vacuum System is indicated for patients who would benefit from a suction device particularly as the device may promote wound healing by the removal of excess exudates, infectious material and tissue debris. XLR8 White Foam Dressing is appropriate for use on the following wounds: • Pressure ulcers • Diabetic/Neuropathic Ulcers • Venous insufficiency ulcers • Traumatic wounds • Post-operative and dehisced surgical wounds • Skin flap and grafts
Foam Dressing Material	Flexible Polyether and Polyester Polyurethane Foam	Polyvinyl Alcohol Dressing
Hydrophobic	Yes	Yes
Sizes:	7.5 cm X 10 cm x 3.3cm 12.5 cm x 18 cm x 3.3 cm 15 cm x 26 cm x 3.3 cm	20 cm x 15 cm x 1 cm 15 cm x 10 cm x 1 cm 7.5 cm x 10 cm x 1 cm
For use with Negative Pressure Wound Therapy Systems	Yes	Yes
Sterile	Yes	Yes
Sterilization Method	EO	Gamma Radiation for White Foam, EO for Silicone Port and Transparent Film
Kit Content	Silicone Tubing Transparent Adhesive Film	Silicone Port Transparent Adhesive Film

15. Summary of Non clinical Tests

Device	Tests	Rationale
XLR8 White Foam Kit	ISO 10993-5 L929 Neutral Red Uptake Cytotoxicity Test	Based on the criteria of the protocol and the ISO 10993-5 Guidelines, the test article meets the requirements of the tests and s not considered to have a cytotoxic effect.
	ISO 10993-10 Kligman Maximization Test	Based on the defined scoring system of Kligman, this is a Grade 1 reaction and the test article is classified as having weak allergenic potential. A Grade 1 sensitization rate is not considered significant and the test article meets the requirements of the ISO 10993-10 guidelines.
	ISO 10993-10 Intracutaneous Injection Test	The test article sites did not show a significantly greater biological reaction than the sites injected with the control article. Based on the criteria of the protocol, the test article meets the requirements of the ISO 10993-10 guidelines.
	Bench Tests for Performance	Results from the bench test shows that the dressing kit components are all compatible and

	Evaluation	performs up to the acceptability criteria.
	Stability Test	Stability tests was performed on our foams and components with 2 year accelerated aging and continuous real time. Devices has passed and met all expectations of the stability tests in terms of bioburden, packaging, seal integrity and performance.

16. **Conclusion & Determination of Substantial Equivalence**

Based on the information presented above, it is concluded that the XLR8 White Foam Dressing Kit is substantially equivalent to the predicate devices and is safe and effective to be used together with a negative pressure wound therapy device.

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

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

April 30, 2015

Genadyne Biotechnologies Incorporated
Mr. Chien-Ming (Andrew) Goh
Vice President
16 Midland Avenue
Hicksville, New York 11801

Re: K142646
Trade/Device Name: Genadyne XLR8 White Foam Dressing Kit
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: Class II
Product Code: OMP
Dated: March 27, 2015
Received: March 30, 2015

Dear Mr. Goh:

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" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of 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,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142646

Device Name
Genadyne XLR8 White Foam Dressing Kit

Indications for Use *(Describe)*
Genadyne XLR8 White Foam Dressing Kit is intended to be used in conjunction with the Genadyne A4-XLR8 Wound Vacuum System (K090638) to deliver negative pressure wound therapy to the wound. Genadyne A4-XLR8 Wound Vacuum System is indicated for patients who would benefit from a suction device particularly as the device may promote wound healing by the removal of excess exudates, infectious material and tissue debris.

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- Skin flap and grafts

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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.

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Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@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."

K142646

September 15, 2014

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

Dear Sir/Madam:

Enclosed please find an eCopy in a DVD, an original and an exact copy of the Traditional 510(k) application for the device that Genadyne Biotechnologies, Inc. intends to market. The device is a Foam Dressing Kit.

The eCopy is an exact duplicate of the paper copy.

We would appreciate a rapid review so that we can plan to distribute the product upon your approval.

If there are any questions, please contact me at (516) 217-0101. Any correspondence referring to this 510(k) submission should be forwarded to the office of:

Mr. Chien-Ming (Andrew) Goh
16 Midland Ave, Hicksville, NY 11801

Sincerely,

Chien-Ming Goh
Vice President and Official Correspondent for
Genadyne Biotechnologies, Inc.

104
1 of 0

Table of Contents

September 15, 2014

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

Dear Sir/Madam:

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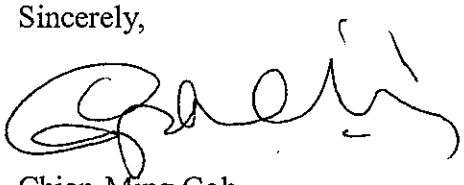
Mr. Chien-Ming (Andrew) Goh
16 Midland Ave, Hicksville, NY 11801

Sincerely,



Chien-Ming Goh
Vice President and Official Correspondent for
Genadyne Biotechnologies, Inc.

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: [redacted] Write the Payment Identification number on your check.

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)	2. CONTACT NAME
GENADYNE BIOTECHNOLOGIES INC 9 Red Ground Rd Old Westbury NY 11568 US	Chien Ming Goh 2.1 E-MAIL ADDRESS andrew@genadyne.com 2.2 TELEPHONE NUMBER (include Area code) 516-4878787 112 2.3 FACSIMILE (FAX) NUMBER (Include Area code) 516-4877878
1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) *****9276	

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

Select an application type:	3.1 Select a center
[X] Premarket notification(510(k)); except for third party	[X] CDRH
[ ] 513(g) Request for Information	[ ] CBER
[ ] Biologics License Application (BLA)	3.2 Select one of the types below
[ ] Premarket Approval Application (PMA)	[X] Original Application
[ ] Modular PMA	Supplement Types:
[ ] Product Development Protocol (PDP)	[ ] Efficacy (BLA)
[ ] Premarket Report (PMR)	[ ] Panel Track (PMA, PMR, PDP)
[ ] 30-Day Notice	[ ] Real-Time (PMA, PMR, PDP)
	[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)

[X] 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: [redacted]

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?

[X] 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 [X] 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

[redacted]

Form FDA 3601 (01/2007)

"Close Window" Print 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)*
09/17/2014	[redacted]	

SECTION A TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Request for Feedback
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-Submission
☐ Premarket Report	☐ Special	☐ Notice of Completion	☒ Traditional	☐ Informational Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Submision Issue Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Day 100 Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Agreement Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Determination Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Study Risk Determination
	☐ Amendment to PMA & HDE Supplement			☐ Other *(specify):*
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission):*
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

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

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name	Establishment Registration Number *(if known)*		
Genadyne Biotechnologies, Inc.	2435947		
Division Name *(if applicable)*	**Phone Number *(including area code)***		
	516-487-8787		
Street Address	**FAX Number *(including area code)***		
16 Midland Ave	516-977-8974		
City	**State / Province**	**ZIP/Postal Code**	**Country**
Hicksville	NY	11801	USA
Contact Name			
Chien Ming GOH			
Contact Title	**Contact E-mail Address**		
Vice President, Regulatory Affairs	andrew@genadyne.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**		

PSC Publishing Services (301) 443-6740 EF

SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE

- ☐ New Device
- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site

- ☐ Change in design, component, or specification:
  - ☐ Software / Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*

- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager

- ☐ Process change:
  - ☐ Manufacturing ☐ Packaging
  - ☐ Sterilization
  - ☐ Other *(specify below)*

- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance Characteristics
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*

- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment

- ☐ Response to FDA correspondence:

- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address

- ☐ Other Reason *(specify):*

SECTION D2 REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access

- ☐ Change in:
  - ☐ Correspondent / Applicant
  - ☐ Design / Device
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol - Feasibility
  - ☐ Protocol - Other
  - ☐ Sponsor

- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ Final

- ☐ Response to FDA Letter Concerning:
  - ☐ Conditional Approval
  - ☐ Deemed Approved
  - ☐ Deficient Final Report
  - ☐ Deficient Progress Report
  - ☐ Deficient Investigator Report
  - ☐ Disapproval
  - ☐ Request Extension of Time to Respond to FDA
  - ☐ Request Meeting
  - ☐ Request Hearing

- ☐ Other Reason *(specify):*

SECTION D3 REASON FOR SUBMISSION - 510(k)

- ☒ New Device
- ☐ Additional or Expanded Indications
- ☐ Change in Technology

- ☐ Other Reason *(specify):*

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	OMP	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

☒ 510 (k) summary attached
☐ 510 (k) statement

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

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K092992	1	A4-XLR8 Foam Dressing	1	Genadyne
2		2		2	
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

Negative Pressure Wound Therapy Foam Dressing Kit

	Trade or Proprietary or Model Name for This Device		Model Number
1	XLR8 White Foam Dressing Kit	1	PVA-FOAM1
2	XLR8 White Foam Small Dressing Kit	2	PVA-SFOAM1
3		3	
4		4	
5		5	

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

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

Data Included in Submission

☒ Laboratory Testing ☐ Animal Trials ☐ Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
OMP		☐ Class I ☒ Class II ☐ Class III ☐ Unclassified

Classification Panel

General & Plastic Surgery

Indications *(from labeling)*

Genadyne XLR8 White Foam Dressing is intended to be used in conjunction with the Genadyne A4-XLR8 Wound Vaccum System (K090638) to deliver negative pressure to the wound. Genadyne A4-XLR8 Wound Vacuum System is indicated for patients who would benefit from a suction device particularly as the device may promote wound healing.

XLR8 White Foam Dressing is appropriate for use on the following wounds: Pressure ulcers, Diabetic/Neuropathic Ulcers, Venous insufficiency Ulcers, Traumatic wounds, Post-operative and dehisced surgical wounds, Skin flap and grafts, undermining and tunneling wounds.

Note: Submission of the information entered in Section H does not affect the need to submit device establishment registration.	FDA Document Number *(if known)*

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

[redacted]

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

SECTION H *(Continued)*

[redacted]

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

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

SECTION I — UTILIZATION OF STANDARDS

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

	Standards No.	Standards Organization	Standards Title	Version	Date
1	10993-5	ISO	Biological evaluation of medical devices	2009	
2	10993-10	ISO	Biological evaluation of medical devices	2009	
3	11137	ISO	Sterilization Of Health Care Products - Radiation	2006	
4	11607-1	ISO	Packaging for Terminally Sterilized Medical devices - Materials etc.	2006	
5	11607-2	ISO	Packaging for Terminally Sterilized Medical devices - Validations etc.	2006	
6					
7					

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.

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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

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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

[redacted]

[redacted]

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

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

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Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

10993-5:2009 Biological Evaluation Of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#2-153	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

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

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

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

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

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
10993-5:2009 Biological Evaluation Of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ◆		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ◆		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ 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.

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

10993-10:2010 Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#2-173	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

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

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
10993-10:2010 Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ᶜ		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ᶜ		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ᶜ		
DESCRIPTION		
JUSTIFICATION		

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

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

11137-1:2006/(R) 2010, Sterilization Of Health Care Products - Radiation - Part 1: Requirements For Development, Validation, And Routine Control Of A Sterilization Process For Medical Devices.

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#14-297	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

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

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

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STANDARD TITLE

11137-1:2006/(R) 2010, Sterilization Of Health Care Products - Radiation - Part 1: Requirements For Development, Validation, And Routine Control Of A Sterilization Process For Medical Devices.

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ◆		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ◆		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ◆		
DESCRIPTION		
JUSTIFICATION		

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

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

11607-2:2006/(R)2010 Packaging For Terminally Sterilized Medical Devices - Part 2: Validation Requirements For Forming Sealing And Assembly Processes

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#14-194	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
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Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

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STANDARD TITLE

11607-2:2006/(R)2010 Packaging For Terminally Sterilized Medical Devices - Part 2: Validation Requirements For Forming Sealing And Assembly Processes

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ⁎		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ⁎		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ⁎		
DESCRIPTION		
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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

11607-1:2006/(R)2010 Packaging For Terminally Sterilized Medical Devices - Part 1: Requirements For Materials, Sterile Barrier Systems And Packaging Systems

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#14-193	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

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STANDARD TITLE
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CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ⁺		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ⁺		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ⁺		
DESCRIPTION		
JUSTIFICATION		

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September 16, 2014

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

Dear Sir/Madam:

In accordance with Section 510(k) of the Federal Food, Drug and Cosmetic Act, and in conformance with 21 CFR Part 807, pre-market notification is hereby made of the intention of to introduce into interstate commerce for commercial distribution, the Genadyne White Foam Dressing Kit.

The following information is being submitted in conformance with 21 CFR Part 807.87, the "DCRND Guidance for Format and Content for Premarket Notification (510(k) Submissions."

Section 1 – General Information

a. Applicant:	Genadyne Biotechnologies Inc. 16 Midland Drive Hicksville, NY 11021 T: (516) 487-8787 F: (516) 977-8974 www.genadyne.com
Registration Number:	2435947
Owner/Operator Number:	9006819
b. Contact Person:	Mr. Chien-Ming Goh Vice President andrew@genadyne.com

c. Trade/Proprietary Name Including Model Number of Device:

Genadyne XLR8 White Foam Dressing Kit, PVA-FOAM1

d. Common Name or Classification Name (21 CFR Part 807.87) of Device:

Negative Pressure Wound Therapy Foam Dressing (21 CFR 878.4780, Product Code OMP) Class II

e. Address of Manufacturing Facility:

Genadyne Biotechnologies, Inc.
16 Midland Drive
Hicksville, NY 11801
T: (516) 487-8787
F: (516) 487-7878
www.genadyne.com

f. Class in which Device has been placed:

Class II

g. Reason for Premarket Notification:

Introduction of a new device that is substantially equivalent to a legally marketed device.

h. Identification of Legally Marketed Device Which We Claim Substantial Equivalence (Predicate Device)

A4-XLR8 Foam Dressing K092992

Section 2 – Summary & Certification

a. 510(k) Summary

Please refer to Attachment A, "510(k) Summary", which is our summary of safety and effectiveness information upon which an equivalence determination can be based. This can be released to the public.

b. Truthful and Accurate Statement

Please refer to Attachment B, Truthful and Accurate Statement which has been signed by a responsible person of the company.

Section 3 – Indication for Use

Please refer to Attachment C, "Indication for Use" statement.

Section 4 – Product Info, Accessories & Labeling

Please refer to Attachment D for the proposed product information and product labeling.

Section 5 – Comparative Information

Please refer to Attachment E for a table of comparison.

Section 6 – Non Clinical Tests

Please refer to Attachment F for the stability test report & Biocompatibility tests.

Section 7 – Sterilization Information

Please refer to Attachment G.

Quality Assurance and Manufacturing Controls:

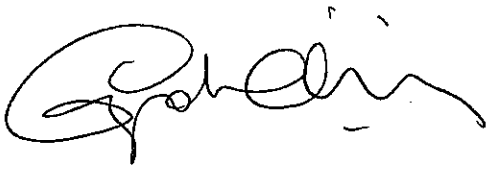
Genadyne Biotechnologies, Inc., operates in compliance with FDA's Good Manufacturing Practice Regulations for Medical Devices (21 CFR Part 820), and, a formally established and controlled Quality Assurance Program. Devices are manufactured and assembled to established and controlled Device Master Record requirements by formally trained and supervised personnel.

We consider our intent to market this device as confidential commercial information and request that it be considered as such by FDA. Our intent to market this device is not considered public information and we have taken precautions to protect this confidentiality.

We would appreciate your reviewing this information at your earliest convenience so that a prompt reply to our request for a clearance can be processed.

If you have any questions, or require additional information, please contact me at 516-217-0101, email at Andrew@genadyne.com or fax at 516-977-8974.

Sincerely,



Chien- Ming Goh
Vice President
Genadyne Biotechnologies, Inc.

Traditional 510k Summary

General Information **Date: July 10, 2014**

1.	**Applicant**	Genadyne Biotechnologies, Inc. 16 Midland Ave, Hicksville, NY 11801 (t) 516.487.8787 (f) 516.977-8974
2.	**Contact Person**	Mr. Chien-Ming GOH (Andrew) Vice President Genadyne Biotechnologies Inc. 16 Midland Ave, Hicksville, NY 11801 (t) 516.217.0101 (f) 516.977.8974
3.	**Trade Name**	Genadyne XLR8 White Foam Dressing Kit (Ref:PVA-FOAM1)
4.	**Common Name**	Foam Dressing
5.	**Classification Name**	Negative Pressure Wound Therapy Powered Suction Pump and Accessories
6.	**Regulation Number**	21 CFR 878.4780
7.	**Product Code**	OMP
8.	**Class in which Device has been placed**	Class II
9.	**Panel**	General & Plastic Surgery
10.	**Reason for Premarket Notification**	New Device
11.	**Identification of Legally Marketed Device Which We Can Claim Substantial Equivalence (Predicate Device)**	A4-XLR8 Foam Dressing K092992
12.	**Brief Description of Device**	Gendayne XLR8 White Foam Dressing Kit is a single-use dressing is housed in a Tyvek/Mylar Peel Pouch.

13. **Indications for use [21 CFR 807.92(a)(5)]**

Genadyne XLR8 White Foam Dressing Kit is intended to be used in conjunction with the Genadyne Wound Vacuum System to deliver negative pressure to the wound. Genadyne Wound Vacuum System is indicated for patients who would benefit from a suction device particularly as the device ma promote wound healing.

XLR8 White Foam Dressing is appropriate for use on the following wounds:

- Pressure ulcers
- Diabetic/Neuropathic Ulcers
- Venous insufficiency Ulcers
- Traumatic wounds
- Post-operative and dehisced surgical wounds
- Skin flap and grafts

14. **Technological Characteristics**

No.		Foam	Port Tubing	Film
1.	Materials Used:	Polyvinyl Alcohol Dressing Moistened with Sterile Water	Silicone	Polyurethane
2.	Size:	15 cm x 10 cm x 1cm 7.5 cm x 10 cm x 1cm	31 inches	26 x 30 cm

Table of Comparison to Predicate Devices:

	Predicate	New
Parameters	Genadyne A4-XLR8 Foam Dressing	Genadyne XLR8 White Foam Dressing Kit
510(k) Number	K092992	TBD
Indications for Use	Genadyne A4-XLR8 Foam Dressing Kits are intended to be used in conjunction with the Genadyne Wound Vacuum System to deliver negative pressure to the wound. Genadyne Wound Vacuum System is indicated for patients who would benefit from a suction device particularly as the device may promote wound healing.	Genadyne XLR8 White Foam Dressing Kits are intended to be used in conjunction with the Genadyne Wound Vacuum to deliver negative pressure to the wound. Genadyne Wound Vacuum System is indicated for patients who would benefit from a suction device particularly as the device may promote wound healing.

	A4-XLR8 Foam Dressing is appropriate for use on the following wounds: • Pressure ulcers • Diabetic/Neuropathic Ulcers • Venous insufficiency ulcers • Traumatic wounds • Post-operative and dehisced surgical wounds • Skin flap and grafts • Undermining and tunneling wounds	XLR8 White Foam Dressing is appropriate for use on the following wounds: • Pressure ulcers • Diabetic/Neuropathic Ulcers • Venous insufficiency ulcers • Traumatic wounds • Post-operative and dehisced surgical wounds • Skin flap and grafts • Undermining and tunneling wounds
Foam Dressing Material	Flexible Polyether and Polyester Polyurethane Foam	Polyvinyl Alcohol Dressing Moistened with Sterile Water
Hydrophobic	Yes	Yes
Sizes:	7.5 cm X 10 cm x 3.3cm 12.5 cm x 18 cm x 3.3 cm 15 cm x 26 cm x 3.3 cm	15 cm x 10 cm x 1cm 7.5 cm x 10 cm x 1cm
For use with Negative Pressure Wound Therapy Systems	Yes	Yes
Sterile	Yes	Yes
Sterilization Method	EO	R
Kit Content	Silicone Tubing Transparent Adhesive Film	Silicone Tubing Transparent Adhesive Film

15. **Conclusion & Determination of Substantial Equivalence**

Based on the information presented above, it is concluded that the XLR8 White Foam Dressing Kit is substantially equivalent to the predicate device.

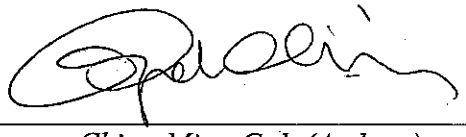
PREMARKET NOTIFICATION

TRUTHFUL AND ACCURATE STATEMENT*

(As Required By 21 CFR 807.87(k))

I certify that in my capacity as Vice President of Genadyne Biotechnologies, Inc., I believe, to the best of my knowledge, that all data and information submitted in the Traditional 510(k) premarket notification are truthful and accurate and that no material fact has been omitted.

(Signature)



Chien-Ming Goh (Andrew)

9/16/2014

(Dated)

(Premarket Notification (510(k)) Number)

* Must be signed by a responsible person of the firm required to submit the premarket notification (e.g., not a consultant for the 510(k) submitter).

INDICATIONS FOR USE

510(k) Number (if known):

Device Name: Genadyne XLR8 White Foam Dressing Kit

Indications For Use:

Genadyne XLR8 White Foam Dressing Kit is intended to be used in conjunction with the Genadyne A4-XLR8 Wound Vacuum System (K090638) to deliver negative pressure to the wound. Genadyne A4-XLR8 Wound Vacuum System is indicated for patients who would benefit from a suction device particularly as the device ma promote wound healing.

XLR8 White Foam Dressing is appropriate for use on the following wounds:

- Pressure ulcers
- Diabetic/Neuropathic Ulcers
- Venous insufficiency Ulcers
- Traumatic wounds
- Post-operative and dehisced surgical wounds
- Skin flap and grafts

Prescription Use __X__ **OR** **Over-The Counter Use_____**
(Per 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Product Description

1.0 Indications for Use:

Genadyne XLR8 White Foam Dressing Kit (**Figures 1**) is intended to be used in conjunction with the Genadyne A4-XLR8 Wound Vacuum System (K090638) to deliver negative pressure to the wound. Genadyne A4-XLR8 Wound Vacuum System is indicated for patients who would benefit from a suction device particularly as the device may promote wound healing.

XLR8 White Foam Dressing Kit is appropriate for use on the following wounds:

- Pressure ulcers
- Diabetic/Neuropathic Ulcers
- Venous insufficiency ulcers
- Traumatic wounds
- Post-operative and dehisced surgical wounds
- Skin flap and grafts

1.1 Product Description:

Genadyne XLR8 White Foam Dressing Kit consist of a rectangular shape foam manufactured using a polyvinyl alcohol foam material (**Figure 1**), a silicone port tubing (**Figure 2**), and a transparent adhesive film dressing (**Figure 3**). This single-use dressing kit is housed in a Tyvek/Mylar Peel Pouch. Each product is sterilized individually.

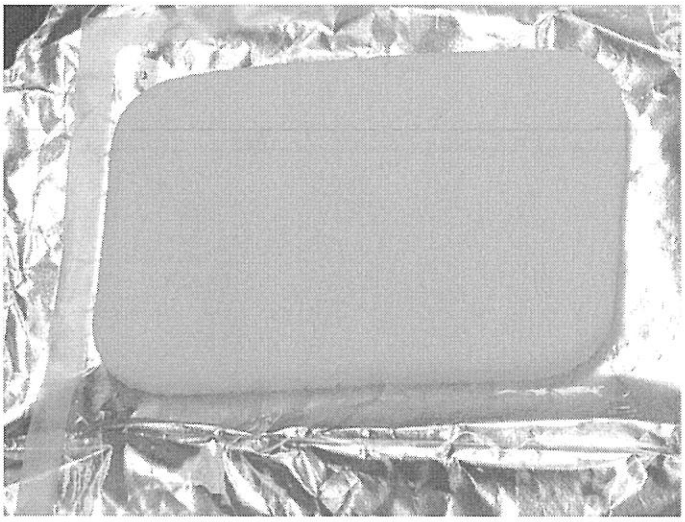
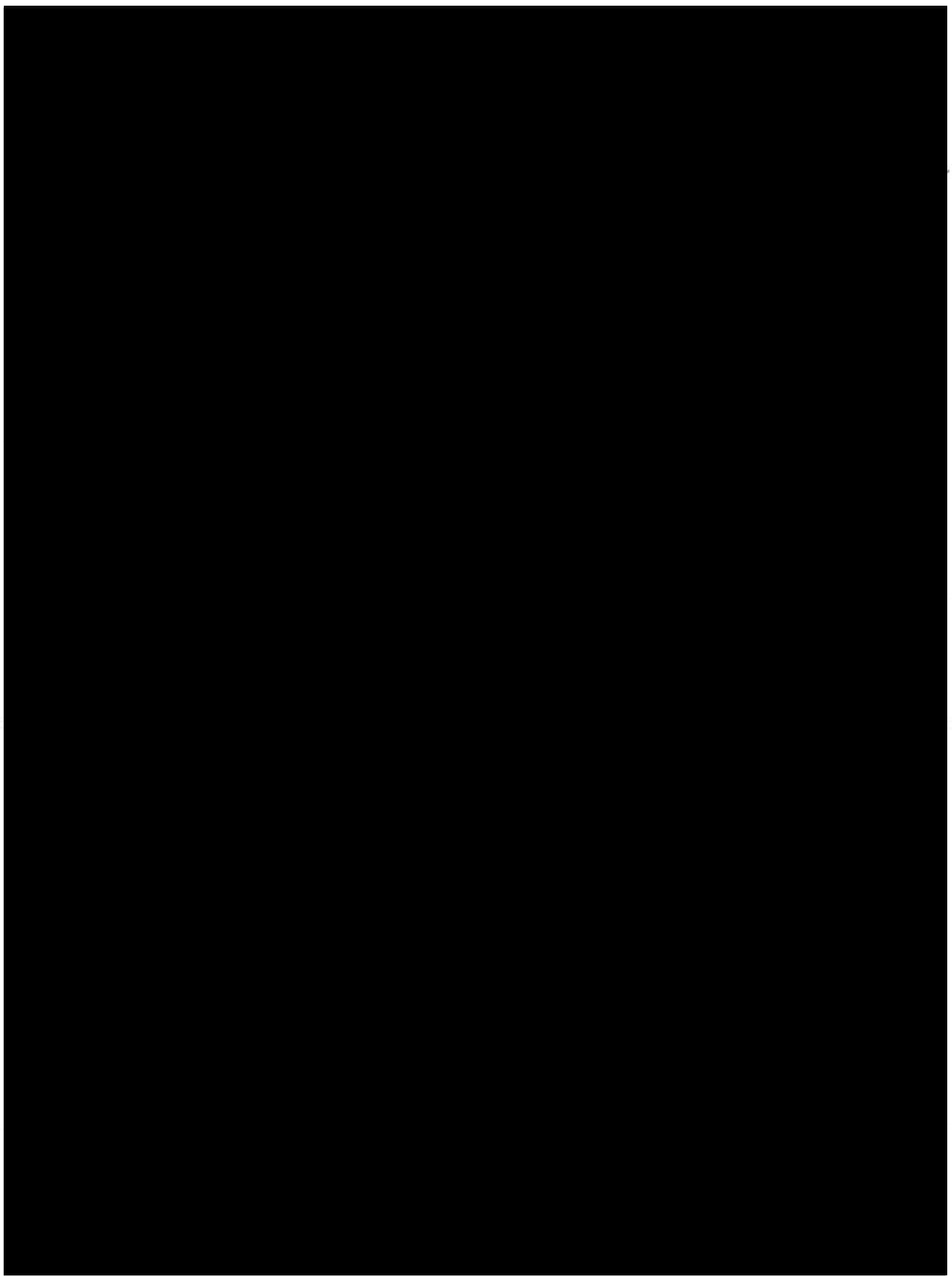


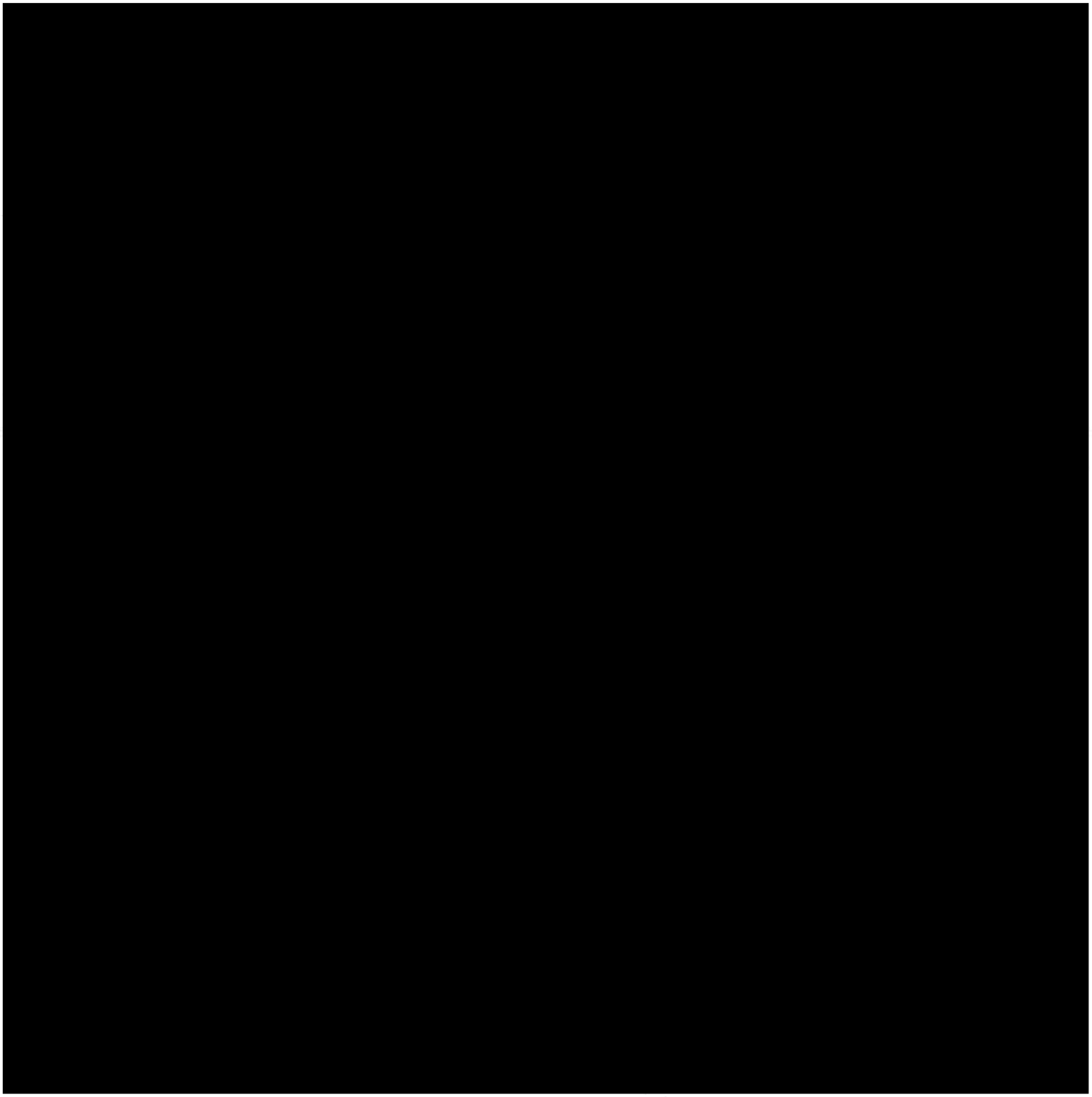
Figure 1



1.2 Nonclinical Testing:

1.3 Product Drawings

Product Drawing



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Predicate Product Comparison

Predicate Product:

Genadyne Biotechnologies A4-XLR8 Foam Dressing was approved on June 29, 2010 under K092992 number.

Predicate Product Comparison Chart

	Predicate	New
Parameters	Genadyne A4-XLR8 Foam Dressing Kit	Genadyne XLR8 White Foam Dressing Kit
510(k) Number	K092992	TBD
Indications for Use	Genadyne A4-XLR8 Foam Dressing Kits are intended to be used in conjunction with the Genadyne Wound Vacuum System to deliver negative pressure to the wound. Genadyne Wound Vacuum System is indicated for patients who would benefit from a suction device particularly as the device may promote wound healing. A4-XLR8 Foam Dressing is appropriate for use on the following wounds: • [redacted] • Diabetic/Neuropathic Ulcers • Venous insufficiency ulcers • Traumatic wounds • Post-operative and dehisced surgical wounds • Skin flap and grafts • [redacted]	Genadyne XLR8 White Foam Dressing Kits are intended to be used in conjunction with the Genadyne Wound Vacuum System to deliver negative pressure to the wound. Genadyne Wound Vacuum System is indicated for patients who would benefit from a suction device particularly as the device may promote wound healing. XLR8 White Foam Dressing is appropriate for use on the following wounds: • Pressure ulcers • Diabetic/Neuropathic Ulcers • Venous insufficiency ulcers • Traumatic wounds • Post-operative and dehisced surgical wounds • Skin flap and grafts • [redacted]
Foam Dressing Material	Flexible Polyether and Polyester Polyurethane Foam	Polyvinyl Alcohol Dressing [redacted]
Hydrophobic	Yes	Yes
Sizes:	7.5 cm X 10 cm x 3.3cm 12.5 cm x 18 cm x 3.3 cm 15 cm x 26 cm x 3.3 cm	15 cm x 10 cm x 1cm 7.5 cm x 10 cm x 1cm
For use with Negative Pressure Wound Therapy Systems	Yes	Yes
Sterile	Yes	Yes

Sterilization Method	EO	[redacted]
Kit Content	Silicone Tubing Transparent Adhesive Film	Silicone [redacted] Transparent Adhesive Film

[redacted]

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(b)(4)Proprietary Information-Testing

K142646/S

(b)(4)Proprietary Information

RETURN RECEIPT REQUESTED

October 10, 2014

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

Dear Sir/Madam:

Enclosed please find an eCopy in a DVD, and an original copy of the response to the K142646 RTA Checklist.

The eCopy is an exact duplicate of the paper copy.

We would appreciate a rapid review so that we can plan to distribute the product upon your approval.

If there are any questions, please contact me at 516-217-0100. Any correspondence referring to this 510(k) submission should be forwarded to:

Mr. Chien-Ming GOH, Genadyne Biotechnologies Inc.,
16 Midland Ave, Hicksville, NY 11801.

Sincerely,

Chien-Ming GOH
Vice President and Official Correspondent for
Genadyne Biotechnologies Inc.

RETURN RECEIPT REQUESTED

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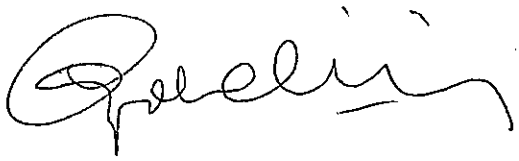


Chien-Ming GOH
Vice President and Official Correspondent for
Genadyne Biotechnologies Inc.

A. Administrative

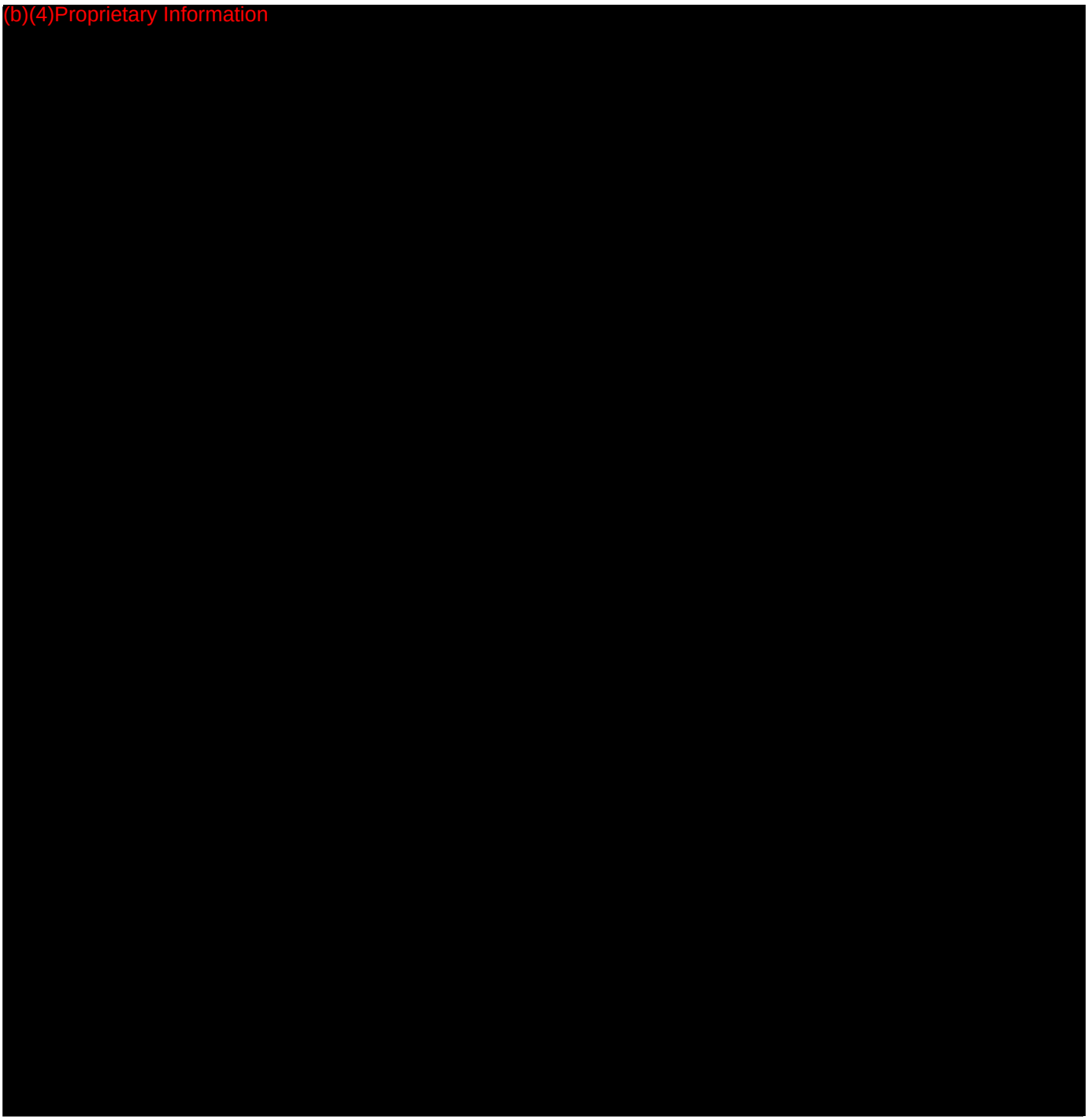
(b)(4)Proprietary Information

B. Device Description

(b)(4)Proprietary Information

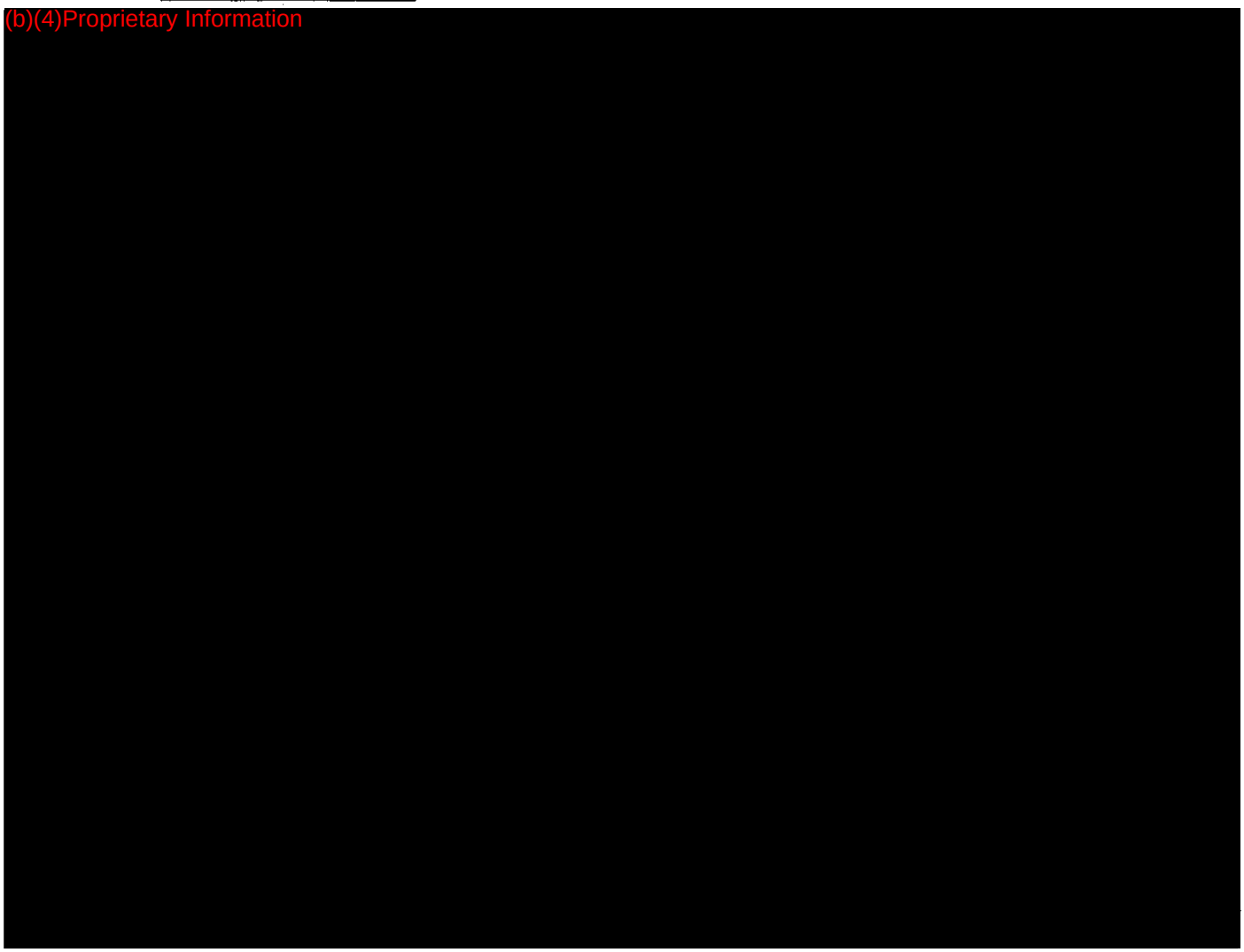
C. Substantial Equivalence Discussion

(b)(4)Proprietary Information



D. Proposed Labeling

(b)(4)Proprietary Information



E. Sterilization

(b)(4)Proprietary Information

Attachment A

Instructions for Use

(b)(4)Proprietary Information

Instruction for Use

Negative Pressure Wound Therapy
White Foam Dressing Kit

Indications for Use

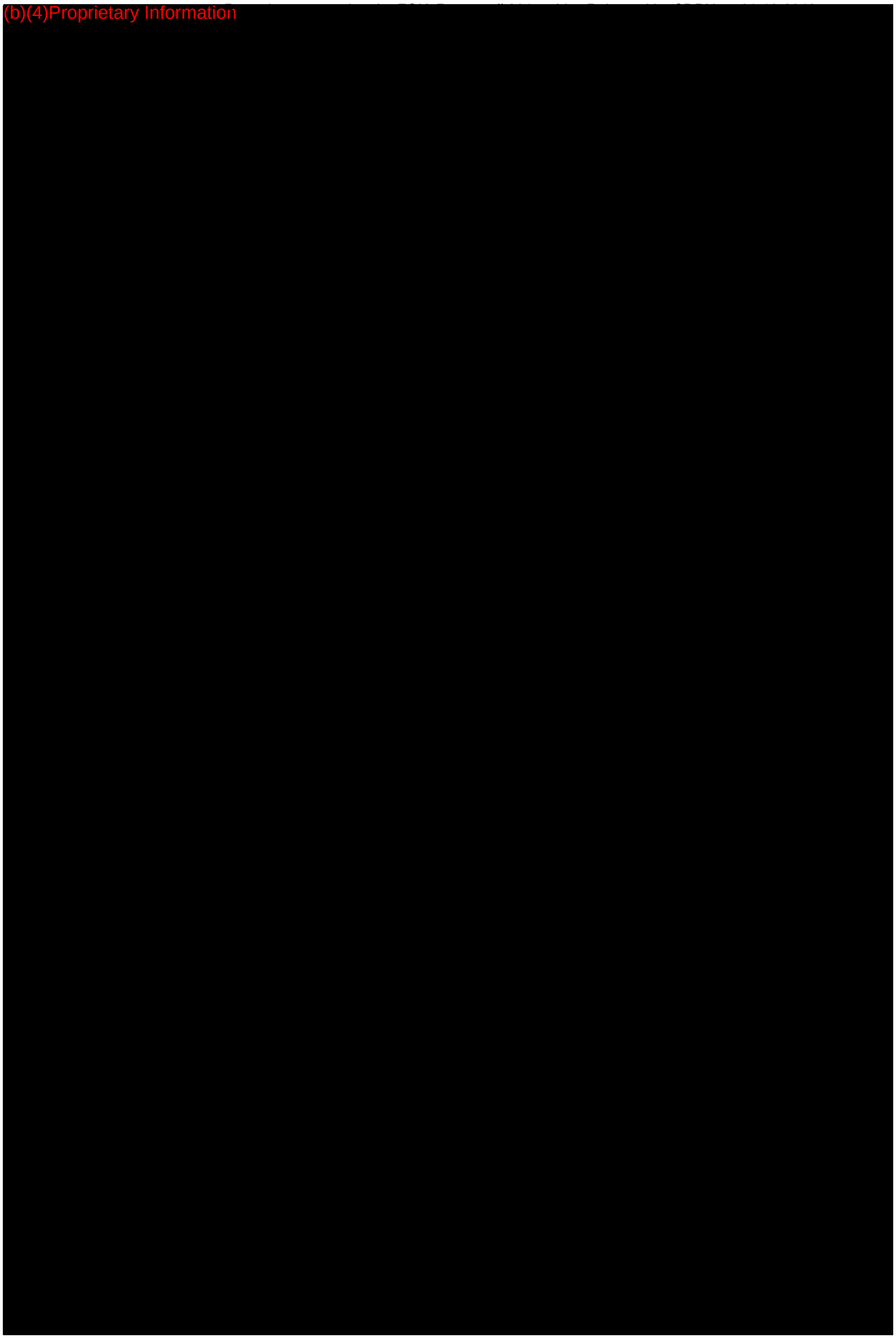
GENADYNE XLR8 White Foam Dressing Kit is intended to be used in conjunction with the Genadyne A4-XLR8 Wound Vacuum System as a wound filler. Genadyne A4-XLR8 Wound Vacuum System is indicated for patients who would benefit from a suction device, particularly as the device may promote wound healing.

Genadyne XLR8 White Foam Dressing is appropriate for use on the following wounds:

- Pressure Ulcers
- Diabetic/Neuropathic Ulcers
- Venous Insufficiency Ulcers
- Traumatic Wounds
- Post-operative and Dehisced Surgical Wounds
- Skin Flap and Grafts

(b)(4)Proprietary Information

(b)(4)Proprietary Information



Attachment B

Sterility Certificates

(b)(4)Proprietary Information

(b)(4)Proprietary Information

(b)(4)Proprietary Information

K142646/ (b)(4)Proprietary Information

RETURN RECEIPT REQUESTED

October 30, 2014

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

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Mr. Chien-Ming GOH, Genadyne Biotechnologies Inc.,
16 Midland Ave, Hicksville, NY 11801.

Sincerely,

Chien-Ming GOH
Vice President and Official Correspondent for
Genadyne Biotechnologies Inc.

146 ICD

RETURN RECEIPT REQUESTED

October 30, 2014

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Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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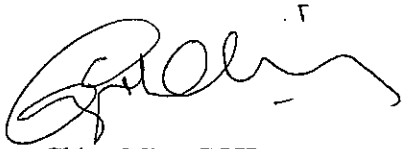

Chien-Ming GOH
Vice President and Official Correspondent for
Genadyne Biotechnologies Inc.

E. Sterilization

(b)(4)Proprietary Information

K142646/S003

March 27, 2015

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

Re: K142646/S002 PVA Foam Dressing

Dear Jiyoung Dang:

Enclosed please find an eCopy in a DVD, an original and an exact copy of the response to the deficiency letter dated January 2, 2015.

The eCopy is an exact duplicate of the paper copy.

We would appreciate a rapid review so that we can plan to distribute the product upon your approval.

If there are any questions, please contact me at (516) 217-0101. Any correspondence referring to this 510(k) submission should be forwarded to the office of:

Mr. Chien-Ming (Andrew) Goh
16 Midland Ave, Hicksville, NY 11801

Sincerely,

Chien-Ming Goh
Vice President and Official Correspondent for
Genadyne Biotechnologies, Inc.

1-00 124

March 27, 2015

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

Re: K142646/S002 PVA Foam Dressing

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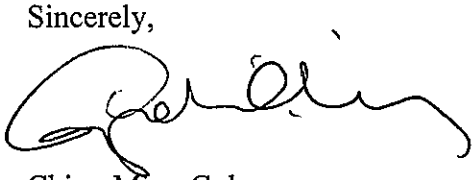
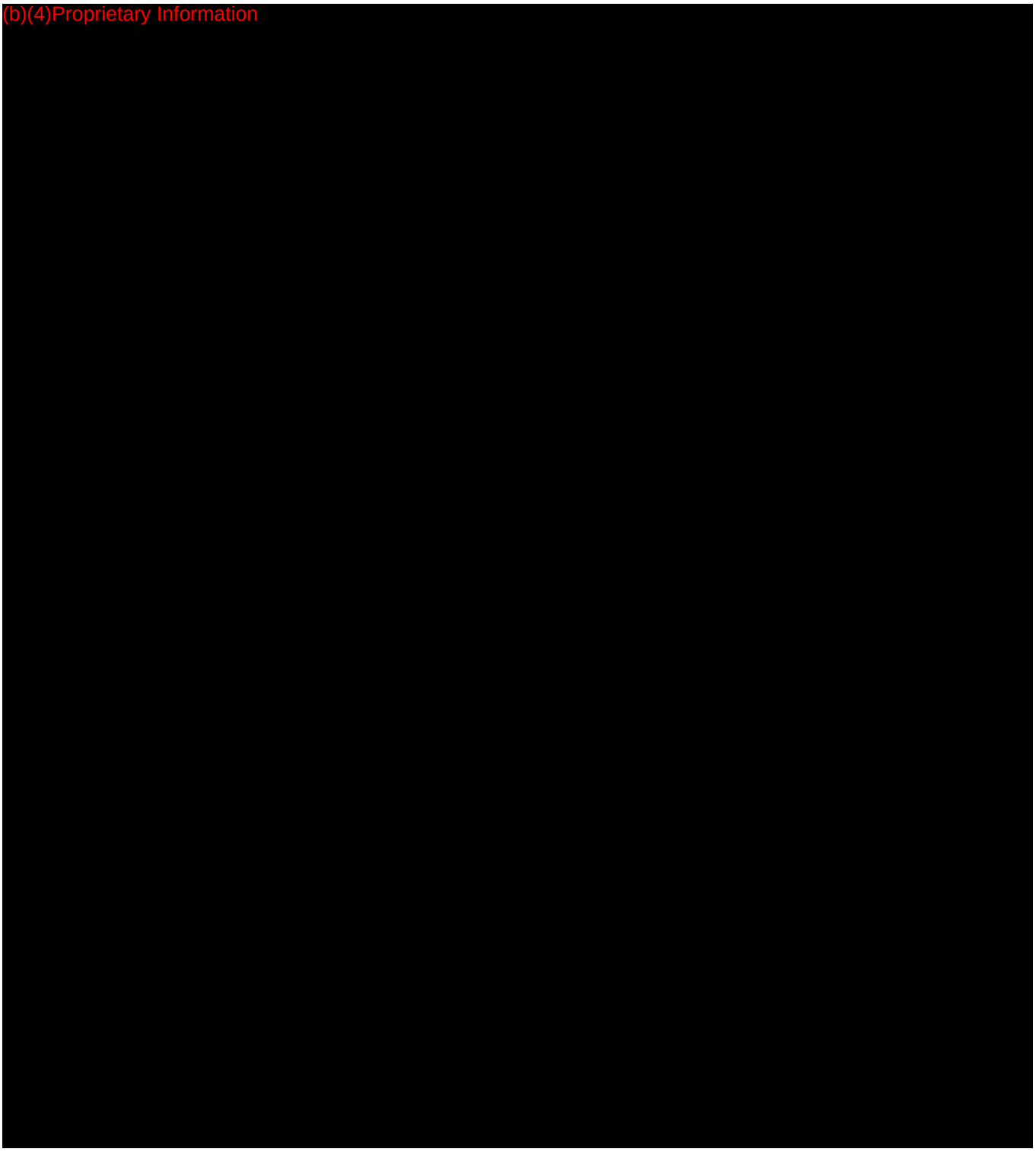
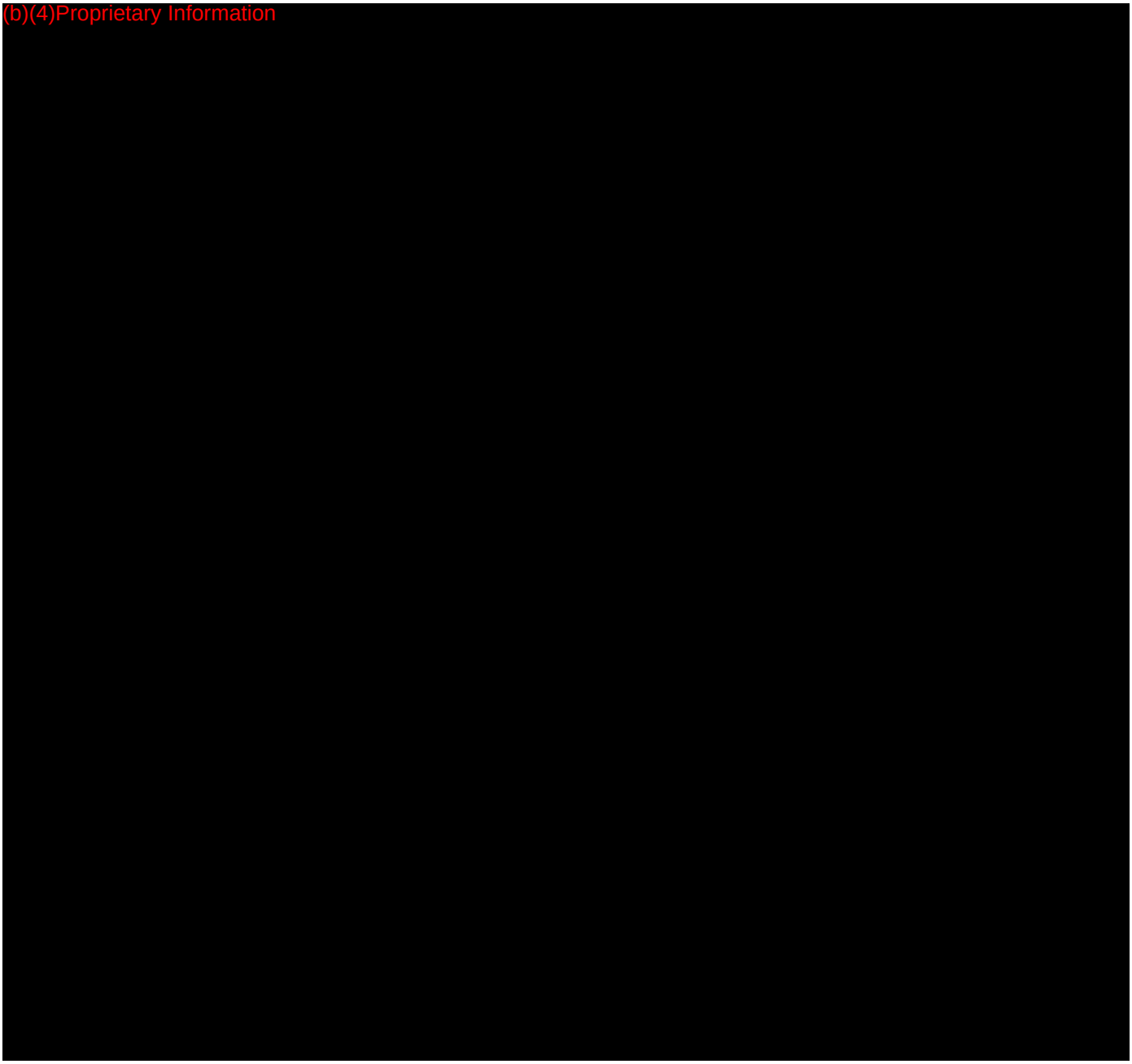
Mr. Chien-Ming (Andrew) Goh
16 Midland Ave, Hicksville, NY 11801

Sincerely,



Chien-Ming Goh
Vice President and Official Correspondent for
Genadyne Biotechnologies, Inc.





Attachment 1-A

(b)(4)Proprietary Information-Testing

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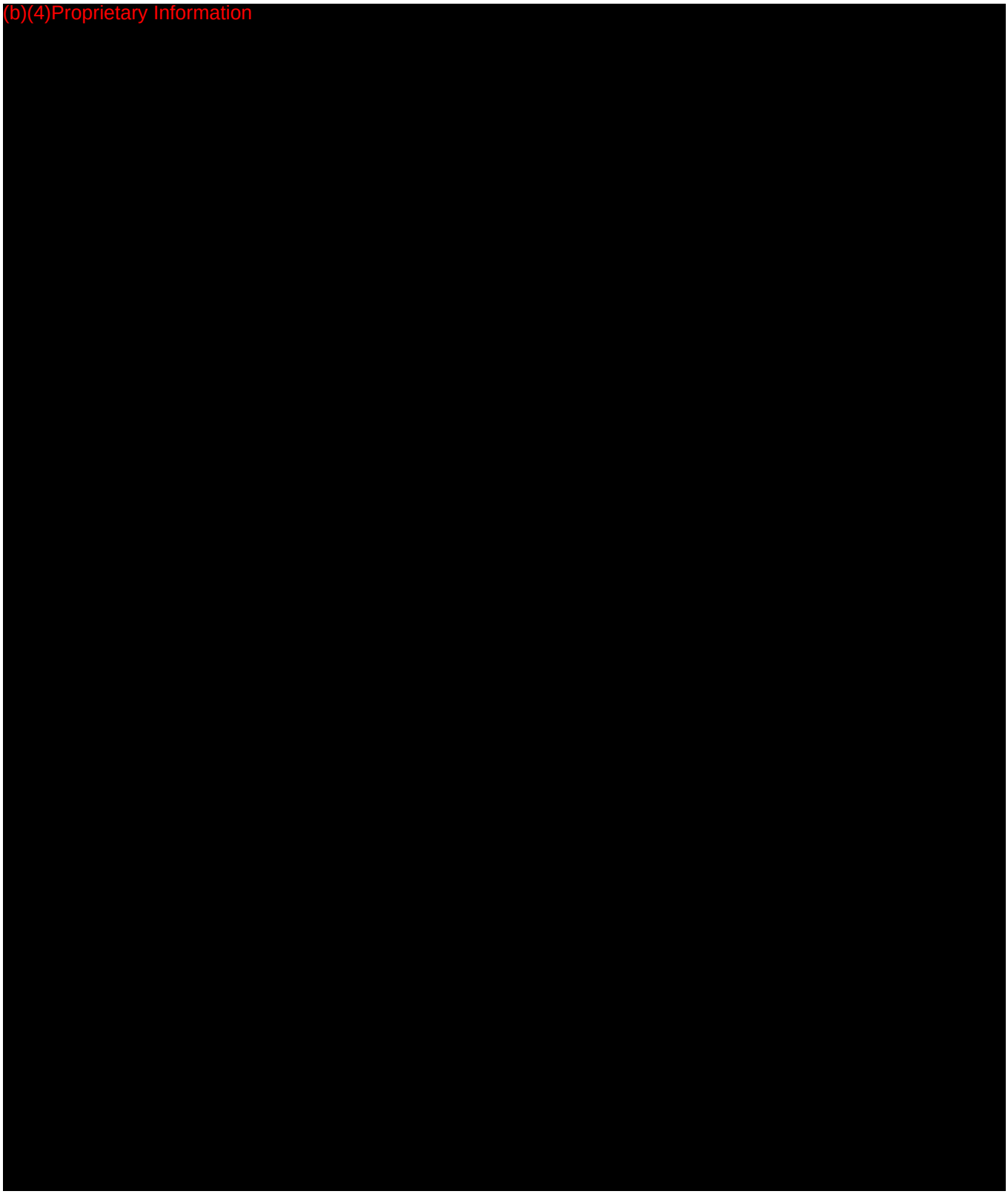


Attachment 2 – A

INDICATIONS FOR USE

510(k) Number (if known):

Device Name: Genadyne XLR8 White Foam Dressing Kit

Indications For Use:

Genadyne XLR8 White Foam Dressing Kit is intended to be used in conjunction with the Genadyne A4 Wound Vacuum System (K082676) as well as the Genadyne A4-XLR8 Wound Vacuum System (K090638) to deliver negative pressure to the wound. Genadyne A4 & A4-XLR8 Wound Vacuum System is indicated for patients who would benefit from a suction device particularly as the device ma promote wound healing by the removal of excess exudates, infectious material and tissue debris.

XLR8 White Foam Dressing is appropriate for use on the following wounds:

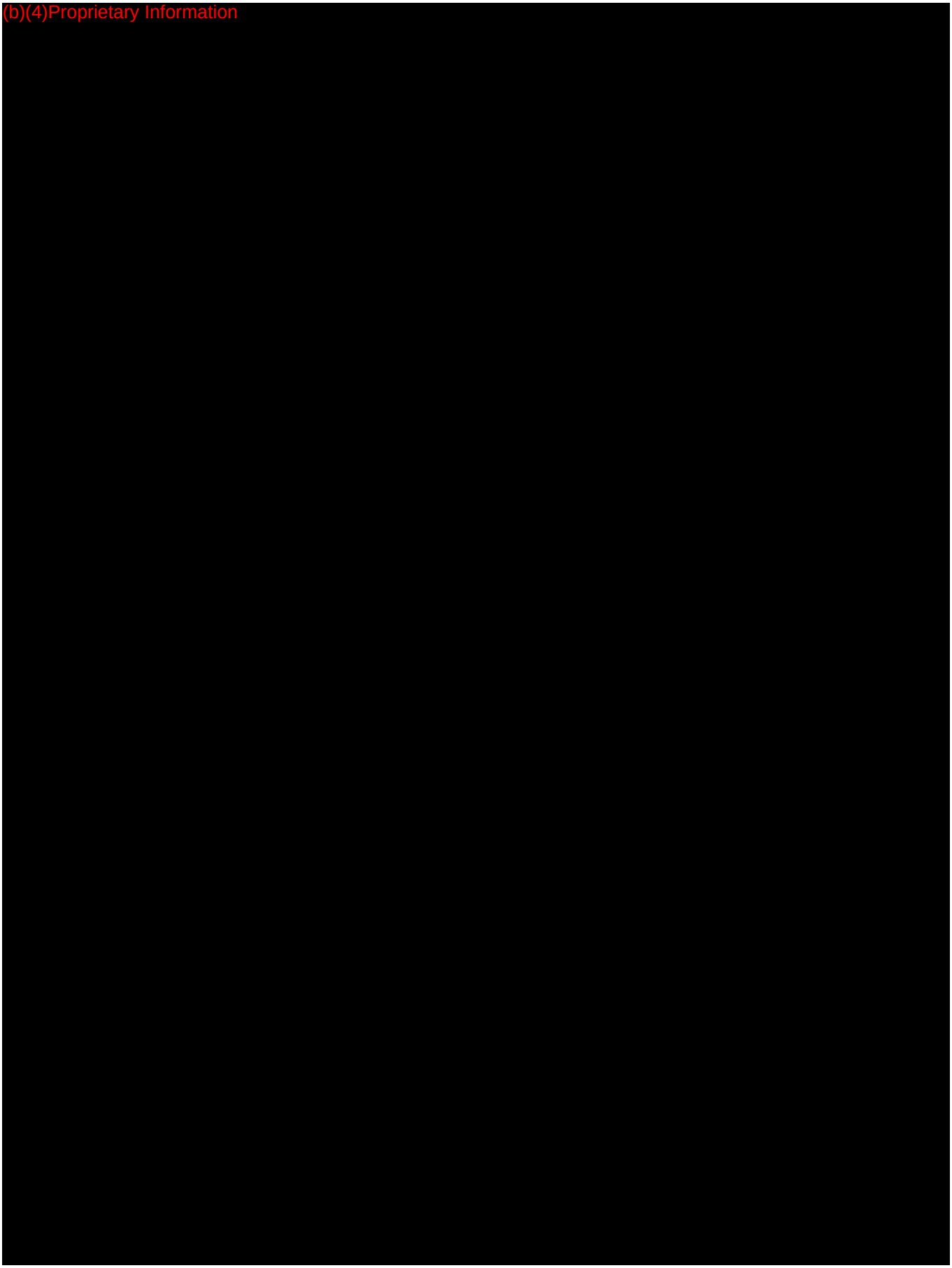
- Pressure ulcers
- Diabetic/Neuropathic Ulcers
- Venous insufficiency Ulcers
- Traumatic wounds
- Post-operative and dehisced surgical wounds
- Skin flap and grafts

Prescription Use ___X__ **OR** **Over-The Counter Use_____**
(Per 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(b)(4)Proprietary Information



(b)(4)Proprietary Information

Attachment 3-A

(b)(4)Proprietary Information-Product Specs

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Attachment 3-B

(b)(4)Proprietary Information-Validation

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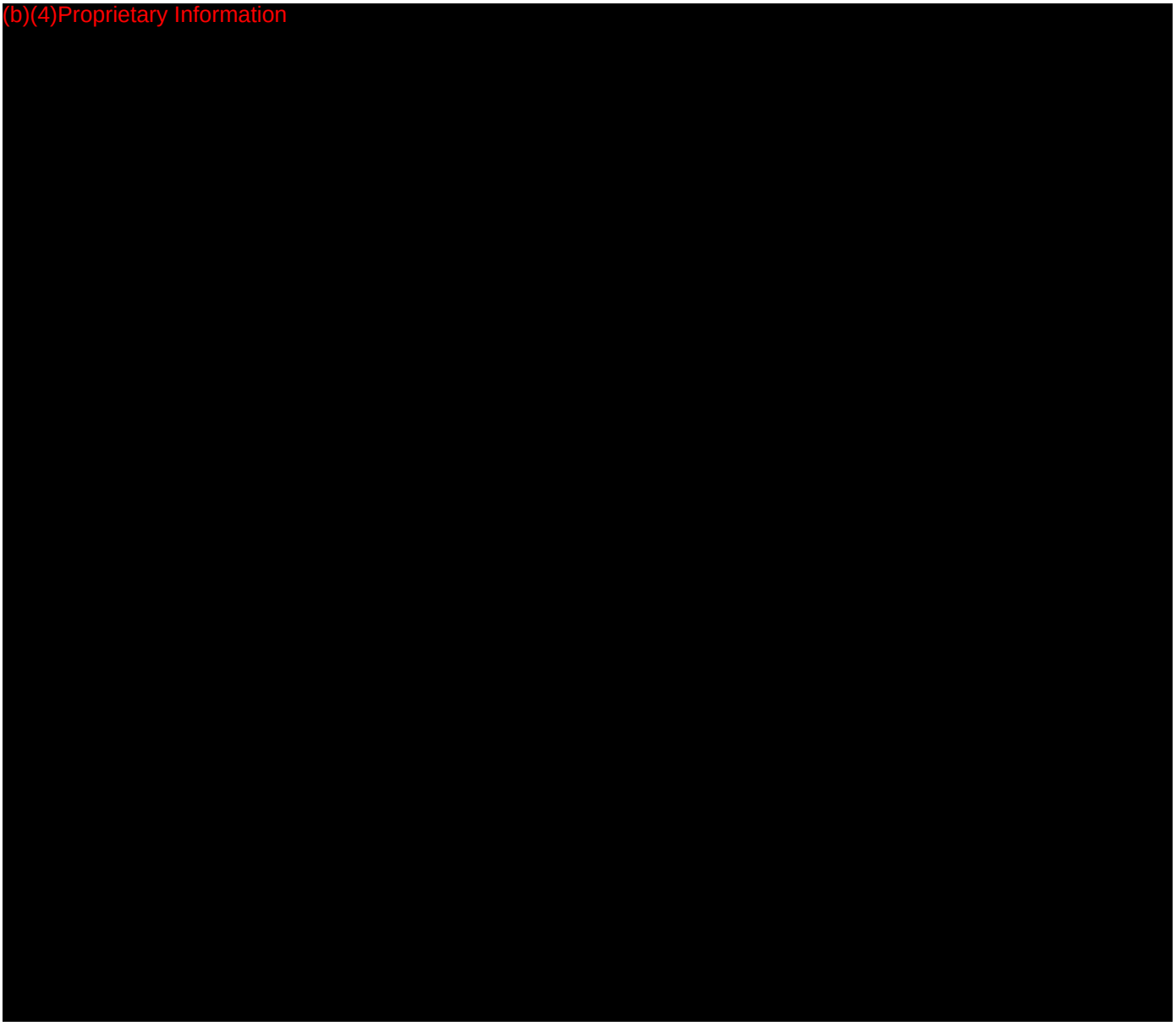


Attachment 4-A

Instruction for Use

Negative Pressure Wound Therapy
White Foam Dressing Kit

Indications for Use

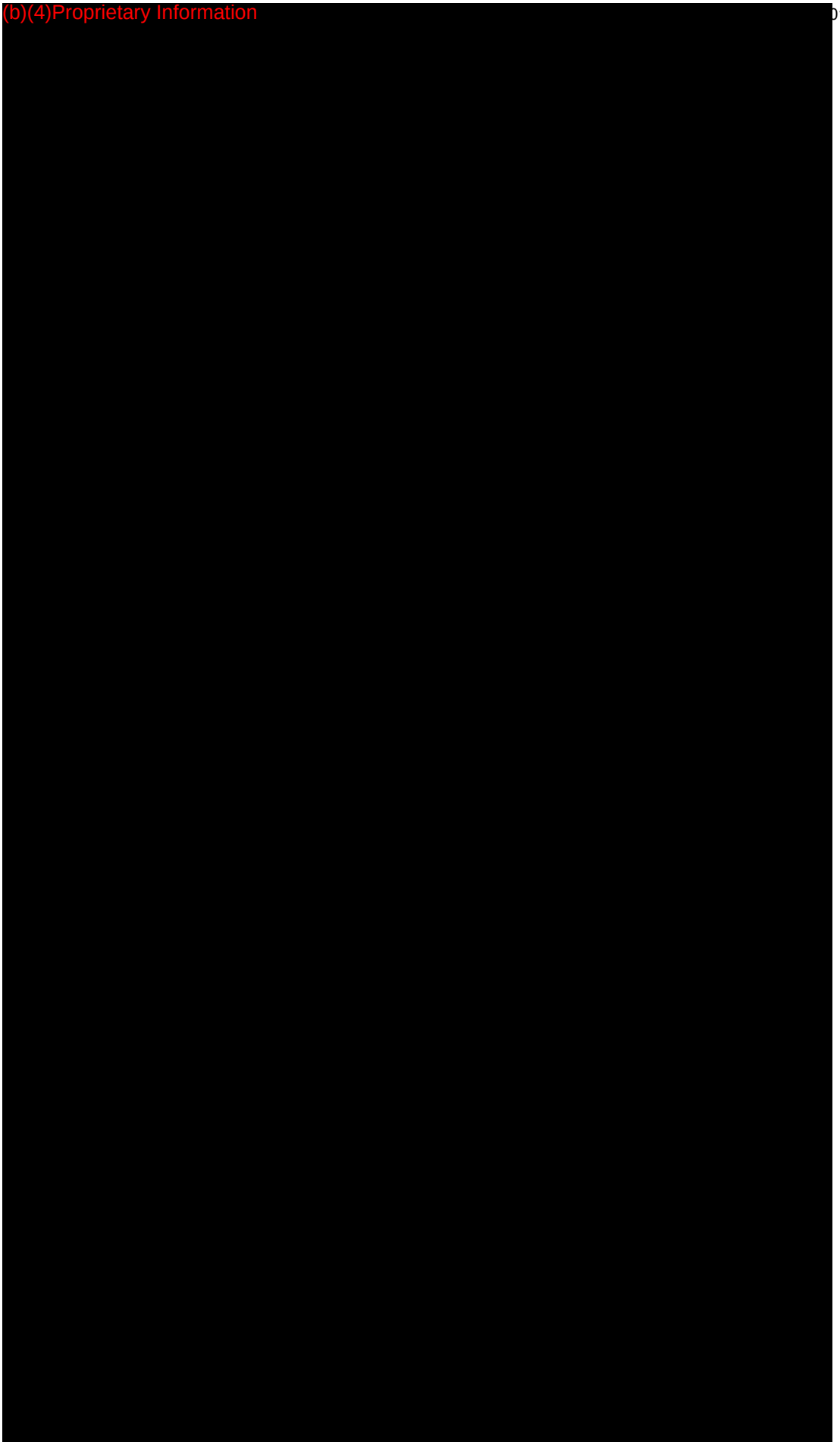
GENADYNE XLR8 White Foam Dressing Kit is intended to be used in conjunction with the Genadyne A4-XLR8 Wound Vacuum System as a wound filler. Genadyne A4-XLR8 Wound Vacuum System is indicated for patients who would benefit from a suction device, particularly as the device may promote wound healing.

Genadyne XLR8 White Foam Dressing is appropriate for use on the following wounds:

- Pressure Ulcers
- Diabetic/Neuropathic Ulcers
- Venous Insufficiency Ulcers
- Traumatic Wounds
- Post-operative and Dehisced Surgical Wounds
- Skin Flap and Grafts

(b)(4)Proprietary Information

(b)(4)Proprietary Information



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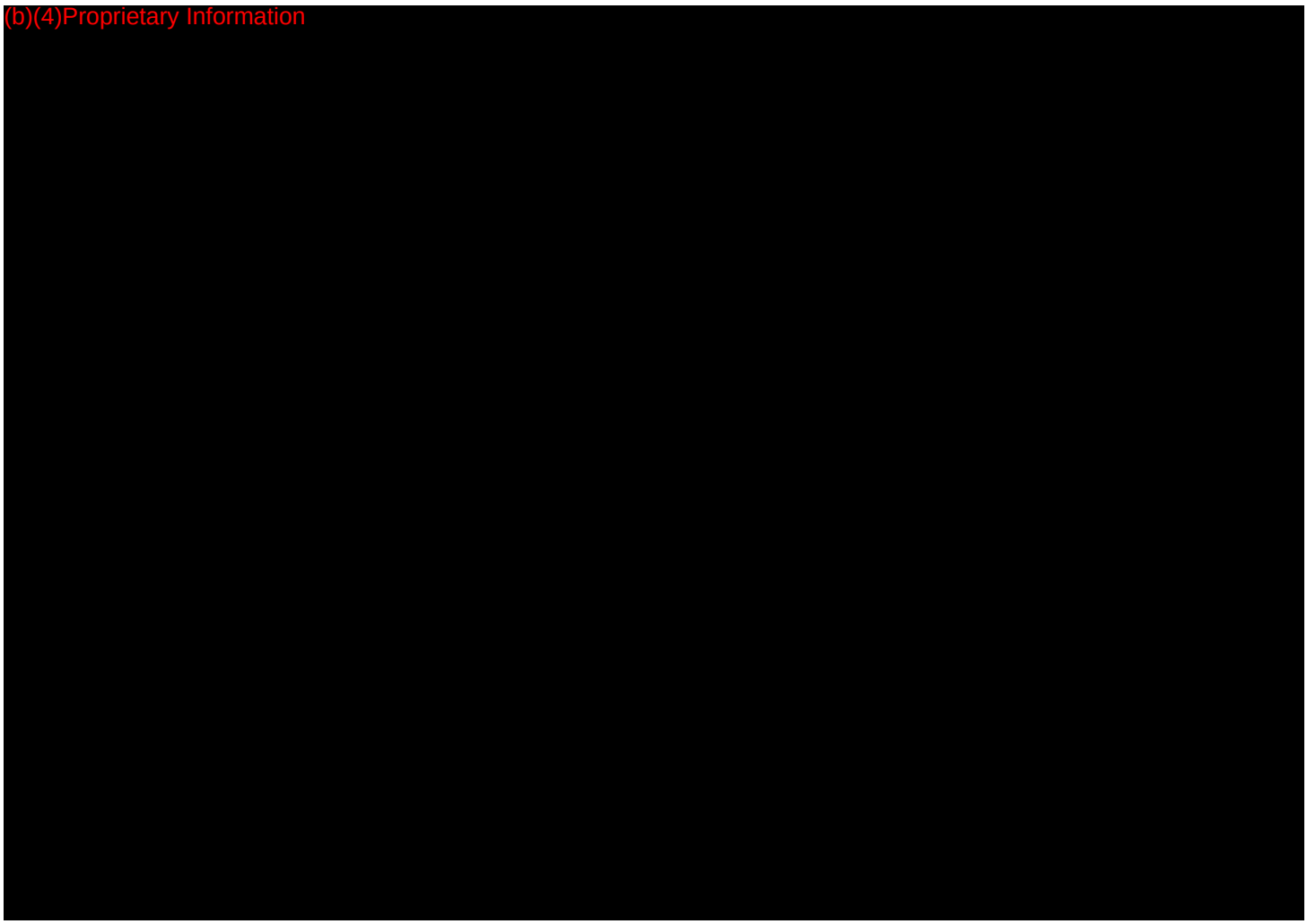

Attachment 5-A

(b)(4)Proprietary Information-Testing

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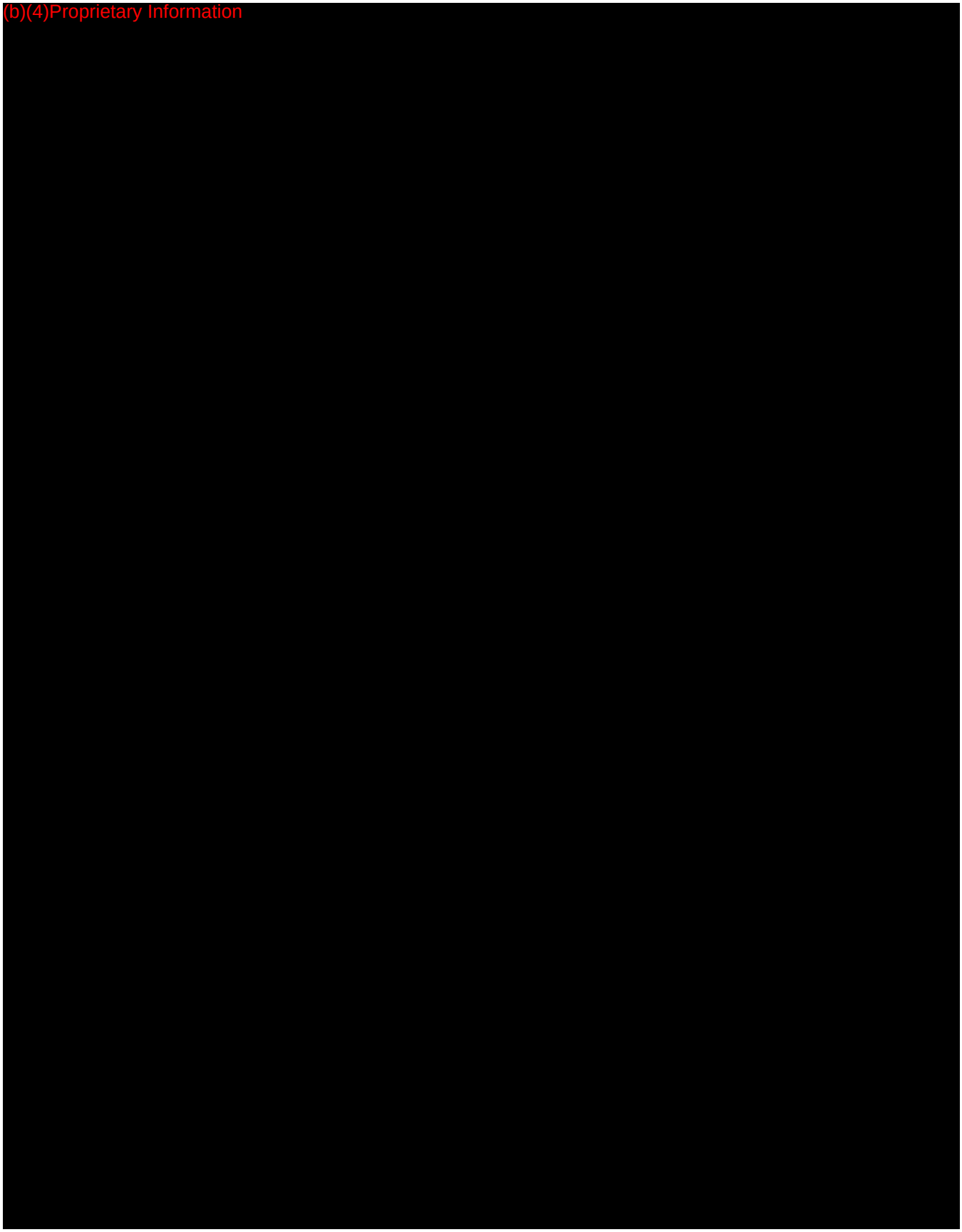

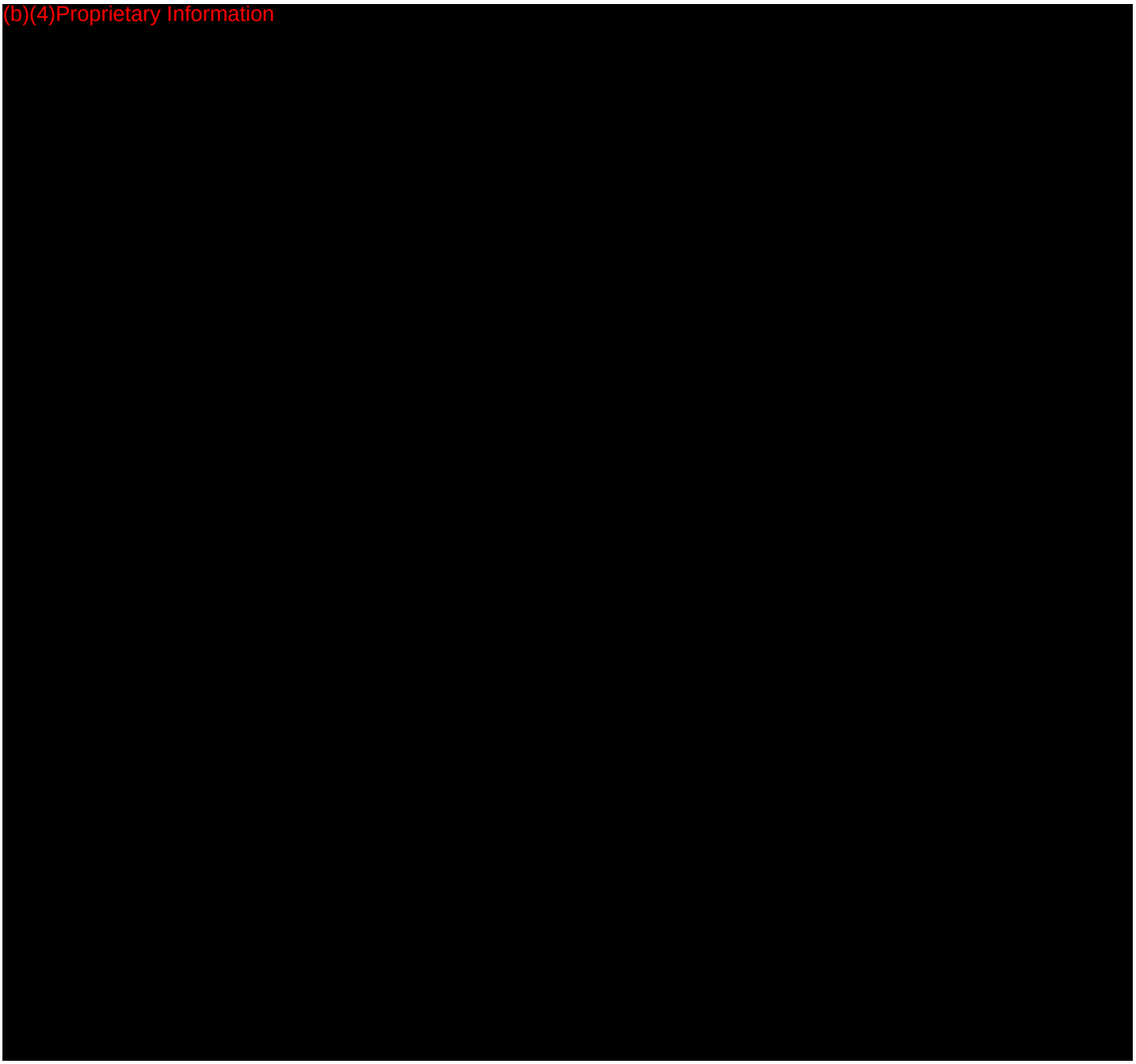

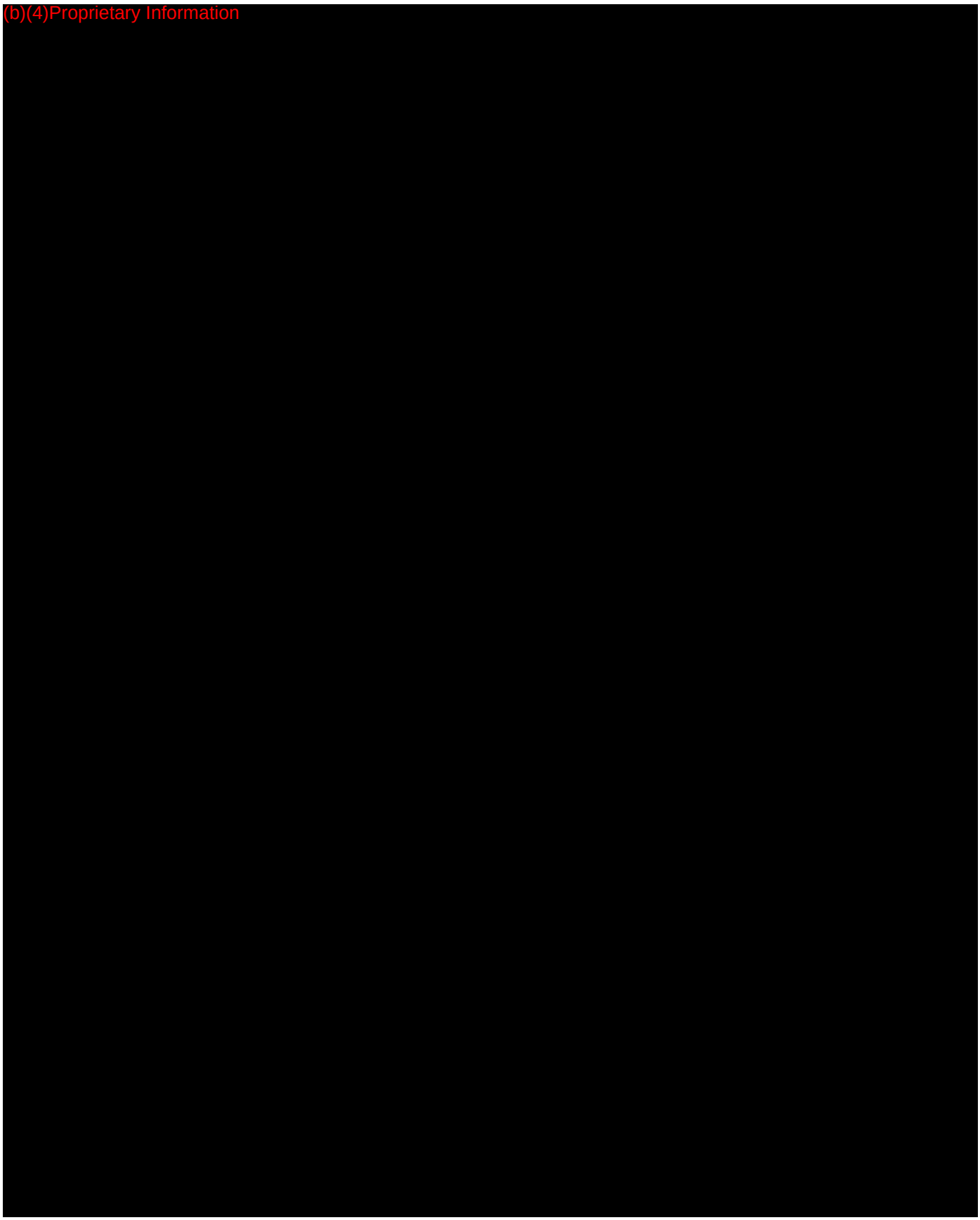

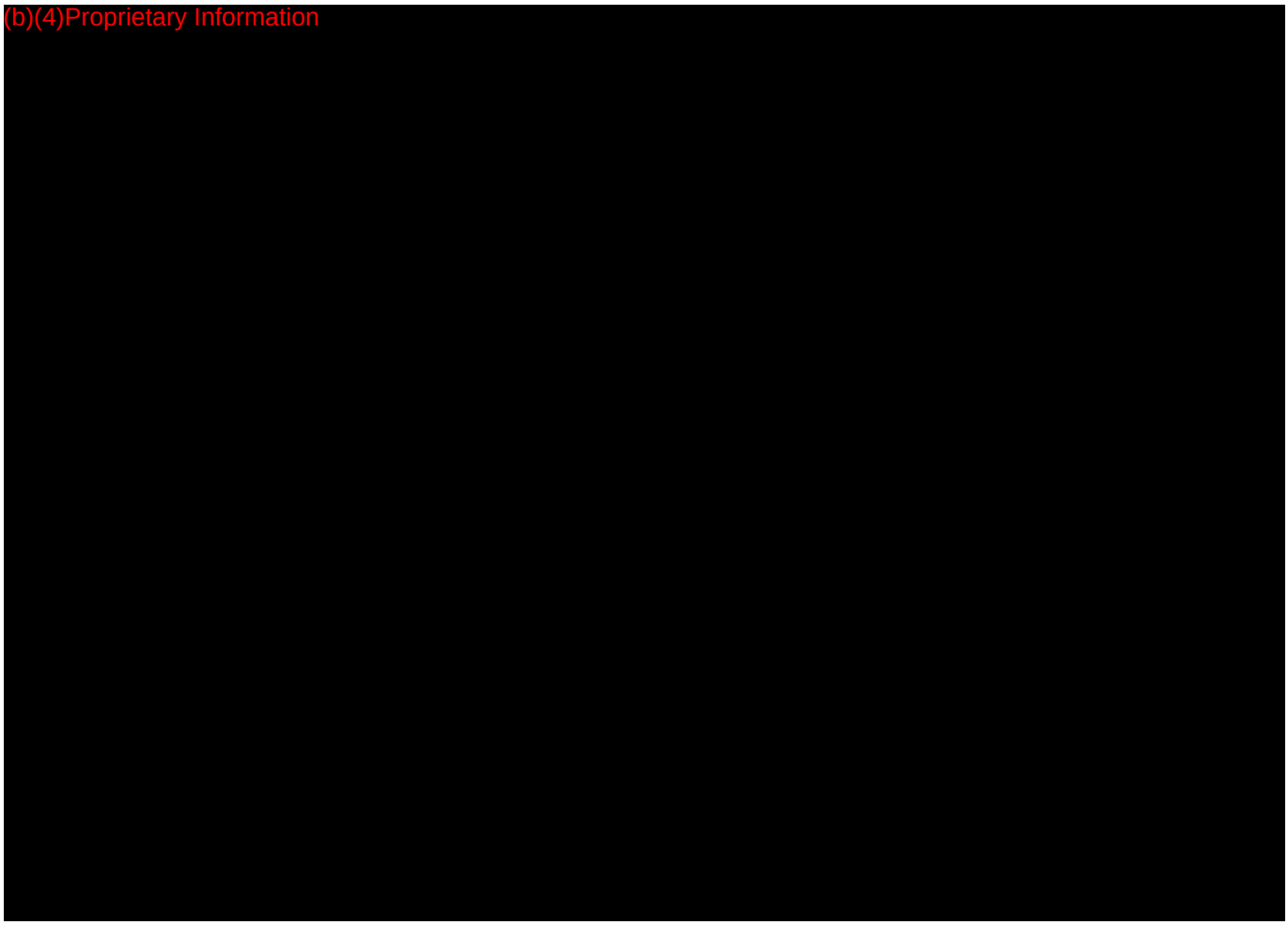

Attachment 7-A

(b)(4)Proprietary Information

Instruction for Use

Negative Pressure Wound Therapy
White Foam Dressing Kit

Indications for Use

GENADYNE XLR8 White Foam Dressing Kit is intended to be used in conjunction with the Genadyne A4-XLR8 Wound Vacuum System as a wound filler. Genadyne A4-XLR8 Wound Vacuum System is indicated for patients who would benefit from a suction device, particularly as the device may promote wound healing.

Genadyne XLR8 White Foam Dressing is appropriate for use on the following wounds:

- Pressure Ulcers
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- Venous Insufficiency Ulcers
- Traumatic Wounds
- Post-operative and Dehisced Surgical Wounds
- Skin Flap and Grafts

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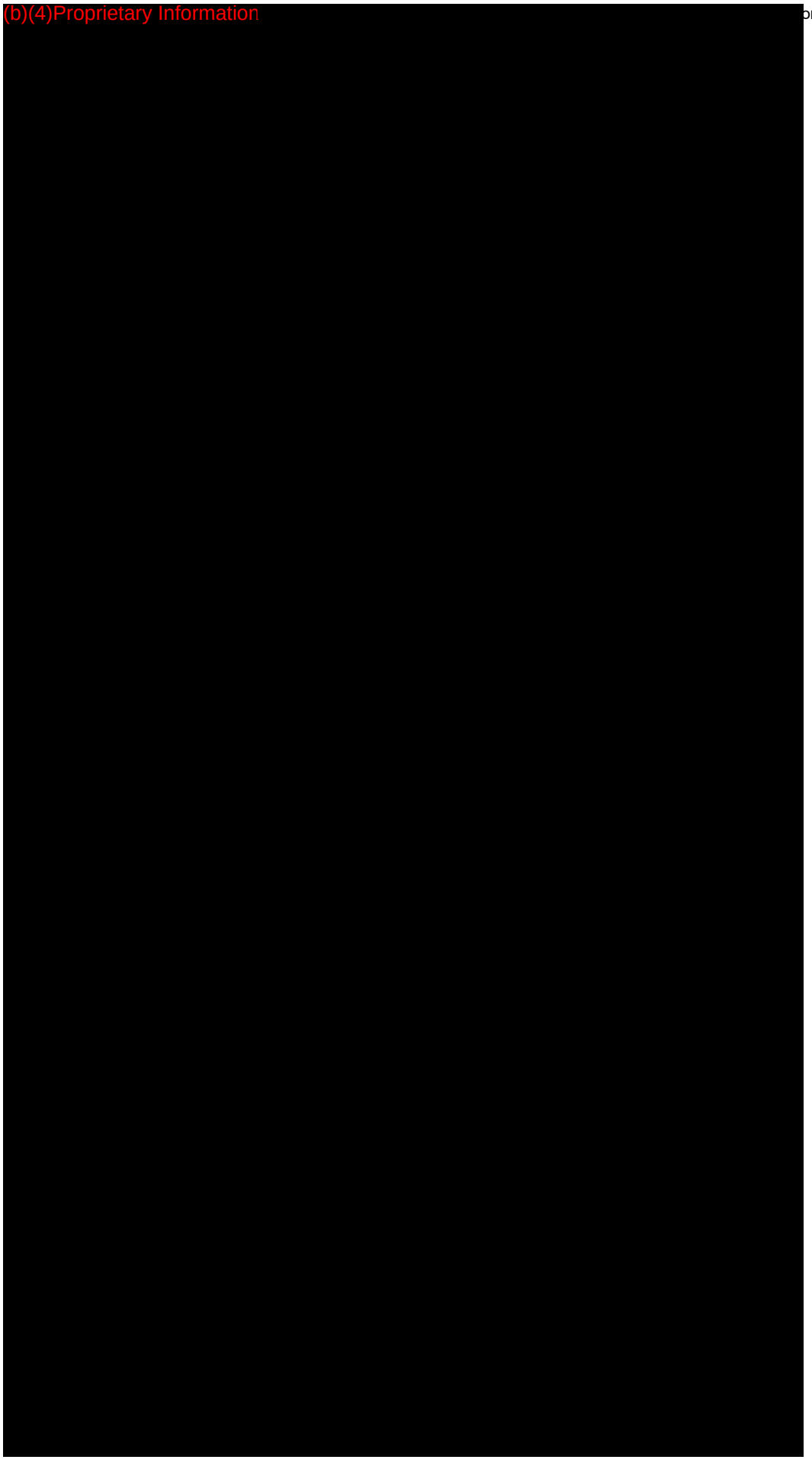
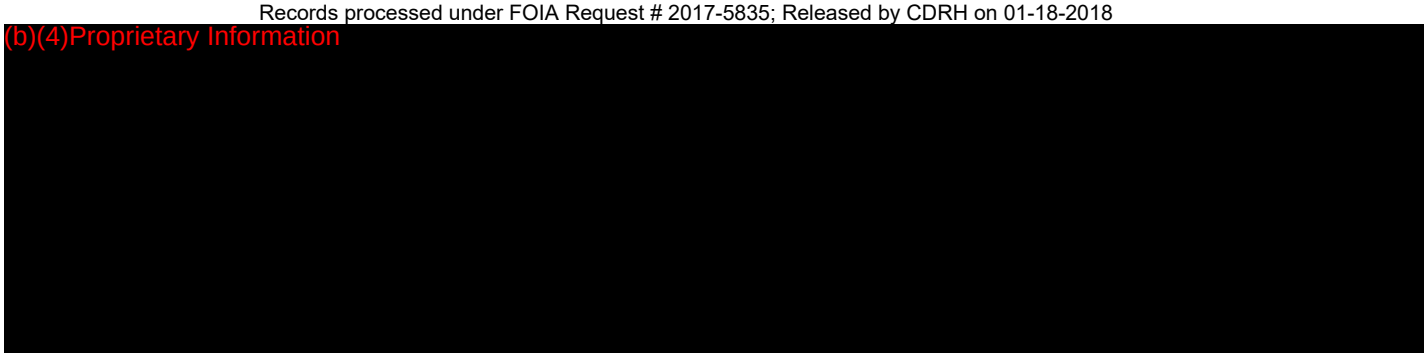


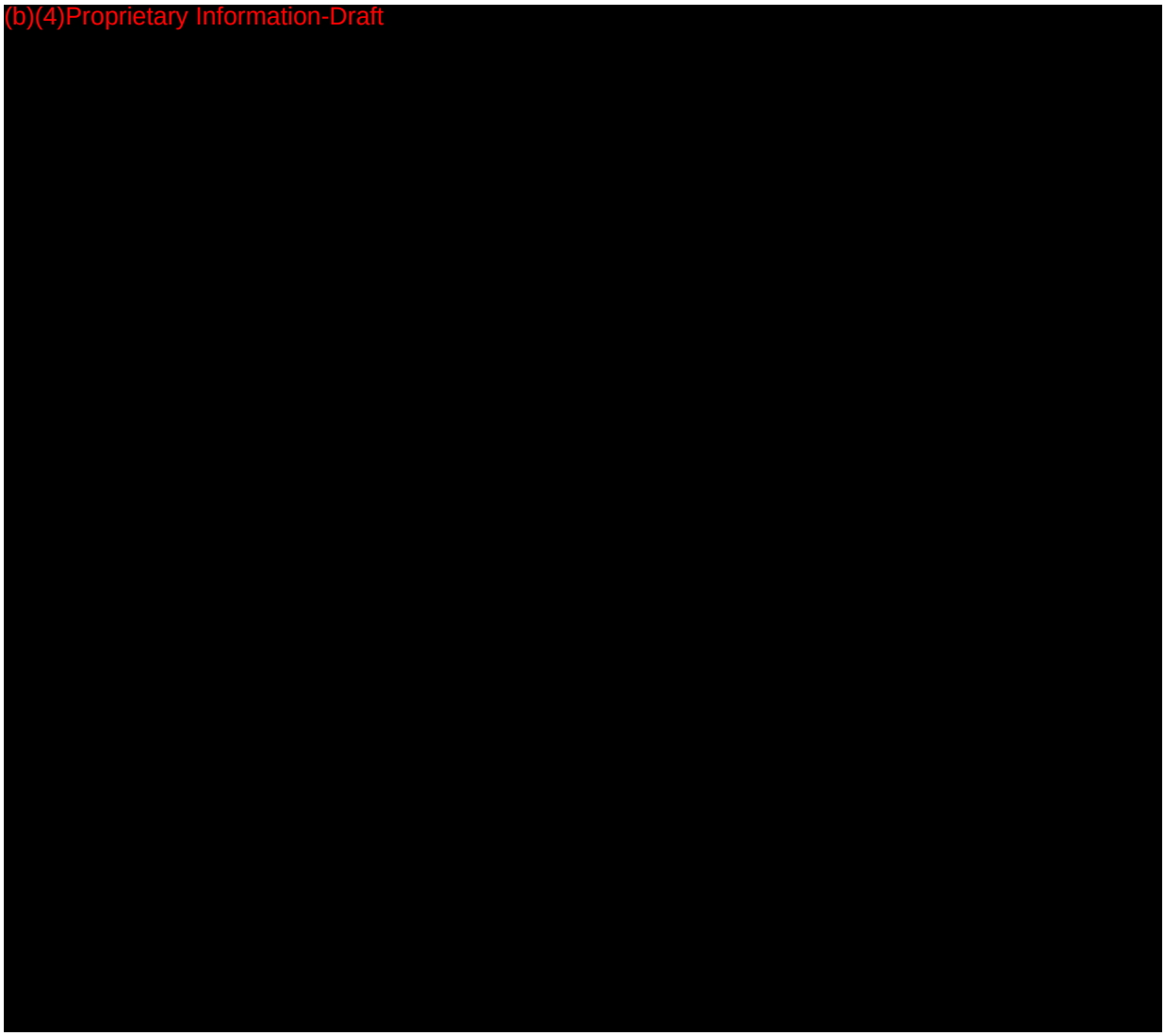
Attachment 7-B

(b)(4)Proprietary Information



(b)(4)Proprietary Information-Draft

(b)(4)Proprietary Information-Draft



(b)(4)Proprietary Information-Draft

(b)(4)Proprietary Information

Attachment 8-A

Traditional 510k Summary

General Information **Date: July 10, 2014**

1.	**Applicant**	Genadyne Biotechnologies, Inc. 16 Midland Ave, Hicksville, NY 11801 (t) 516.487.8787 (f) 516.977-8974
2.	**Contact Person**	Mr. Chien-Ming GOH (Andrew) Vice President Genadyne Biotechnologies Inc. 16 Midland Ave, Hicksville, NY 11801 (t) 516.217.0101 (f) 516.977.8974
3.	**Trade Name**	Genadyne XLR8 White Foam Dressing Kit (Ref:PVA-FOAM1)
4.	**Common Name**	Foam Dressing
5.	**Classification Name**	Negative Pressure Wound Therapy Powered Suction Pump and Accessories
6.	**Regulation Number**	21 CFR 878.4780
7.	**Product Code**	OMP
8.	**Class in which Device has been placed**	Class II
9.	**Panel**	General & Plastic Surgery
10.	**Reason for Premarket Notification**	New Device
11.	**Identification of Legally Marketed Device Which We Can Claim Substantial Equivalence (Predicate Device)**	A4-XLR8 Foam Dressing K092992 & A4-XLR8 Wound Vacuum System K090638
12.	**Brief Description of Device**	The Genadyne XLR8 White Foam Kit consists of a XLR8 Port, XLR8 Transparent Film and a XLR8 White Foam. Each component are packaged, sealed and sterilized individually and then bagged

into a kit.

13. **Indications for use [21 CFR 807.92(a)(5)]**

Genadyne XLR8 White Foam Dressing Kit is intended to be used in conjunction with the Genadyne Wound Vacuum System to deliver negative pressure to the wound. Genadyne Wound Vacuum System is indicated for patients who would benefit from a suction device particularly as the device may promote wound healing by the removal of excess exudates, infectious material and tissue debris.

XLR8 White Foam Dressing is appropriate for use on the following wounds:

- Pressure ulcers
- Diabetic/Neuropathic Ulcers
- Venous insufficiency Ulcers
- Traumatic wounds
- Post-operative and dehisced surgical wounds
- Skin flap and grafts

14**. Technological Characteristics**

No.		Foam	Port Tubing	Film
1.	Materials Used:	Polyvinyl Alcohol Dressing	Silicone	Polyurethane
2.	Size:	20 cm x 15 cm x 1 cm 15 cm x 10 cm x 1 cm 7.5 cm x 10 cm x 1 cm	31 inches	26 x 30 cm

Table of Comparison to Predicate Devices:

	Predicate	New
Parameters	Genadyne A4-XLR8 Foam Dressing	Genadyne XLR8 White Foam Dressing Kit
510(k) Number	K092992	TBD
Indications for Use	Genadyne A4-XLR8 Foam Dressing Kits are intended to be used in conjunction with the Genadyne Wound Vacuum System to deliver negative pressure to the wound. Genadyne Wound Vacuum System is indicated for patients who would benefit from a suction device particularly as the device may promote wound healing by the	Genadyne XLR8 White Foam Dressing Kits are intended to be used in conjunction with the Genadyne Wound Vacuum to deliver negative pressure to the wound. Genadyne Wound Vacuum System is indicated for patients who would benefit from a suction device particularly as the device may promote wound healing by the removal of excess

	removal of excess exudates, infectious material and tissue debris. A4-XLR8 Foam Dressing is appropriate for use on the following wounds: • Pressure ulcers • Diabetic/Neuropathic Ulcers • Venous insufficiency ulcers • Traumatic wounds • Post-operative and dehisced surgical wounds • Skin flap and grafts • Undermining and tunneling wounds	exudates, infectious material and tissue debris. XLR8 White Foam Dressing is appropriate for use on the following wounds: • Pressure ulcers • Diabetic/Neuropathic Ulcers • Venous insufficiency ulcers • Traumatic wounds • Post-operative and dehisced surgical wounds • Skin flap and grafts • Undermining and tunneling wounds
Foam Dressing Material	Flexible Polyether and Polyester Polyurethane Foam	Polyvinyl Alcohol Dressing
Hydrophobic	Yes	Yes
Sizes:	7.5 cm X 10 cm x 3.3cm 12.5 cm x 18 cm x 3.3 cm 15 cm x 26 cm x 3.3 cm	20 cm x 15 cm x 1 cm 15 cm x 10 cm x 1 cm 7.5 cm x 10 cm x 1 cm
For use with Negative Pressure Wound Therapy Systems	Yes	Yes
Sterile	Yes	Yes
Sterilization Method	EO	R for White Foam, EO for Silicone Port and Transparent Film
Kit Content	Silicone Tubing Transparent Adhesive Film	Silicone Port Transparent Adhesive Film

15. Summary of Non clinical Tests

Device	Tests	Rationale
XLR8 White Foam Kit	ISO 10993-5 L929 Neutral Red Uptake Cytotoxicity Test	Based on the criteria of the protocol and the ISO 10993-5 Guidelines, the test article meets the requirements of the tests and s not considered to have a cytotoxic effect.
	ISO 10993-10 Kligman Maximization Test	Based on the defined scoring system of Kligman, this is a Grade 1 reaction and the test article is classified as having weak allergenic potential. A Grade 1 sensitization rate is not considered significant and the test article meets the requirements of the ISO 10993-10 guidelines.
	ISO 10993-10 Intracutaneous Injection Test	The test article sites did not show a significantly greater biological reaction than the sites injected with the control article. Based on the criteria of the protocol, the test article meets the requirements of the ISO 10993-10 guidelines.
	Bench Tests for Performance Evaluation	Results from the bench test shows that the dressing kit components are all compatible and performs up to the acceptability criteria.
	Stability Test	Stability tests was performed on our foams and components with 2 year accelerated aging and continuous real time. Devices has passed and met all expectations of the stability tests in terms of

		bioburden, packaging, seal integrity and performance.

16. **Conclusion & Determination of Substantial Equivalence**

Based on the information presented above, it is concluded that the XLR8 White Foam Dressing Kit is substantially equivalent to the predicate devices and is safe and effective to be used together with a negative pressure wound therapy device.

From: Nielsen, Joseph A. (CDRH)
To: Dugard, Christopher
Subject: RE: K142646 sponsor interaction
Date: Monday, April 13, 2015 8:19:15 AM

(b) (5) [redacted]

Thanks Joe

From: Dugard, Christopher
Sent: Friday, April 10, 2015 4:06 PM
To: Nielsen, Joseph A. (CDRH)
Subject: K142646 sponsor interaction

Hi Joe,

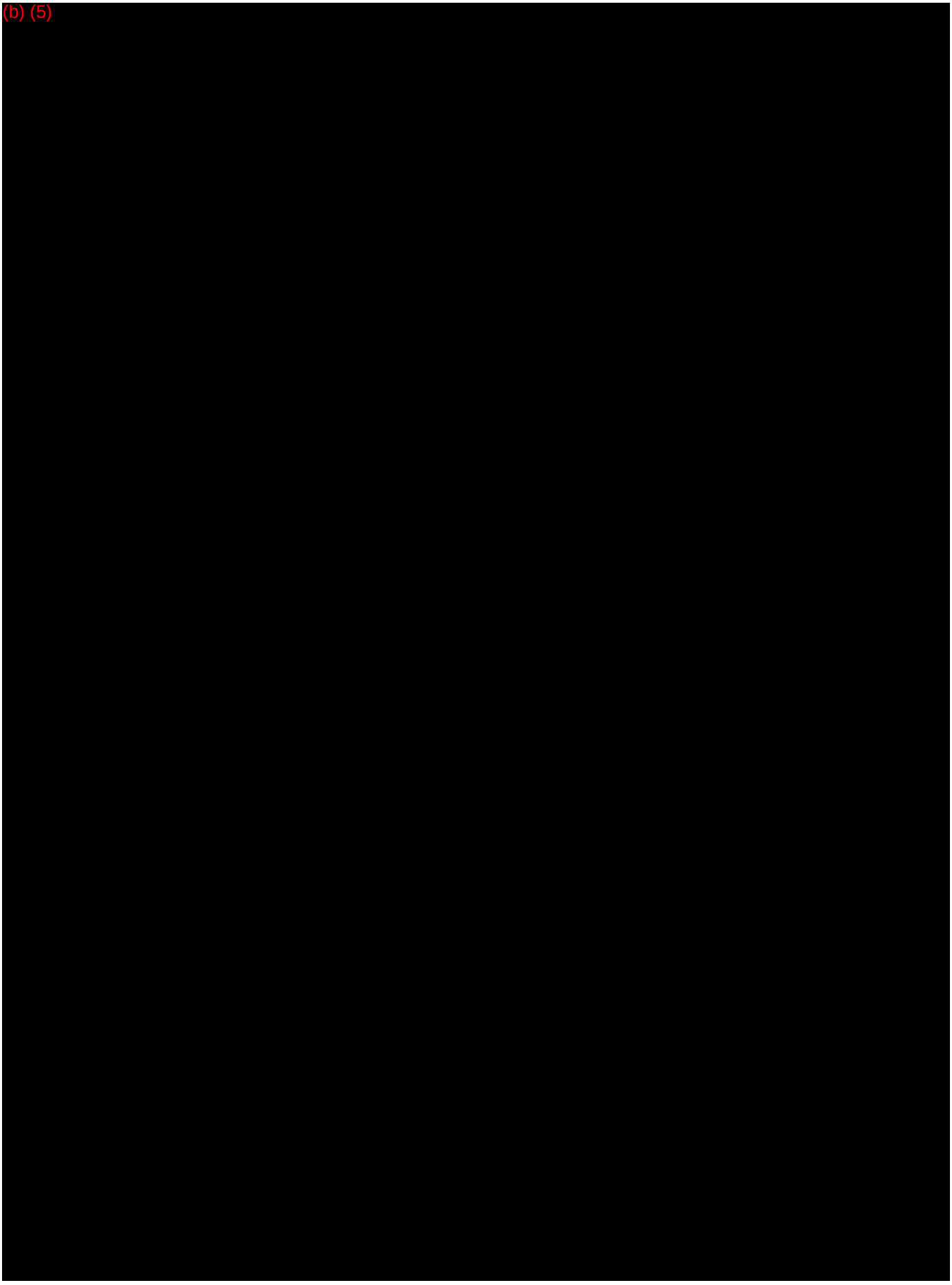
(b) (5) [redacted]

Chris

Dear Mr. Goh,

(b) (5) [redacted]

(b) (5)



(b) (5)

[redacted]

Regards,

Christopher K. Dugard
Biologist
Plastic and Reconstructive Surgery Devices Branch 2
FDA/CDRH/ODE/DSD

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=480&B=485&E=&S=E

From: Andrew Goh
To: Dugard, Christopher
Cc: Preston Liu
Subject: Re: K142646 (b)(4)Proprietary
Date: Thursday, April 23, 2015 5:30:02 PM

(b) (5)

Regards,

Andrew Goh

On Apr 23, 2015, at 17:29, Dugard, Christopher <Christopher.Dugard@fda.hhs.gov> wrote:

Hi Andrew,

(b) (5)

Thanks,

Christopher K. Dugard
Biologist
Plastic and Reconstructive Surgery Devices Branch 2
FDA/CDRH/ODE/DSD

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=480&B=485&E=&S=E

From: Andrew Goh [mailto:chiengoh@genadyne.com]
Sent: Thursday, April 23, 2015 4:49 PM
To: Dugard, Christopher
Cc: Preston Liu
Subject: RE: K142646 request for additional information

Christopher,

(b) (5)

Thanks.

Regards,

Andrew Goh
GENADYNE Affairs
Office: +1 (516) 217 0100
Fax: +1 (516) 977 8974
Genadyne Biotechnologies
16 Midland Ave
Hicksville, NY 11801

<!--[if !vml]--><!--[endif]-->

www.genadyne.com andrew@genadyne.com USA

From: Dugard, Christopher [mailto:Christopher.Dugard@fda.hhs.gov]
Sent: Thursday, April 23, 2015 1:31 PM
To: Andrew Goh
Cc: Preston Liu
Subject: RE: K142646 (b)(4)Proprietary

Hi Mr. Goh,

(b) (5) [redacted]

Thanks,

Christopher K. Dugard
Biologist
Plastic and Reconstructive Surgery Devices Branch 2
FDA/CDRH/ODE/DSD

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From: Andrew Goh [mailto:chiengoh@genadyne.com]
Sent: Wednesday, April 22, 2015 11:16 AM
To: Dugard, Christopher
Cc: Preston Liu; Nielsen, Joseph A. (CDRH)
Subject: RE: K142646 (b)(4)Proprietary

(b) (5) [redacted].

Regards,

Andrew Goh
GENADYNE Affairs
www.genadyne.com
Office: +1 (516) 217 0100
Fax: +1 (516) 977 8974
andrew@genadyne.com
Genadyne Biotechnologies
16 Midland Ave
Hicksville, NY 11801
USA

<!--[if !vml]--><!--[endif]-->

From: Andrew Goh
Sent: Wednesday, April 22, 2015 11:16 AM
To: 'Dugard, Christopher'
Cc: Preston Liu; Nielsen, Joseph A. (CDRH)
Subject: RE: K142646 (b)(4)Proprietary
Importance: High

Hi Christopher,

(b) (5)

Thanks!

Regards,

Andrew Goh
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www.genadyne.com

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Fax: +1 (516) 977 8974
andrew@genadyne.com

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16 Midland Ave
Hicksville, NY 11801
USA

<!--[if !vml]--><!--[endif]-->

From: Dugard, Christopher [mailto:Christopher.Dugard@fda.hhs.gov]
Sent: Tuesday, April 21, 2015 3:59 PM
To: Andrew Goh
Cc: Preston Liu; Nielsen, Joseph A. (CDRH)
Subject: RE: K142646 (b)(4)Proprietary

Mr. Goh,

(b) (5)

Regards,

Christopher K. Dugard
Biologist
Plastic and Reconstructive Surgery Devices Branch 2
FDA/CDRH/ODE/DSD

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Sent: Friday, April 17, 2015 4:36 PM
To: Dugard, Christopher
Cc: Preston Liu; Nielsen, Joseph A. (CDRH)
Subject: RE: K142646 (b)(4)Proprietary
Importance: High

Christopher,

(b) (5)

Thanks.

Regards,

Andrew Goh
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www.genadyne.com

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Sent: Friday, April 17, 2015 3:23 PM
To: Andrew Goh
Cc: Preston Liu; Nielsen, Joseph A. (CDRH)
Subject: RE: K142646 (b)(4)Proprietary

Mr. Goh,

(b) (5)

(b) (5)

[redacted]

Thank you and have a nice weekend,

Christopher K. Dugard
Biologist
Plastic and Reconstructive Surgery Devices Branch 2
FDA/CDRH/ODE/DSD

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Sent: Thursday, April 16, 2015 12:18 PM
To: Dugard, Christopher
Cc: Preston Liu
Subject: RE: K142646 (b)(4)Proprietary

Hi Christopher,

(b) (5)

[redacted]

Regards,

Andrew Goh
GENADYNE Affairs
www.genadyne.com

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andrew@genadyne.com

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Hicksville, NY 11801
USA

<!--[if !vml]--><!--[endif]-->

From: Dugard, Christopher [mailto:Christopher.Dugard@fda.hhs.gov]
Sent: Monday, April 13, 2015 9:40 AM
To: Andrew Goh
Cc: Nielsen, Joseph A. (CDRH)
Subject: K142646 (b)(4)Proprietary

Dear Mr. Goh,

(b) (5)

[redacted]

(b) (5)

[redacted]

Regards,

Christopher K. Dugard
Biologist
Plastic and Reconstructive Surgery Devices Branch 2
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From: Andrew Goh
To: Dugard, Christopher
Cc: Preston Liu
Subject: RE: K142646 (b)(4)Proprietary
Date: Thursday, April 16, 2015 12:19:07 PM
Attachments: image001.png
Attachments.zip
K142646 email response.docx

Hi Christopher,

(b) (5)

Regards,

Andrew Goh
Vice President
R&D and Regulatory Affairs

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Fax: +1 (516) 977 8974
andrew@genadyne.com

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Cc: Nielsen, Joseph A. (CDRH)
Subject: K142646 (b)(4)Proprietary

Dear Mr. Goh,

(b) (5)

(b) (5)

[redacted]

Regards,

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From: Andrew Goh
To: Dugard, Christopher
Cc: Preston Liu; Nielsen, Joseph A. (CDRH)
Subject: RE: K142646 (b)(4)Proprietary
Date: Friday, April 17, 2015 4:04:59 PM
Attachments: image001.png

Christopher,

(b) (5)

Regards,

Andrew Goh
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R&D and Regulatory Affairs

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andrew@genadyne.com

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Cc: Preston Liu; Nielsen, Joseph A. (CDRH)
Subject: RE: K142646 request for additional information

Mr. Goh,

(b) (5)

(b) (5)

[redacted]

Christopher K. Dugard
Biologist
Plastic and Reconstructive Surgery Devices Branch 2
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(b) (5)

(b) (5)

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From: Andrew Goh
To: Dugard, Christopher
Cc: Preston Liu; Nielsen, Joseph A. (CDRH)
Subject: RE: K142646 (b)(4)Proprietary
Date: Friday, April 17, 2015 4:36:28 PM
Attachments: image001.png
RPT-03-001 Rev B1.pdf
PVA Traditional 510K Summary C.docx
K142646 Form 3881.pdf
Attachment 3.1 Revised Indication for Use Statement.doc
Importance: High

Christopher,

(b) (5)

Thanks.

Regards,

Andrew Goh
Vice President
R&D and Regulatory Affairs

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Fax: +1 (516) 977 8974
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Cc: Preston Liu; Nielsen, Joseph A. (CDRH)
Subject: RE: K142646 (b)(4)Proprietary

Mr. Goh,

(b) (5)

(b) (5)

[redacted]

Thank you and have a nice weekend,

Christopher K. Dugard
Biologist
Plastic and Reconstructive Surgery Devices Branch 2
FDA/CDRH/ODE/DSD

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Subject: RE: K142646 (b)(4)Proprietary

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[redacted]

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Subject: K142646 (b)(4)Proprietary

Dear Mr. Goh,

(b) (5)

(b) (5)

[redacted]

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From: Cheng, Cindy
To: Dugard, Christopher
Subject: RE: K142646 request for additional information
Date: Monday, April 13, 2015 4:00:44 PM
Attachments: image001.png

(b) (5)

[redacted]

From: Dugard, Christopher
Sent: Monday, April 13, 2015 3:47 PM
To: Andrew Goh
Cc: Cheng, Cindy
Subject: RE: K142646 request for additional information

Andrew,

(b) (5)

[redacted]

Christopher K. Dugard
Biologist
Plastic and Reconstructive Surgery Devices Branch 2
FDA/CDRH/ODE/DSD

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From: Andrew Goh [mailto:chiengoh@genadyne.com]
Sent: Monday, April 13, 2015 3:40 PM
To: Dugard, Christopher
Subject: RE: K142646 request for additional information

Chris,

(b) (5)

[redacted]

Regards,

Andrew Goh
Vice President
R&D and Regulatory Affairs

www.genadyne.com

Office: +1 (516) 217 0100

Fax: +1 (516) 977 8974
andrew@genadyne.com

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16 Midland Ave
Hicksville, NY 11801
USA

From: Dugard, Christopher [mailto:Christopher.Dugard@fda.hhs.gov]
Sent: Monday, April 13, 2015 3:22 PM
To: Andrew Goh
Subject: RE: K142646 request for additional information

Hi Andrew,

(b) (5)

[redacted]

Christopher K. Dugard
Biologist
Plastic and Reconstructive Surgery Devices Branch 2
FDA/CDRH/ODE/DSD

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From: Andrew Goh [mailto:chiengoh@genadyne.com]
Sent: Monday, April 13, 2015 3:12 PM
To: Dugard, Christopher
Cc: Nielsen, Joseph A. (CDRH)
Subject: RE: K142646 request for additional information

Hi Christopher,

(b) (5)

[redacted]

Regards,

Andrew Goh
Vice President
R&D and Regulatory Affairs

www.genadyne.com

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Fax: +1 (516) 977 8974
andrew@genadyne.com

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16 Midland Ave
Hicksville, NY 11801
USA

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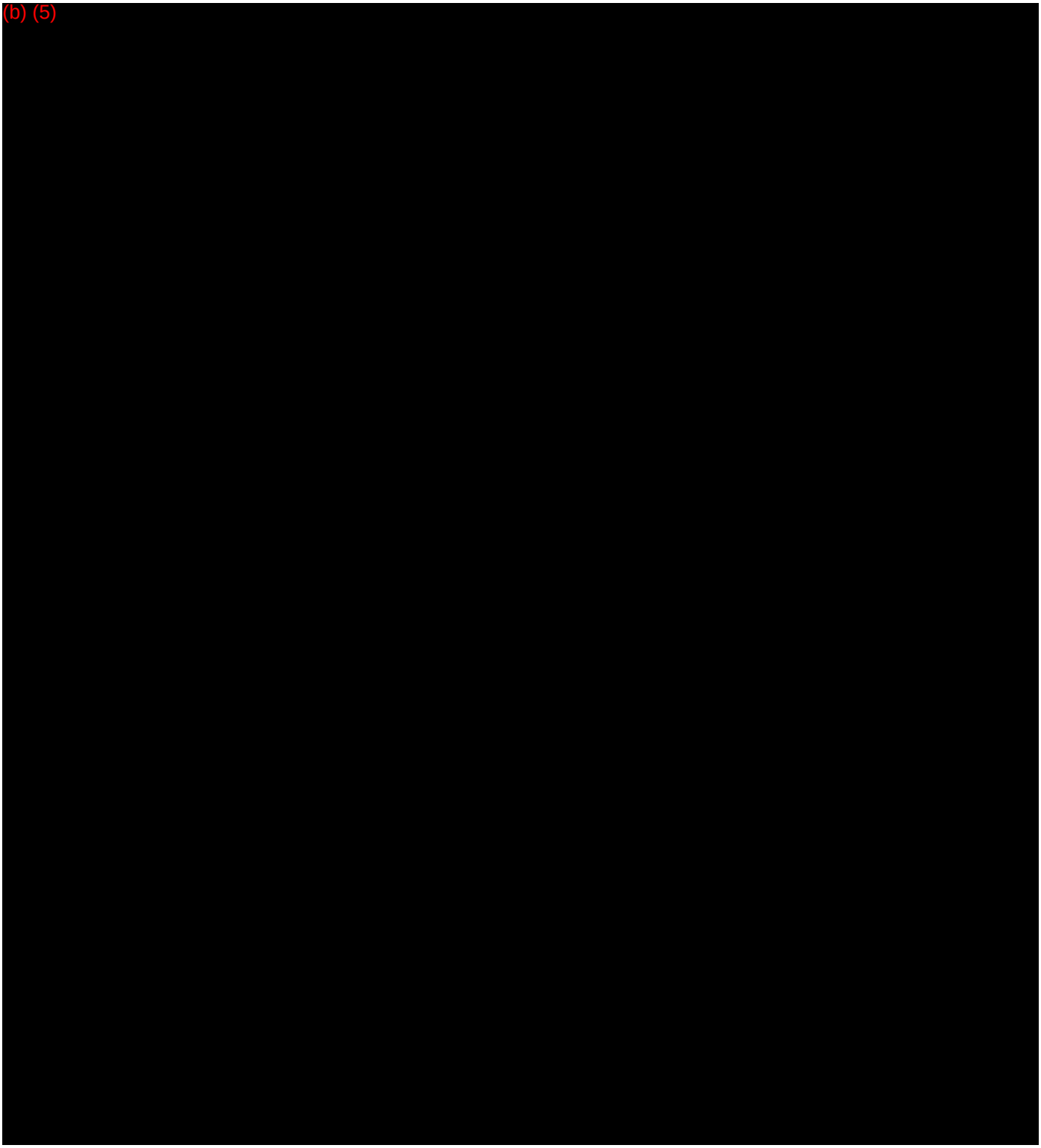
From: Dugard, Christopher [mailto:Christopher.Dugard@fda.hhs.gov]
Sent: Monday, April 13, 2015 9:40 AM
To: Andrew Goh
Cc: Nielsen, Joseph A. (CDRH)
Subject: K142646 request for additional information

Dear Mr. Goh,

(b) (5)



(b) (5)

[redacted]

Regards,

Christopher K. Dugard
Biologist
Plastic and Reconstructive Surgery Devices Branch 2
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From: Andrew Goh
To: Dugard, Christopher
Cc: Preston Liu; Nielsen, Joseph A. (CDRH)
Subject: RE: K142646 (b)(4)Proprietary
Date: Wednesday, April 22, 2015 11:17:13 AM
Attachments: image001.png
Importance: High

Hi Christopher,

(b) (5)

Thanks!

Regards,

Andrew Goh
Vice President
R&D and Regulatory Affairs

www.genadyne.com

Office: +1 (516) 217 0100

Fax: +1 (516) 977 8974
andrew@genadyne.com

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To: Andrew Goh
Cc: Preston Liu; Nielsen, Joseph A. (CDRH)
Subject: RE: K142646 (b)(4)Proprietary

Mr. Goh,

(b) (5)

Regards,

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Sent: Friday, April 17, 2015 4:36 PM
To: Dugard, Christopher
Cc: Preston Liu; Nielsen, Joseph A. (CDRH)
Subject: RE: K142646 (b)(4)Proprietary
Importance: High

Christopher,

(b) (5)

Thanks.

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Cc: Preston Liu; Nielsen, Joseph A. (CDRH)
Subject: RE: K142646 (b)(4)Proprietary

Mr. Goh,

(b) (5)

(b) (5)

[redacted]

Thank you and have a nice weekend,

Christopher K. Dugard
Biologist
Plastic and Reconstructive Surgery Devices Branch 2
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Sent: Thursday, April 16, 2015 12:18 PM
To: Dugard, Christopher
Cc: Preston Liu
Subject: RE: K142646 (b)(4)Proprietary

Hi Christopher,

(b) (5)

[redacted]

Regards,

Andrew Goh
Vice President
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Fax: +1 (516) 977 8974
andrew@genadyne.com

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From: Dugard, Christopher [mailto:Christopher.Dugard@fda.hhs.gov]
Sent: Monday, April 13, 2015 9:40 AM
To: Andrew Goh
Cc: Nielsen, Joseph A. (CDRH)
Subject: K142646 (b)(4)Proprietary

Dear Mr. Goh,

(b) (5)

[redacted]

(b) (5)

[redacted]

Regards,

Christopher K. Dugard
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From: Cheng, Cindy
To: Dugard, Christopher
Subject: RE: K142646 request for additional information
Date: Monday, April 13, 2015 4:05:05 PM
Attachments: image001.png

(b)

From: Dugard, Christopher
Sent: Monday, April 13, 2015 4:05 PM
To: Cheng, Cindy
Subject: RE: K142646 request for additional information

(b) (5)

Chris

From: Cheng, Cindy
Sent: Monday, April 13, 2015 4:01 PM
To: Dugard, Christopher
Subject: RE: K142646 request for additional information

(b) (5)

From: Dugard, Christopher
Sent: Monday, April 13, 2015 3:47 PM
To: Andrew Goh
Cc: Cheng, Cindy
Subject: RE: K142646 request for additional information

Andrew,

(b) (5)

Christopher K. Dugard
Biologist
Plastic and Reconstructive Surgery Devices Branch 2
FDA/CDRH/ODE/DSD

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=480&B=485&E=&S=E

From: Andrew Goh [mailto:chiengoh@genadyne.com]
Sent: Monday, April 13, 2015 3:40 PM
To: Dugard, Christopher

Subject: RE: K142646 request for additional information

Chris

(b) (5)

[redacted]

Thanks.

Regards,

Andrew Goh
Vice President
R&D and Regulatory Affairs

www.genadyne.com

Office: +1 (516) 217 0100

Fax: +1 (516) 977 8974
andrew@genadyne.com

Genadyne Biotechnologies
16 Midland Ave
Hicksville, NY 11801
USA

From: Dugard, Christopher [mailto:Christopher.Dugard@fda.hhs.gov]
Sent: Monday, April 13, 2015 3:22 PM
To: Andrew Goh
Subject: RE: K142646 request for additional information

Hi Andrew,

(b) (5)

[redacted]

Christopher K. Dugard
Biologist
Plastic and Reconstructive Surgery Devices Branch 2
FDA/CDRH/ODE/DSD

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From: Andrew Goh [mailto:chiengoh@genadyne.com]
Sent: Monday, April 13, 2015 3:12 PM
To: Dugard, Christopher
Cc: Nielsen, Joseph A. (CDRH)
Subject: RE: K142646 request for additional information

Hi Christopher,

(b) (5)

[redacted]

Regards,

Andrew Goh
Vice President
R&D and Regulatory Affairs

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andrew@genadyne.com

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Hicksville, NY 11801
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From: Dugard, Christopher [mailto:Christopher.Dugard@fda.hhs.gov]
Sent: Monday, April 13, 2015 9:40 AM
To: Andrew Goh
Cc: Nielsen, Joseph A. (CDRH)
Subject: K142646 request for additional information

Dear Mr. Goh,

(b) (5)

[redacted]

(b) (5)

Regards,

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Biologist
Plastic and Reconstructive Surgery Devices Branch 2
FDA/CDRH/ODE/DSD

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From: Andrew Goh
To: Dugard, Christopher
Cc: Preston Liu; Nielsen, Joseph A. (CDRH)
Subject: RE: K142646 (b)(4)Proprietary
Date: Wednesday, April 22, 2015 11:19:13 AM
Attachments: image001.png
RPT-03-001 Rev C.pdf

(b) (5) .

Regards,

Andrew Goh
Vice President
R&D and Regulatory Affairs

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Fax: +1 (516) 977 8974
andrew@genadyne.com

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16 Midland Ave
Hicksville, NY 11801
USA

From: Andrew Goh
Sent: Wednesday, April 22, 2015 11:16 AM
To: 'Dugard, Christopher'
Cc: Preston Liu; Nielsen, Joseph A. (CDRH)
Subject: RE: K142646 request for additional information
Importance: High

Hi Christopher,

(b) (5)

Thanks!

Regards,

Andrew Goh
Vice President
R&D and Regulatory Affairs

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From: Dugard, Christopher [mailto:Christopher.Dugard@fda.hhs.gov]
Sent: Tuesday, April 21, 2015 3:59 PM
To: Andrew Goh
Cc: Preston Liu; Nielsen, Joseph A. (CDRH)
Subject: RE: K142646 (b)(4)Proprietary

Mr. Goh,

(b) (5)

[redacted]

Regards,

Christopher K. Dugard
Biologist
Plastic and Reconstructive Surgery Devices Branch 2
FDA/CDRH/ODE/DSD

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From: Andrew Goh [mailto:chiengoh@genadyne.com]
Sent: Friday, April 17, 2015 4:36 PM
To: Dugard, Christopher
Cc: Preston Liu; Nielsen, Joseph A. (CDRH)
Subject: RE: K142646 (b)(4)Proprietary
Importance: High

Christopher,

(b) (5)

[redacted]

Thanks.

Regards,

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Mr. Goh,

(b) (5)

Christopher K. Dugard
Biologist
Plastic and Reconstructive Surgery Devices Branch 2
FDA/CDRH/ODE/DSD

From: Andrew Goh [mailto:chiengoh@genadyne.com]
Sent: Thursday, April 16, 2015 12:18 PM
To: Dugard, Christopher
Cc: Preston Liu
Subject: RE: K142646 (b)(4)Proprietary

Hi Christopher,

(b) (5)
[redacted]

Regards,

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Cc: Nielsen, Joseph A. (CDRH)
Subject: K142646 (b)(4)Proprietary

Dear Mr. Goh,

(b) (5)
[redacted]

(b) (5)

[redacted]

Regards,

Christopher K. Dugard
Biologist
Plastic and Reconstructive Surgery Devices Branch 2
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From: Cheng, Cindy
To: Dugard, Christopher
Subject: RE: K142646 request for additional information
Date: Thursday, April 16, 2015 2:28:18 PM
Attachments: image001.png

(b) (5)

From: Dugard, Christopher
Sent: Thursday, April 16, 2015 2:28 PM
To: Cheng, Cindy
Subject: FW: K142646 request for additional information

Hi Cindy,

(b) (5)

Chris

From: Andrew Goh [mailto:chiengoh@genadyne.com]
Sent: Thursday, April 16, 2015 12:18 PM
To: Dugard, Christopher
Cc: Preston Liu
Subject: RE: K142646 request for additional information

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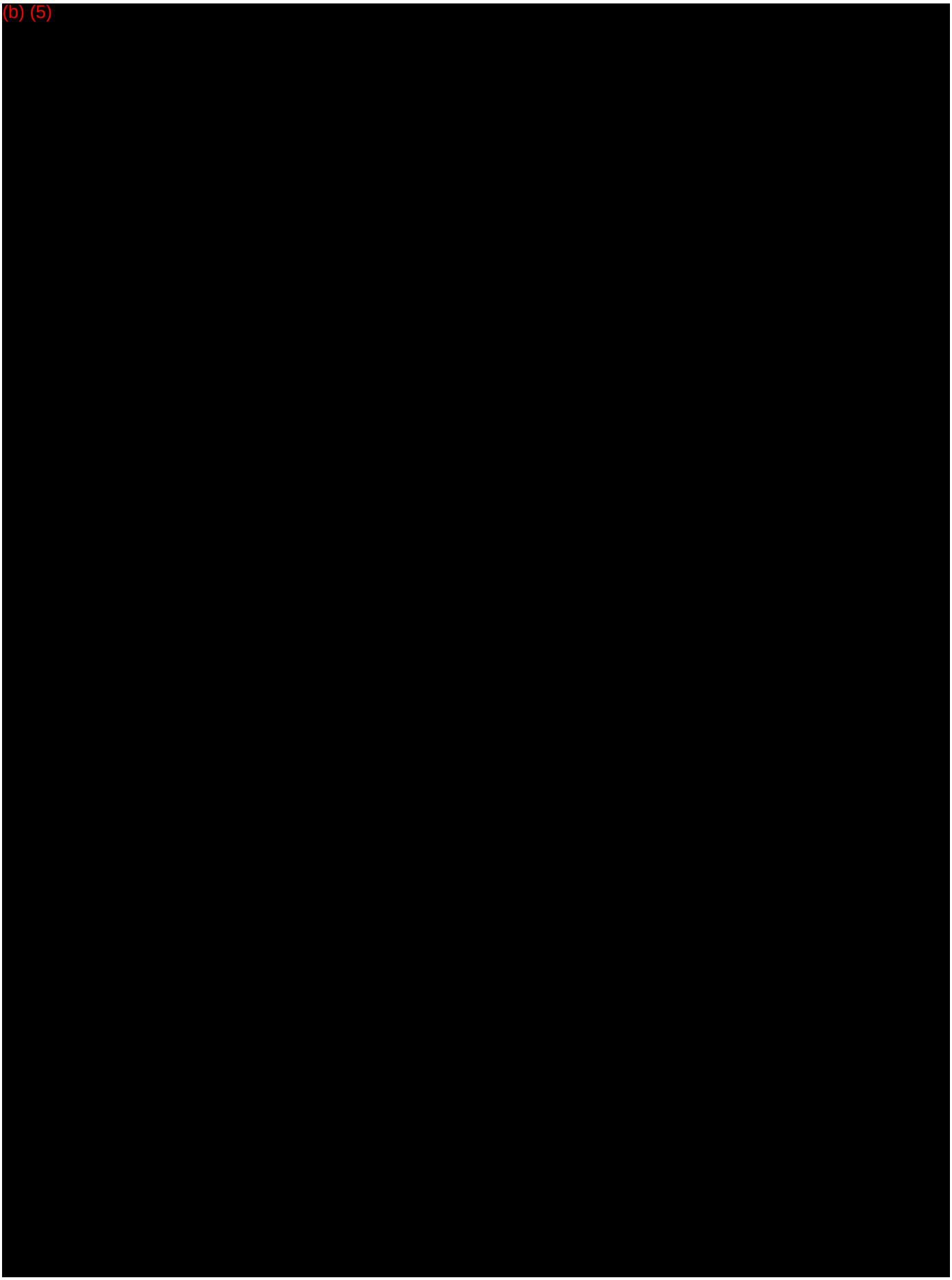
Sent: Monday, April 13, 2015 9:40 AM
To: Andrew Goh
Cc: Nielsen, Joseph A. (CDRH)
Subject: K142646 request for additional information

Dear Mr. Goh,

(b) (5)

(b) (5)



(b) (5)

[redacted]

Regards,

Christopher K. Dugard
Biologist
Plastic and Reconstructive Surgery Devices Branch 2
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From: Preston Liu
To: Dugard, Christopher; Andrew Goh
Subject: RE: K142646 (b)(4)Proprietary
Date: Thursday, April 23, 2015 2:45:29 PM
Attachments: image005.png
MVP-2012-003-PQ ETO Final Report.pdf
MVP-2012-003-PQ ETO Protocol.pdf

Dear Christopher,

(b) (5)

Thank you.

Regards,

Preston Liu
Engineer
R&D and Regulatory Affairs

www.genadyne.com

Office: +1 (516) 217 0100

Fax: +1 (516) 977 8974
PrestonL@genadyne.com

Genadyne Biotechnologies
16 Midland Ave
Hicksville, NY 11801
USA

From: Dugard, Christopher [mailto:Christopher.Dugard@fda.hhs.gov]
Sent: Thursday, April 23, 2015 1:31 PM
To: Andrew Goh
Cc: Preston Liu
Subject: RE: K142646 (b)(4)Proprietary

Hi Mr. Goh,

(b) (5)

Thanks,

Christopher K. Dugard
Biologist

Plastic and Reconstructive Surgery Devices Branch 2
FDA/CDRH/ODE/DSD

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=480&B=485&E=&S=E

From: Andrew Goh [mailto:chiengoh@genadyne.com]
Sent: Wednesday, April 22, 2015 11:16 AM
To: Dugard, Christopher
Cc: Preston Liu; Nielsen, Joseph A. (CDRH)
Subject: RE: K142646 (b)(4)Proprietary

(b) (5) .

Regards,

Andrew Goh
Vice President
R&D and Regulatory Affairs

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Fax: +1 (516) 977 8974
andrew@genadyne.com

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Hicksville, NY 11801
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Sent: Wednesday, April 22, 2015 11:16 AM
To: 'Dugard, Christopher'
Cc: Preston Liu; Nielsen, Joseph A. (CDRH)
Subject: RE: K142646(b)(4)Proprietary Information
Importance: High

Hi Christopher,

(b) (5)

Thanks!

Regards,

Andrew Goh
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R&D and Regulatory Affairs

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andrew@genadyne.com

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Sent: Tuesday, April 21, 2015 3:59 PM
To: Andrew Goh
Cc: Preston Liu; Nielsen, Joseph A. (CDRH)
Subject: RE: K142646 (b)(4)Proprietary

Mr. Goh,

(b) (5)

Regards,

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Biologist
Plastic and Reconstructive Surgery Devices Branch 2
FDA/CDRH/ODE/DSD

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From: Andrew Goh [mailto:chiengoh@genadyne.com]
Sent: Friday, April 17, 2015 4:36 PM
To: Dugard, Christopher
Cc: Preston Liu; Nielsen, Joseph A. (CDRH)
Subject: RE: K142646 (b)(4)Proprietary
Importance: High

Christopher,

(b) (5)

Thanks.

Regards,

Andrew Goh
Vice President
R&D and Regulatory Affairs

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To: Andrew Goh
Cc: Preston Liu; Nielsen, Joseph A. (CDRH)
Subject: RE: K142646 (b)(4)Proprietary

Mr. Goh,

(b) (5)

Thank you and have a nice weekend,

Christopher K. Dugard
Biologist
Plastic and Reconstructive Surgery Devices Branch 2
FDA/CDRH/ODE/DSD

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=480&B=485&E=&S=E

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To: Dugard, Christopher
Cc: Preston Liu
Subject: RE: K142646 (b)(4)Proprietary

Hi Christopher,

(b) (5)
[redacted]

Regards,

Andrew Goh
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R&D and Regulatory Affairs

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Fax: +1 (516) 977 8974
andrew@genadyne.com

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Sent: Monday, April 13, 2015 9:40 AM
To: Andrew Goh
Cc: Nielsen, Joseph A. (CDRH)
Subject: K142646 (b)(4)Proprietary

Dear Mr. Goh,

(b) (5)
[redacted]

(b) (5)

[redacted]

Regards,

Christopher K. Dugard
Biologist
Plastic and Reconstructive Surgery Devices Branch 2
FDA/CDRH/ODE/DSD

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=480&B=485&E=&S=E

From: Cheng, Cindy
To: Dugard, Christopher
Subject: RE: K142646 request for additional information
Date: Friday, April 17, 2015 10:03:32 AM
Attachments: image001.png

Hi Chris,

(b) (5) [redacted]

Thanks!
Cindy

From: Dugard, Christopher
Sent: Thursday, April 16, 2015 2:28 PM
To: Cheng, Cindy
Subject: FW: K142646 request for additional information

Hi Cindy,

(b) (5) [redacted]

Chris

From: Andrew Goh [mailto:chiengoh@genadyne.com]
Sent: Thursday, April 16, 2015 12:18 PM
To: Dugard, Christopher
Cc: Preston Liu
Subject: RE: K142646 request for additional information

Hi Christopher,

(b) (5) [redacted]

Regards,

Andrew Goh
Vice President
R&D and Regulatory Affairs

www.genadyne.com

Office: +1 (516) 217 0100

Fax: +1 (516) 977 8974
andrew@genadyne.com

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From: Dugard, Christopher [mailto:Christopher.Dugard@fda.hhs.gov]
Sent: Monday, April 13, 2015 9:40 AM
To: Andrew Goh
Cc: Nielsen, Joseph A. (CDRH)
Subject: K142646 request for additional information

Dear Mr. Goh,

(b) (5)

(b) (5)

[redacted]

Regards,

Christopher K. Dugard
Biologist
Plastic and Reconstructive Surgery Devices Branch 2
FDA/CDRH/ODE/DSD

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From: Andrew Goh
To: Dugard, Christopher
Cc: Preston Liu
Subject: RE: K142646 (b)(4)Proprietary
Date: Thursday, April 23, 2015 4:49:29 PM
Attachments: image001.png

Christopher,

(b) (5)

Thanks.

Regards,

Andrew Goh
Vice President
R&D and Regulatory Affairs

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Fax: +1 (516) 977 8974
andrew@genadyne.com

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From: Dugard, Christopher [mailto:Christopher.Dugard@fda.hhs.gov]
Sent: Thursday, April 23, 2015 1:31 PM
To: Andrew Goh
Cc: Preston Liu
Subject: RE: K142646 (b)(4)Proprietary

Hi Mr. Goh,

(b) (5)

Thanks,

Christopher K. Dugard
Biologist
Plastic and Reconstructive Surgery Devices Branch 2
FDA/CDRH/ODE/DSD

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Sent: Wednesday, April 22, 2015 11:16 AM
To: Dugard, Christopher
Cc: Preston Liu; Nielsen, Joseph A. (CDRH)
Subject: RE: K142646 (b)(4)Proprietary n

(b) (5) .

Regards,

Andrew Goh
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Importance: High

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Cc: Preston Liu; Nielsen, Joseph A. (CDRH)
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Mr. Goh,

(b) (5) [redacted]

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Christopher K. Dugard
Biologist
Plastic and Reconstructive Surgery Devices Branch 2
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Sent: Friday, April 17, 2015 4:36 PM
To: Dugard, Christopher
Cc: Preston Liu; Nielsen, Joseph A. (CDRH)
Subject: RE: K142646 (b)(4)Proprietary [redacted]
Importance: High

Christopher,

(b) (5) [redacted]

Thanks.

Regards,

Andrew Goh
Vice President
R&D and Regulatory Affairs

Office: +1 (516) 217 0100

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Mr. Goh,

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Christopher K. Dugard
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Plastic and Reconstructive Surgery Devices Branch 2

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Dear Mr. Goh,

(b) (5)

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From: Cheng, Cindy
To: Dugard, Christopher
Cc: Nielsen, Joseph A. (CDRH)
Subject: RE: K142646 request for additional information
Date: Friday, April 17, 2015 10:37:06 AM
Attachments: K142646-S003.ENG-MECH.Consult-Part2.pdf
image001.png

Hi Chris,

(b) (5) [redacted]

Cindy

From: Dugard, Christopher
Sent: Friday, April 17, 2015 10:04 AM
To: Cheng, Cindy
Subject: RE: K142646 request for additional information

(b) (5) [redacted],

Chris

From: Cheng, Cindy
Sent: Friday, April 17, 2015 10:03 AM
To: Dugard, Christopher
Subject: RE: K142646 request for additional information

Hi Chris,

(b) (5) [redacted]

Thanks!
Cindy

From: Dugard, Christopher
Sent: Thursday, April 16, 2015 2:28 PM
To: Cheng, Cindy
Subject: FW: K142646 request for additional information

Hi Cindy,

(b) (5) [redacted]

Chris

From: Andrew Goh [mailto:chiengoh@genadyne.com]
Sent: Thursday, April 16, 2015 12:18 PM
To: Dugard, Christopher
Cc: Preston Liu
Subject: RE: K142646 request for additional information

Hi Christopher,

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Cc: Nielsen, Joseph A. (CDRH)
Subject: K142646 request for additional information

Dear Mr. Goh,

(b) (5)

(b) (5)

[redacted]

Regards,

Christopher K. Dugard
Biologist
Plastic and Reconstructive Surgery Devices Branch 2
FDA/CDRH/ODE/DSD

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From: Preston Liu
To: Andrew Goh; Dugard, Christopher
Subject: RE: K142646 (b)(4)Proprietary
Date: Thursday, April 23, 2015 5:30:58 PM

Dear Christopher,

(b) (5)

Thank you.

Regards,

Preston Liu
Engineer
R&D and Regulatory Affairs

www.genadyne.com

Office: +1 (516) 217 0100

Fax: +1 (516) 977 8974
PrestonL@genadyne.com

Genadyne Biotechnologies
16 Midland Ave
Hicksville, NY 11801
USA

From: Andrew Goh
Sent: Thursday, April 23, 2015 5:30 PM
To: Dugard, Christopher
Cc: Preston Liu
Subject: Re: K142646 (b)(4)Proprietary

(b) (5)

Thank you.

Regards,

Andrew Goh

On Apr 23, 2015, at 17:29, Dugard, Christopher <Christopher.Dugard@fda.hhs.gov> wrote:

> Hi Andrew,
>
> (b) (5)
>
> Thanks,
>
> Christopher K. Dugard
> Biologist
> Plastic and Reconstructive Surgery Devices Branch 2
> FDA/CDRH/ODE/DSD
>
> *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=480&B=485&E=&S=E

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Sent: Thursday, April 23, 2015 4:49 PM
To: Dugard, Christopher
Cc: Preston Liu
Subject: RE: K142646 (b)(4)Proprietary

Christopher,

(b) (5)

Thanks.

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Sent: Thursday, April 23, 2015 1:31 PM
To: Andrew Goh
Cc: Preston Liu
Subject: RE: K142646 (b)(4)Proprietary

Hi Mr. Goh,

(b) (5)

Thanks,

Christopher K. Dugard
Biologist
Plastic and Reconstructive Surgery Devices Branch 2

FDA/CDRH/ODE/DSD

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=480&B=485&E=&S=E

From: Andrew Goh [mailto:chiengoh@genadyne.com]
Sent: Wednesday, April 22, 2015 11:16 AM
To: Dugard, Christopher
Cc: Preston Liu; Nielsen, Joseph A. (CDRH)
Subject: RE: K142646 (b)(4)Proprietary

(b) (5)

Regards,

Andrew Goh
Vice President
R&D and Regulatory Affairs

www.genadyne.com

Office: +1 (516) 217 0100

Fax: +1 (516) 977 8974
andrew@genadyne.com

Genadyne Biotechnologies
16 Midland Ave
Hicksville, NY 11801
USA

From: Andrew Goh
Sent: Wednesday, April 22, 2015 11:16 AM
To: 'Dugard, Christopher'
Cc: Preston Liu; Nielsen, Joseph A. (CDRH)
Subject: RE: K142646 (b)(4)Proprietary
Importance: High

Hi Christopher,

(b) (5)

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Sent: Tuesday, April 21, 2015 3:59 PM
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Cc: Preston Liu; Nielsen, Joseph A. (CDRH)
Subject: RE: K142646 (b)(4)Proprietary

Mr. Goh,

(b) (5)

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Importance: High

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Plastic and Reconstructive Surgery Devices Branch 2
FDA/CDRH/ODE/DSD

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[redacted]

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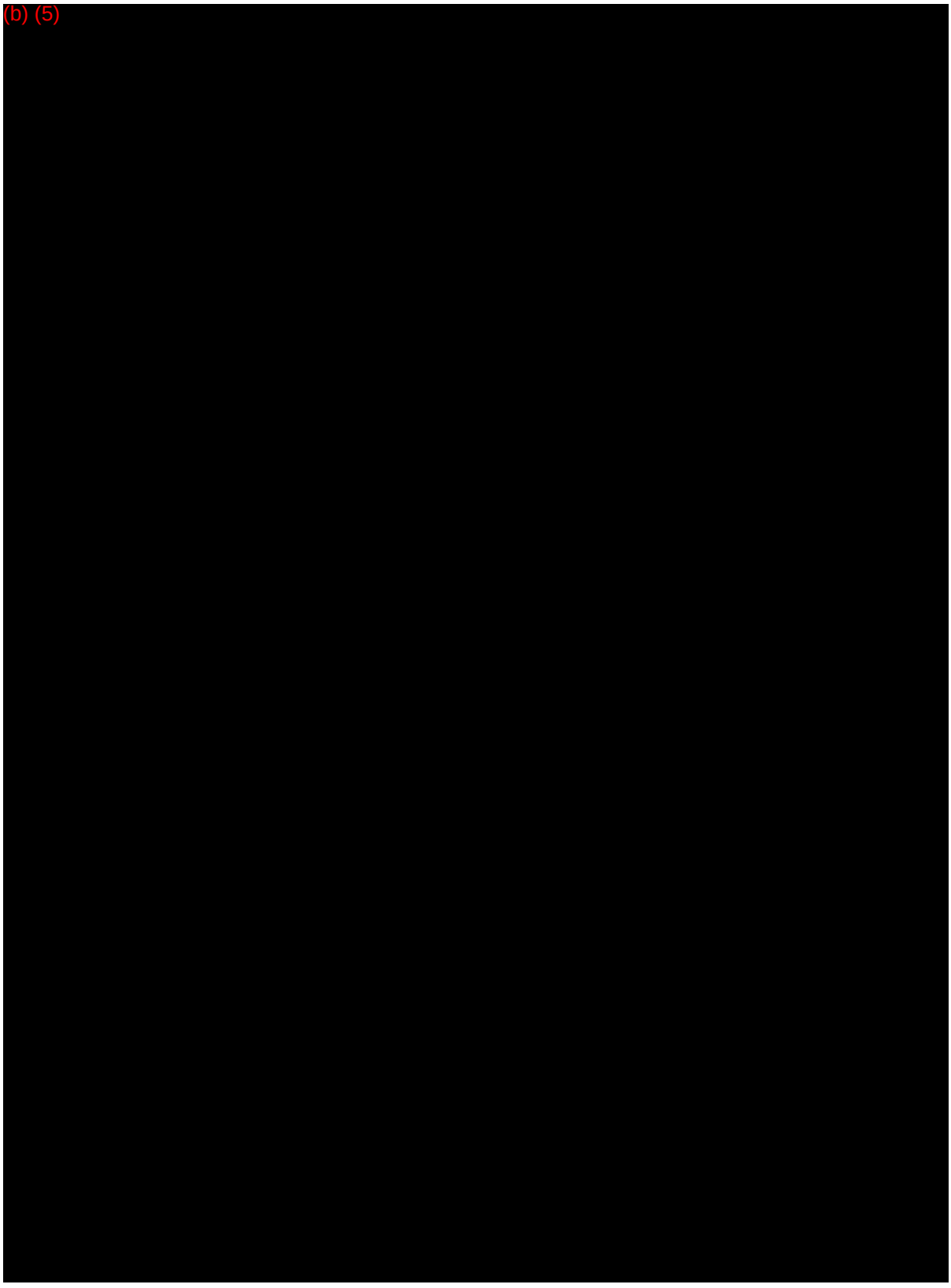
Cc: Nielsen, Joseph A. (CDRH)
Subject: K142646 (b)(4)Proprietary

Dear Mr. Goh,

(b) (5)
[redacted]

(b) (5)



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From: Cheng, Cindy
To: Dugard, Christopher
Subject: RE: K142646 request for additional information
Date: Tuesday, April 21, 2015 2:32:50 PM
Attachments: image001.png
K142646-S003.ENG-MECH.Consult-Part3.pdf

Hey Chris,

(b) (5)

Cindy

From: Dugard, Christopher
Sent: Tuesday, April 21, 2015 11:17 AM
To: Cheng, Cindy
Subject: FW: K142646 request for additional information
Importance: High

Hi Cindy,

(b) (5)

Chris

From: Andrew Goh [mailto:chiengoh@genadyne.com]
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To: Dugard, Christopher
Cc: Preston Liu; Nielsen, Joseph A. (CDRH)
Subject: RE: K142646 request for additional information
Importance: High

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16 Midland Ave
Hicksville, NY 11801

www.genadyne.com andrew@genadyne.com USA

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From: Preston Liu
To: Dugard, Christopher
Cc: Andrew Goh
Subject: RE: K142646 (b)(4)Proprietary
Date: Tuesday, April 28, 2015 12:56:10 PM

Dear Christopher,

(b) (5)

Thank you.

Regards,

Preston Liu
Engineer
R&D and Regulatory Affairs

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> (b) (5)
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> Plastic and Reconstructive Surgery Devices Branch 2
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Mr. Goh,

(b) (5)

(b) (5) [redacted]

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(b) (5)

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Biologist

Plastic and Reconstructive Surgery Devices Branch 2
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From: Cheng, Cindy
To: Dugard, Christopher
Subject: RE: K142646 request for additional information
Date: Wednesday, April 22, 2015 11:52:42 AM
Attachments: K142646-S003.ENG-MECH.Consult-FINAL.pdf
image001.png

Chris-

(b) (5)

Cindy

From: Dugard, Christopher
Sent: Wednesday, April 22, 2015 11:44 AM
To: Cheng, Cindy
Subject: FW: K142646 request for additional information

(b) (5)

Chris

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Subject: K142646 request for additional information

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(b) (5)

[redacted]

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[redacted]

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From: Preston Liu
To: Dugard, Christopher
Cc: Andrew Goh
Subject: RE: K142646 (b)(4)Proprietary
Date: Wednesday, April 29, 2015 10:35:54 AM
Attachments: (b)(4)Proprietary Information

Dear Christopher,

(b) (5)

Thank you.

Regards,

Preston Liu
Engineer
R&D and Regulatory Affairs

www.genadyne.com

Office: +1 (516) 217 0100

Fax: +1 (516) 977 8974
PrestonL@genadyne.com

Genadyne Biotechnologies
16 Midland Ave
Hicksville, NY 11801
USA

From: Dugard, Christopher [mailto:Christopher.Dugard@fda.hhs.gov]
Sent: Wednesday, April 29, 2015 10:03 AM
To: Preston Liu
Cc: Andrew Goh
Subject: RE: K142646 (b)(4)Proprietary

Hi Preston,

(b) (5)

(b) (5) [redacted]

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Plastic and Reconstructive Surgery Devices Branch 2
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From: Preston Liu [mailto:PrestonL@genadyne.com]
Sent: Tuesday, April 28, 2015 12:56 PM
To: Dugard, Christopher
Cc: Andrew Goh
Subject: RE: K142646 (b)(4)Proprietary [redacted]

Dear Christopher,

(b) (6) [redacted]

Thank you.

Regards,

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Engineer
R&D and Regulatory Affairs

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Cc: Preston Liu
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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=480&B=485&E=&S=E

From: Andrew Goh [mailto:chiengoh@genadyne.com]
Sent: Friday, April 17, 2015 4:36 PM
To: Dugard, Christopher
Cc: Preston Liu; Nielsen, Joseph A. (CDRH)
Subject: RE: K142646 (b)(4)Proprietary
Importance: High

Christopher,

(b) (5)

Thanks.

Regards,

Andrew Goh
Vice President
R&D and Regulatory Affairs

www.genadyne.com

Office: +1 (516) 217 0100

Fax: +1 (516) 977 8974
andrew@genadyne.com

Genadyne Biotechnologies
16 Midland Ave
Hicksville, NY 11801
USA

From: Dugard, Christopher [mailto:Christopher.Dugard@fda.hhs.gov]
Sent: Friday, April 17, 2015 3:23 PM
To: Andrew Goh
Cc: Preston Liu; Nielsen, Joseph A. (CDRH)
Subject: RE: K142646 (b)(4)Proprietary

Mr. Goh,

(b) (5)

(b) (5)

[redacted]

Christopher K. Dugard
Biologist
Plastic and Reconstructive Surgery Devices Branch 2
FDA/CDRH/ODE/DSD

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=480&B=485&E=&S=E

From: Andrew Goh [mailto:chiengoh@genadyne.com]
Sent: Thursday, April 16, 2015 12:18 PM
To: Dugard, Christopher
Cc: Preston Liu
Subject: RE: K142646 (b)(4)Proprietary

Hi Christopher,

(b) (5)

[redacted]

Regards,

Andrew Goh
Vice President
R&D and Regulatory Affairs

www.genadyne.com

Office: +1 (516) 217 0100

Fax: +1 (516) 977 8974
andrew@genadyne.com

Genadyne Biotechnologies
16 Midland Ave
Hicksville, NY 11801
USA

From: Dugard, Christopher [mailto:Christopher.Dugard@fda.hhs.gov]
Sent: Monday, April 13, 2015 9:40 AM
To: Andrew Goh

Cc: Nielsen, Joseph A. (CDRH)
Subject: K142646 (b)(4)Proprietary

Dear Mr. Goh,

(b) (5)

(b) (5)

[redacted]

Regards,

Christopher K. Dugard
Biologist
Plastic and Reconstructive Surgery Devices Branch 2
FDA/CDRH/ODE/DSD

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=480&B=485&E=&S=E

DEPARTMENT OF HEALTH AND HUMAN SERVICES MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993

K142646/S003 ENG-MECH Review

Date: April 7, 2015
To: Chris Dugard, M.S., Lead Reviewer (CDRH/ODE/DSD/PRSB2)
From: Cindy Cheng, Ph.D., Biomedical Engineer (CDRH/ODE/DSD/PRSB2)

Sponsor: Genadyne Biotechnologies
Device: XLR8 White Foam Dressing Kit
Consult due date: April 217, 2015

Table of Contents

I. ENG-MECH Recommendation

(b)(4)Proprietary Information

[redacted]

Food and Drug Administration
Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993

II. Review Scope

(b)(4)Proprietary Information

[redacted]

III. Regulatory History

(b)(4)Proprietary Information

[redacted]

IV. Indications for Use

Genadyne XLR8 White Foam Dressing Kit is intended to be used in conjunction with the Genadyne A4 Wound Vacuum System (K082676) as well as the Genadyne A4-XLR8 Wound Vacuum System (K090638) to deliver negative pressure to the wound. Genadyne A4 & A4-XLR8 Wound Vacuum System is indicated for patients who would benefit from a suction device particularly as the device may promote wound healing by the removal of excess exudates, infectious material and tissue debris.

V. Device Description

(b)(4)Proprietary Information

[redacted]

VI. Predicate Device

(b)(4)Proprietary Information

[redacted]

Food and Drug Administration
Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993

VII. Original Deficiency

(b)(4)Proprietary Information

[redacted]

VIII. Sponsor's Response to Deficiency and Summary of Testing

(b)(4)Proprietary Information

[redacted]

DEPARTMENT OF HEALTH AND HUMAN SERVICES MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993

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Food and Drug Administration
Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993

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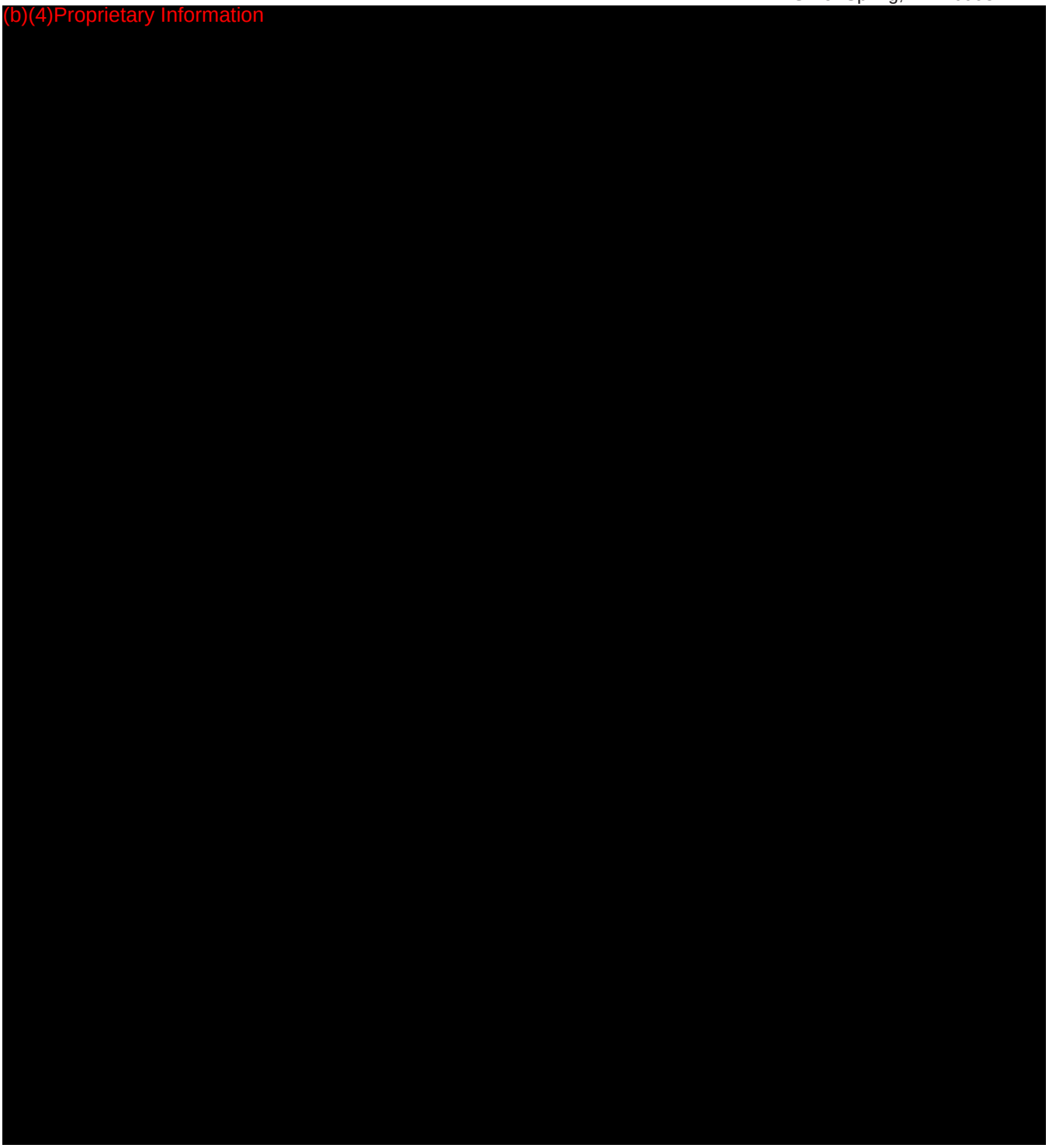

Food and Drug Administration
Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993

(b)(4)Proprietary Information

IX. Specific Questions from Lead Reviewer

(b)(4)Proprietary Information

X. Deficiencies

(b)(4)Proprietary Information

DEPARTMENT OF HEALTH AND HUMAN SERVICES MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993

(b)(4)Proprietary Information

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Food and Drug Administration
Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993

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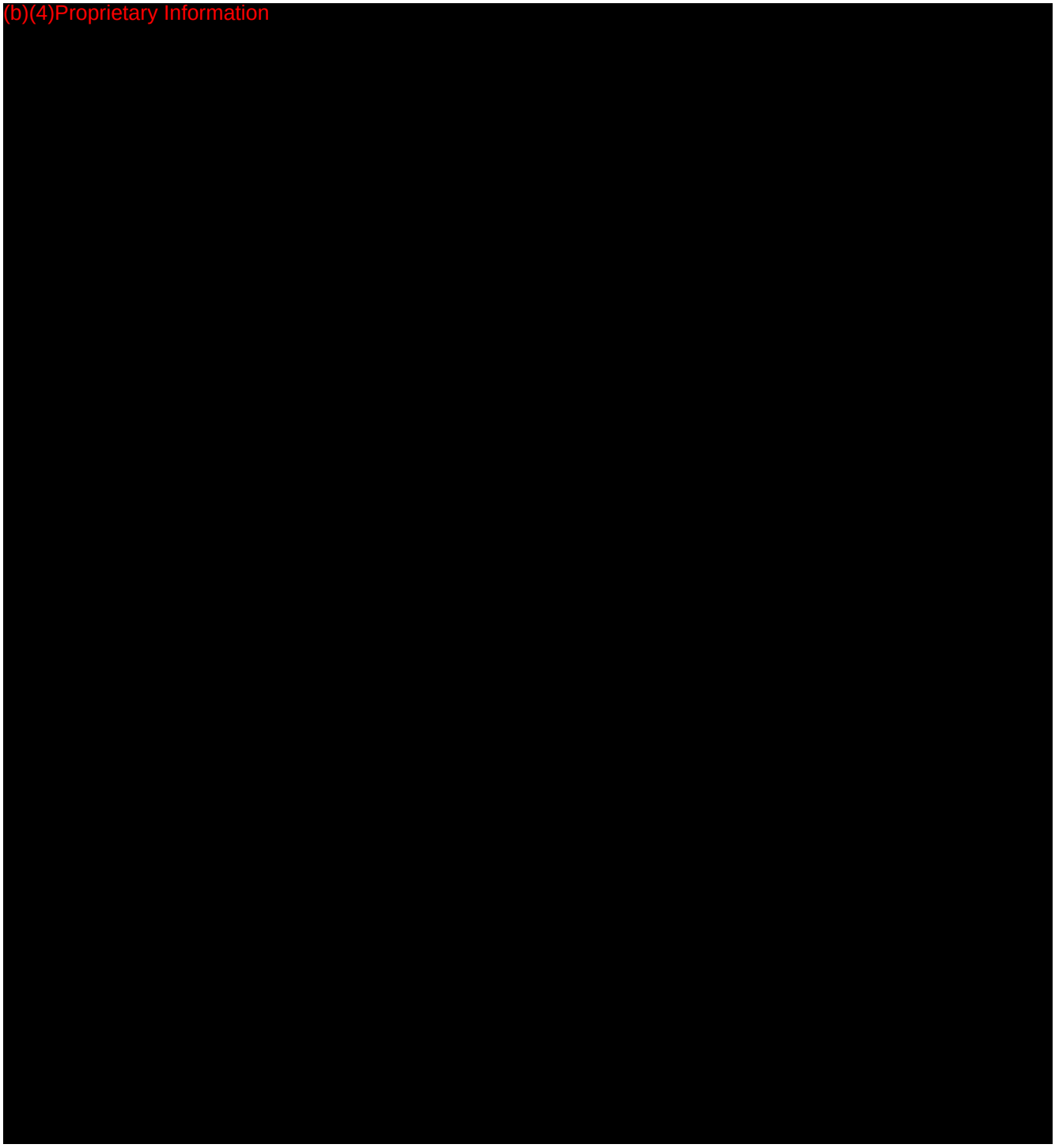

Food and Drug Administration
Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993

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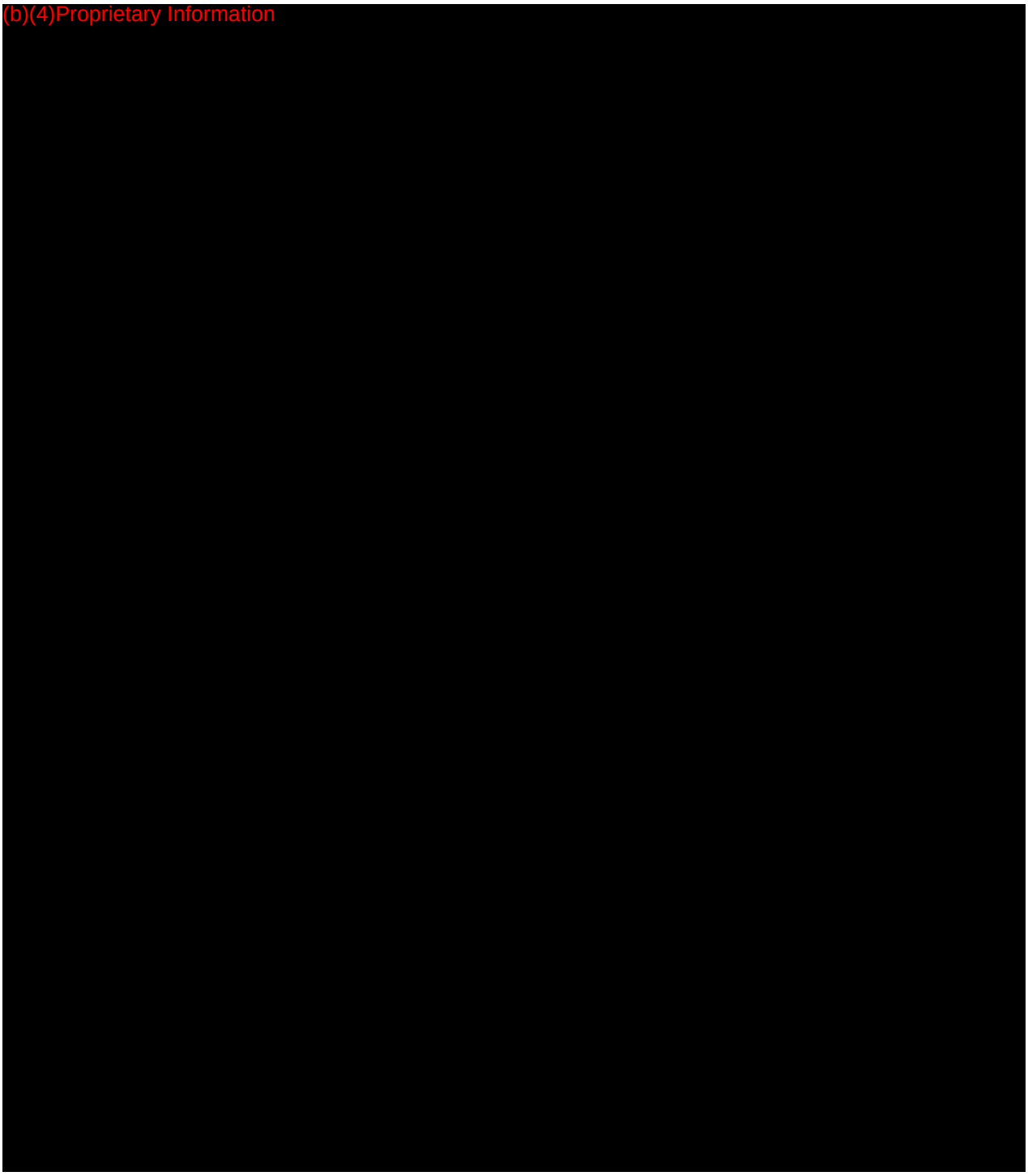

Food and Drug Administration
Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993

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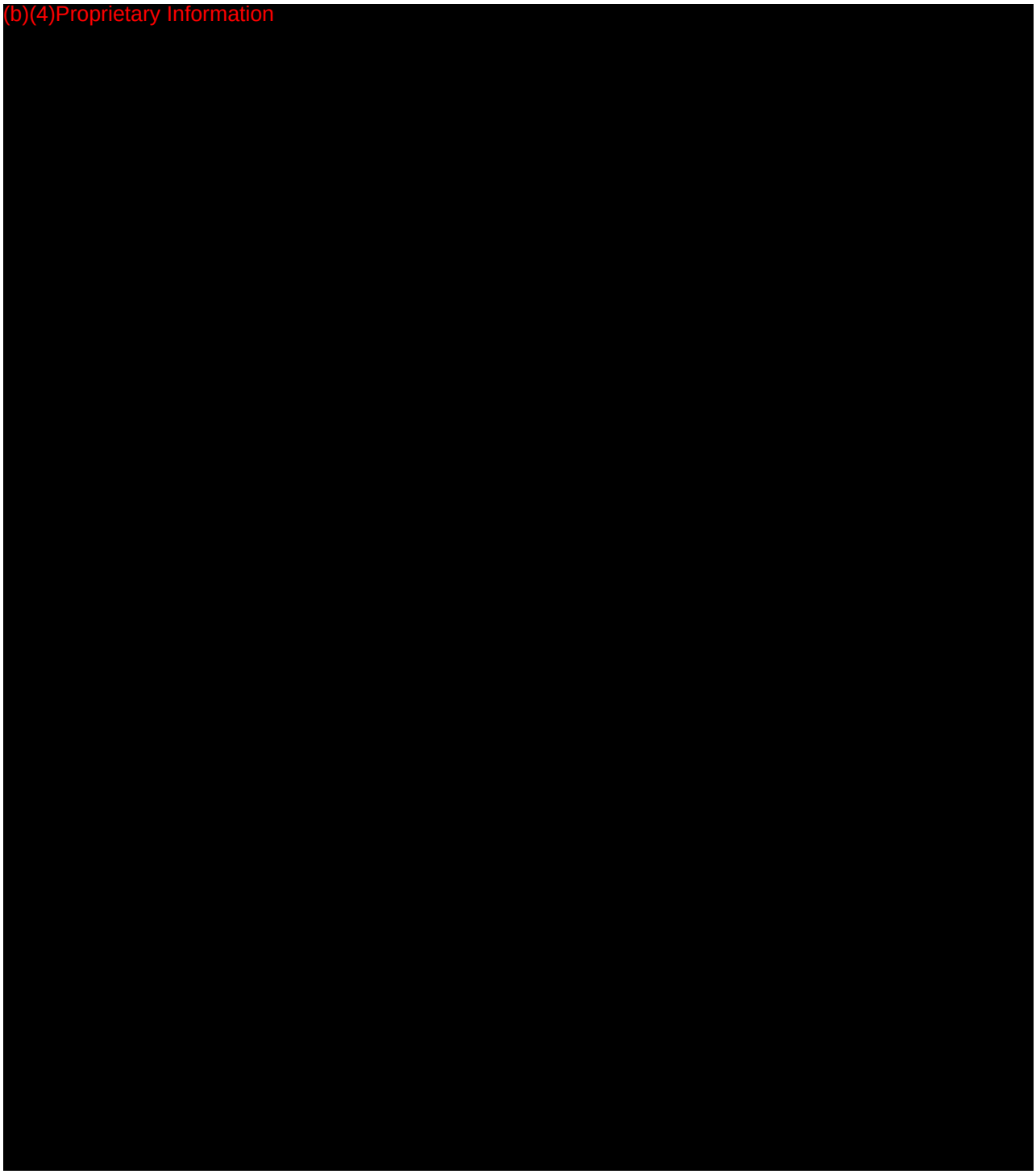

DEPARTMENT OF HEALTH AND HUMAN SERVICES MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993

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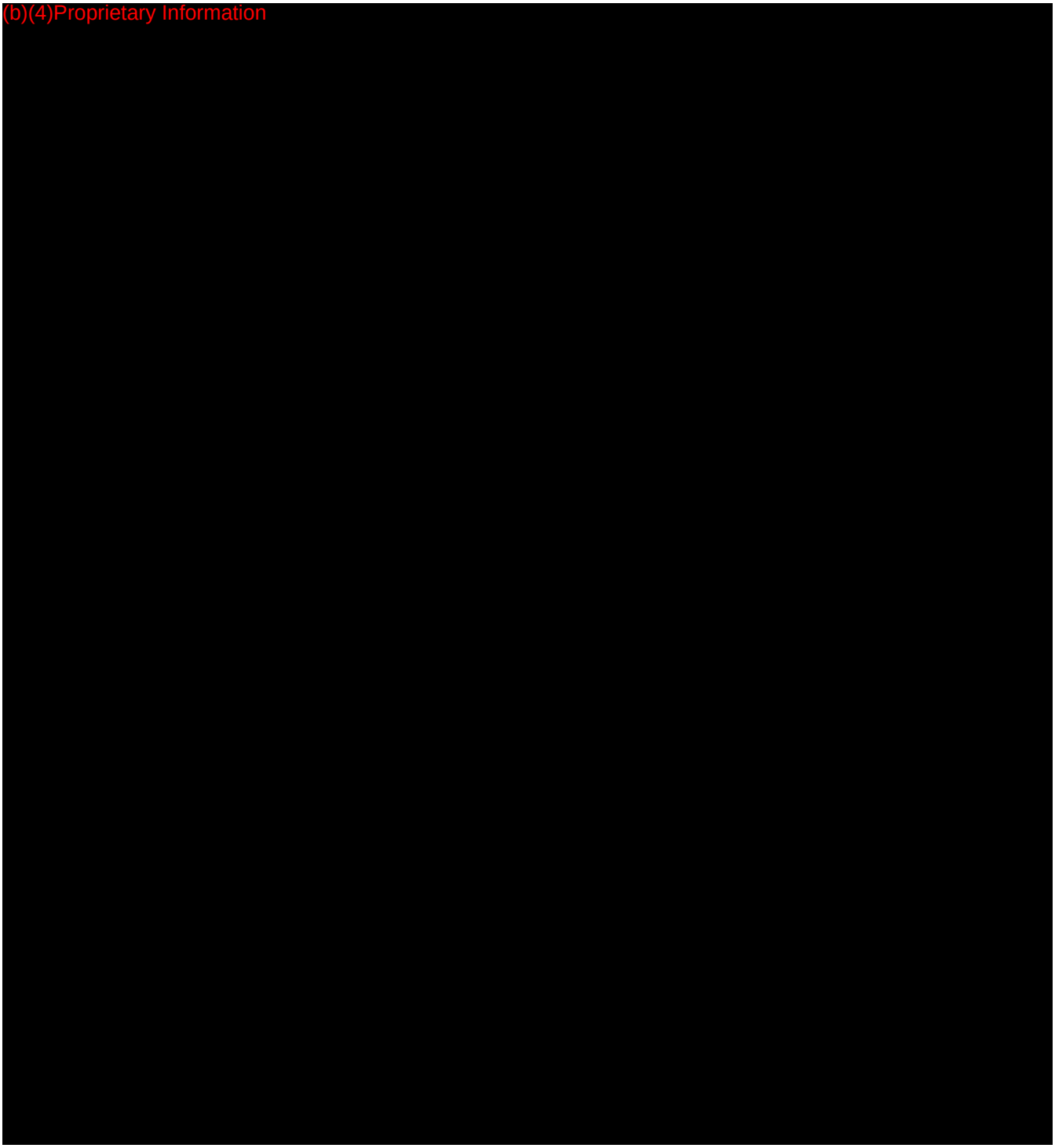

DEPARTMENT OF HEALTH AND HUMAN SERVICES MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993

(b)(4)Proprietary Information

[redacted]

XI. Interactive Review

(b)(4)Proprietary Information

[redacted]

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Reviewer Sign-Off	Cindy Cheng -S 2015.04.21 14:28:32 -04'00'
Branch Chief Sign-Off	

DEPARTMENT OF HEALTH AND HUMAN SERVICES MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993

K142646/S003 ENG-MECH Review

Date: April 7, 2015
To: Chris Dugard, M.S., Lead Reviewer (CDRH/ODE/DSD/PRSB2)
From: Cindy Cheng, Ph.D., Biomedical Engineer (CDRH/ODE/DSD/PRSB2)

Sponsor: Genadyne Biotechnologies
Device: XLR8 White Foam Dressing Kit
Consult due date: April 217, 2015

Table of Contents

I. ENG-MECH Recommendation

(b)(4)Proprietary Information

[redacted]

Food and Drug Administration
Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993

II. Review Scope

(b)(4)Proprietary Information

[redacted]

III. Regulatory History

(b)(4)Proprietary Information

[redacted]

IV. Indications for Use

Genadyne XLR8 White Foam Dressing Kit is intended to be used in conjunction with the Genadyne A4 Wound Vacuum System (K082676) as well as the Genadyne A4-XLR8 Wound Vacuum System (K090638) to deliver negative pressure to the wound. Genadyne A4 & A4-XLR8 Wound Vacuum System is indicated for patients who would benefit from a suction device particularly as the device may promote wound healing by the removal of excess exudates, infectious material and tissue debris.

V. Device Description

The subject device is a foam dressing kit indicated for use with specific Genadyne NPWT pumps.

The subject device is a rectangular shaped foam manufactured using a polyvinyl alcohol foam material, a silicone port tubing, and a transparent adhesive film dressing. This single-use dressing kit is housed in a Tyvek/Mylar Peel Pouch. Each product is sterilized individually.

The foam dressing is composed of flexible polyether and polyester polyurethane foam and comes in the following sizes: 7.5cm x 10cm x 3.3cm, 12.5cm x 18cm x 3.3cm, and 15cm x 26cm x 3.3cm.

VI. Predicate Device

Genadyne A4-XLR8 Foam Dressing (K092992)

Food and Drug Administration
Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993

VII. Original Deficiency

(b)(4)Proprietary Information

[redacted]

VIII. Sponsor's Response to Deficiency and Summary of Testing

(b)(4)Proprietary Information

[redacted]

Food and Drug Administration
Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993

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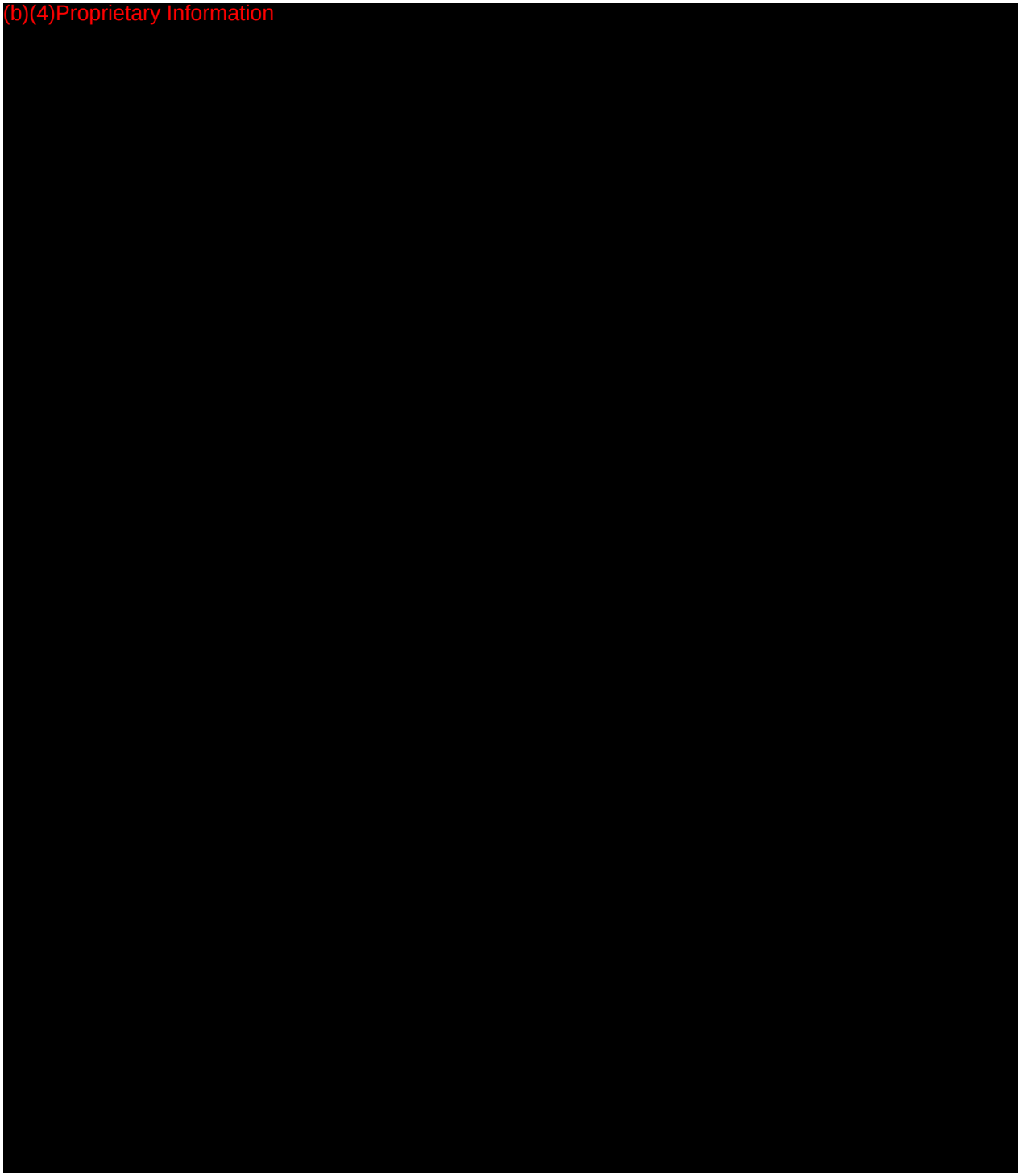

Food and Drug Administration
Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993

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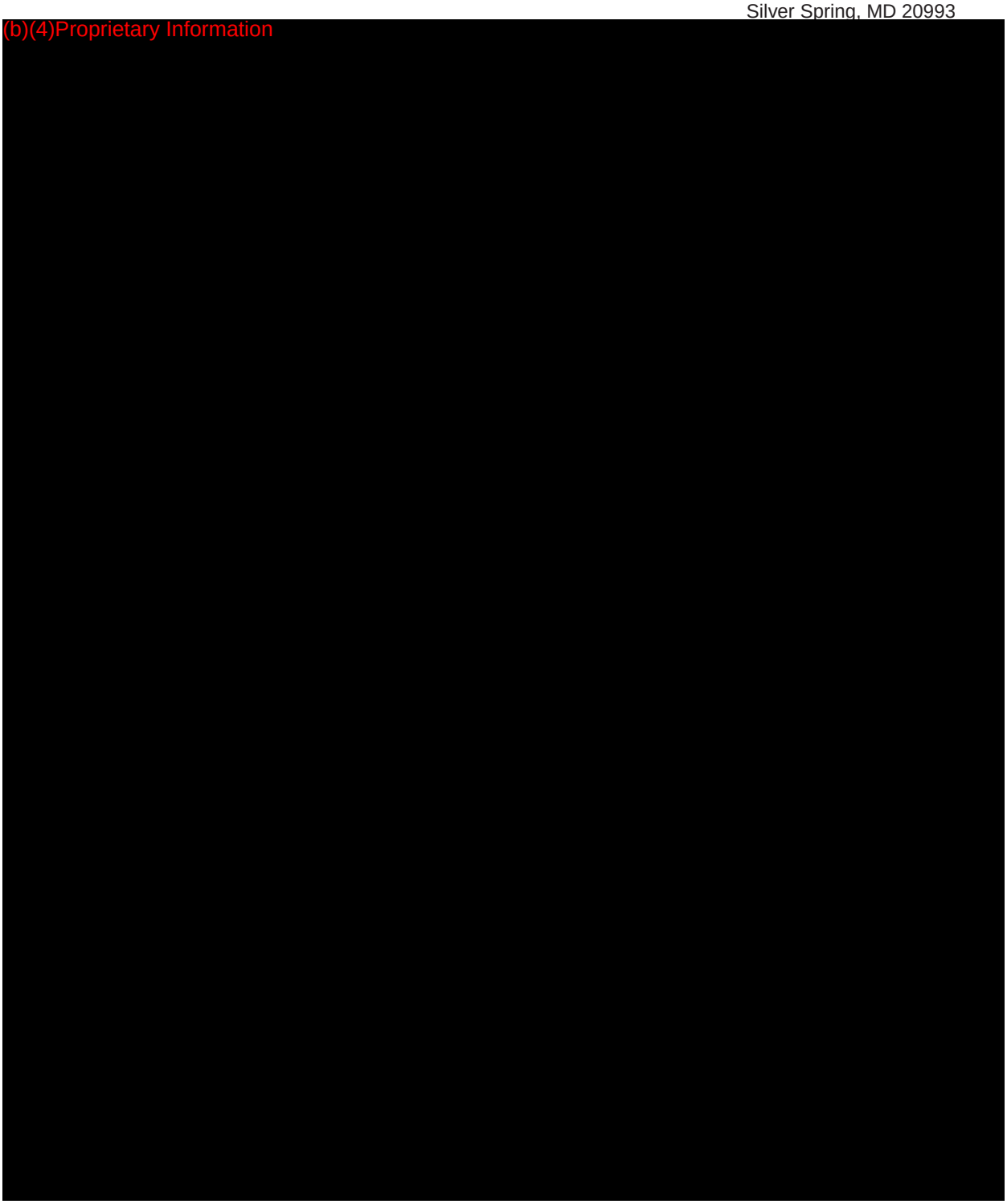


Food and Drug Administration
Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993

(b)(4)Proprietary Information

IX. Specific Questions from Lead Reviewer

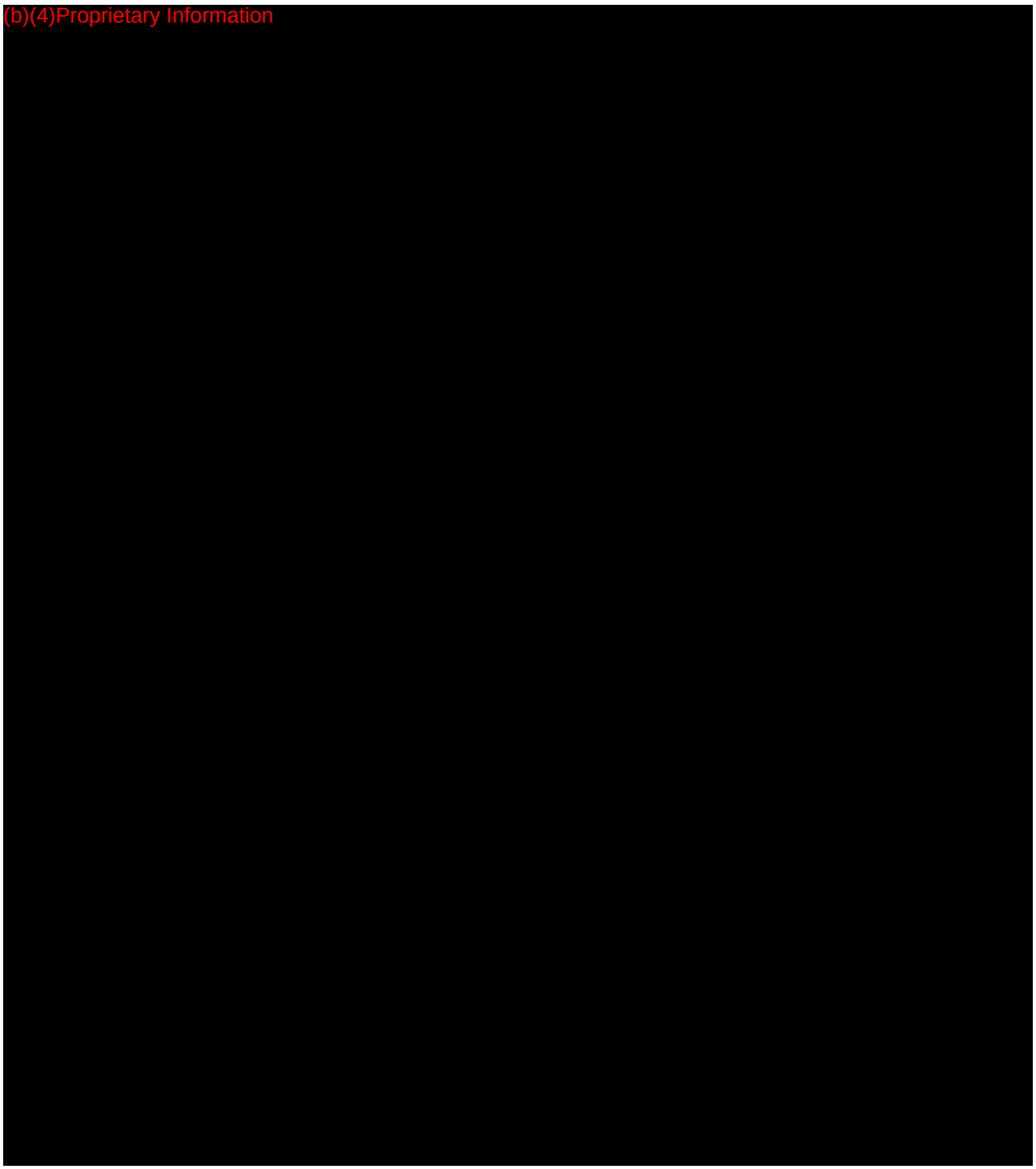
(b)(4)Proprietary Information

X. Deficiencies

(b)(4)Proprietary Information

Food and Drug Administration
Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993

(b)(4)Proprietary Information



Food and Drug Administration
Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993

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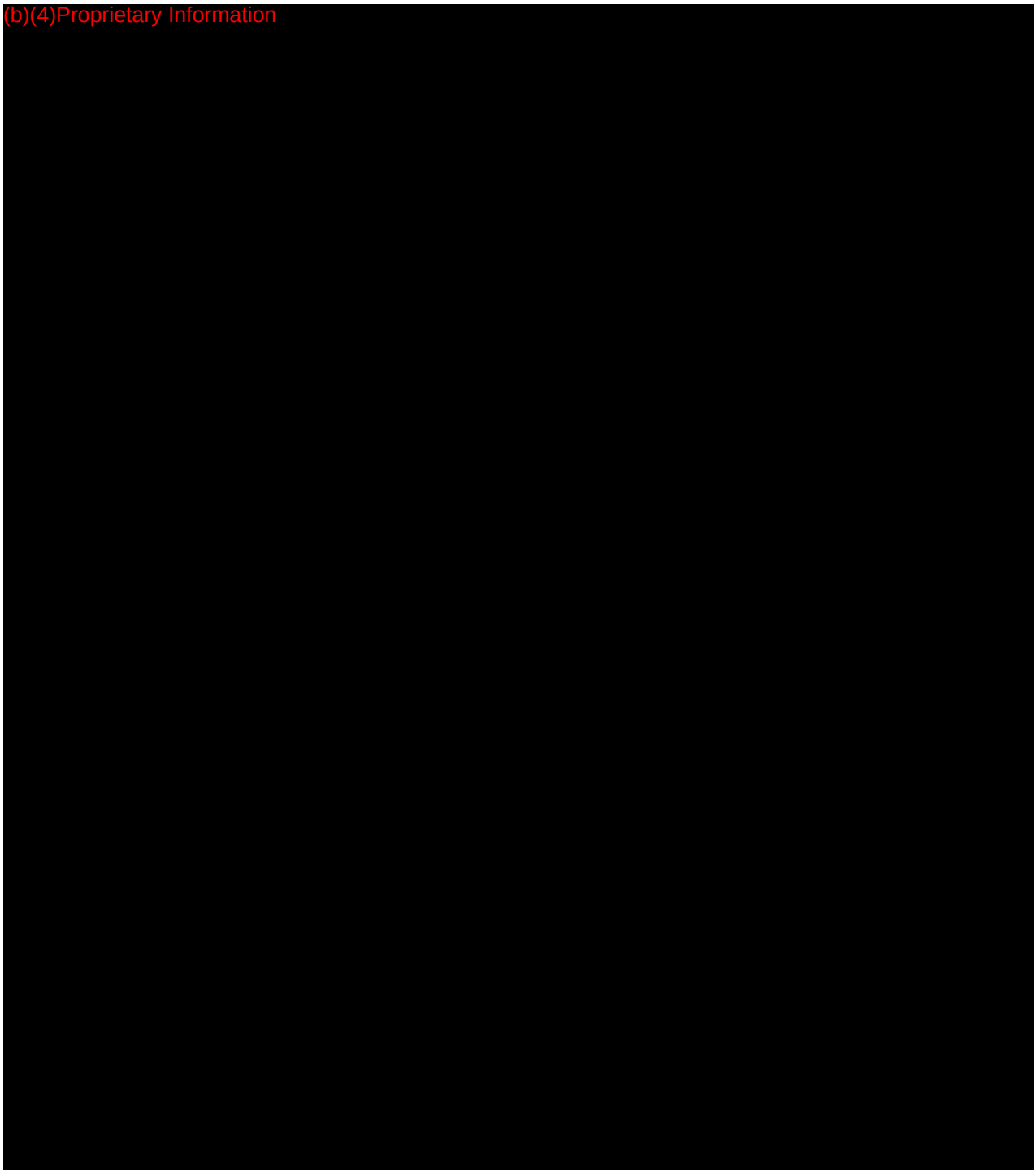

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Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993

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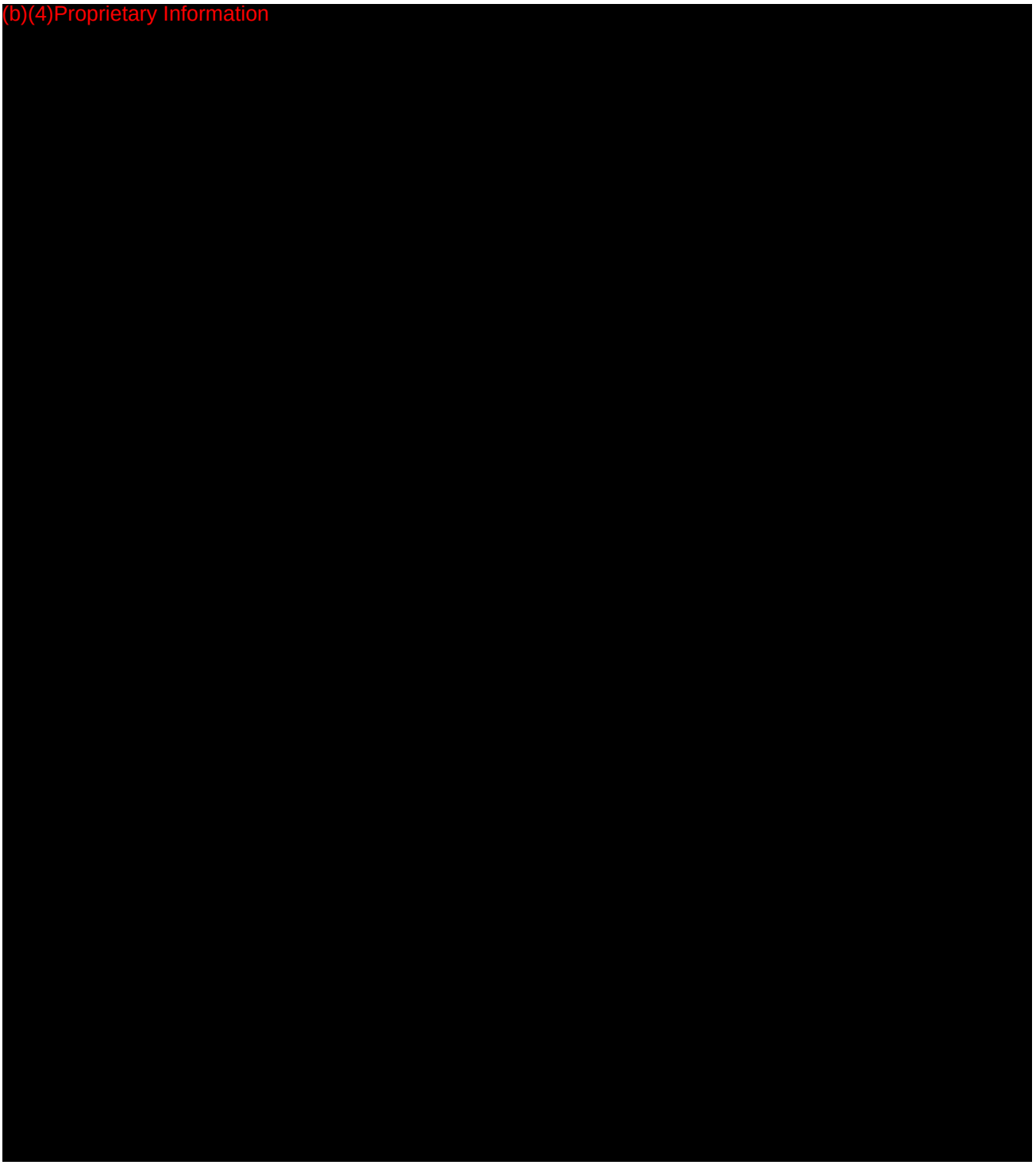


Food and Drug Administration
Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993

(b)(4)Proprietary Information

[redacted]

XI. Interactive Review

(b)(4)Proprietary Information

[redacted]

DEPARTMENT OF HEALTH AND HUMAN SERVICES MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993

(b)(4)Proprietary Information

[redacted]

Digital Signature Concurrence Table	
Reviewer Sign-Off	Cindy Cheng -S 2015.04.17 10:35:02 -04'00'
Branch Chief Sign-Off	

DEPARTMENT OF HEALTH AND HUMAN SERVICES MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993

K142646/S003 ENG-MECH Review

Date: April 22, 2015
To: Chris Dugard, M.S., Lead Reviewer (CDRH/ODE/DSD/PRSB2)
From: Cindy Cheng, Ph.D., Biomedical Engineer (CDRH/ODE/DSD/PRSB2)

Sponsor: Genadyne Biotechnologies
Device: XLR8 White Foam Dressing Kit
Consult due date: April 22, 2015

Table of Contents

I. ENG-MECH Recommendation

(b)(4)Proprietary Information

[redacted]

Food and Drug Administration
Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993

II. Review Scope

(b)(4)Proprietary Information

[redacted]

III. Regulatory History

(b)(4)Proprietary Information

[redacted]

IV. Indications for Use

Genadyne XLR8 White Foam Dressing Kit is intended to be used in conjunction with the Genadyne A4 Wound Vacuum System (K082676) as well as the Genadyne A4-XLR8 Wound Vacuum System (K090638) to deliver negative pressure to the wound. Genadyne A4 & A4-XLR8 Wound Vacuum System is indicated for patients who would benefit from a suction device particularly as the device may promote wound healing by the removal of excess exudates, infectious material and tissue debris.

V. Device Description

The subject device is a foam dressing kit indicated for use with specific Genadyne NPWT pumps.

The subject device is a rectangular shaped foam manufactured using a polyvinyl alcohol foam material, a silicone port tubing, and a transparent adhesive film dressing. This single-use dressing kit is housed in a Tyvek/Mylar Peel Pouch. Each product is sterilized individually.

The foam dressing is composed of flexible polyether and polyester polyurethane foam and comes in the following sizes: 7.5cm x 10cm x 3.3cm, 12.5cm x 18cm x 3.3cm, and 15cm x 26cm x 3.3cm.

VI. Predicate Device

Genadyne A4-XLR8 Foam Dressing (K092992)

Food and Drug Administration
Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993

VII. Original Deficiency

(b)(4)Proprietary Information

[redacted]

VIII. Sponsor's Response to Deficiency and Summary of Testing

(b)(4)Proprietary Information

[redacted]

DEPARTMENT OF HEALTH AND HUMAN SERVICES MEMORANDUM

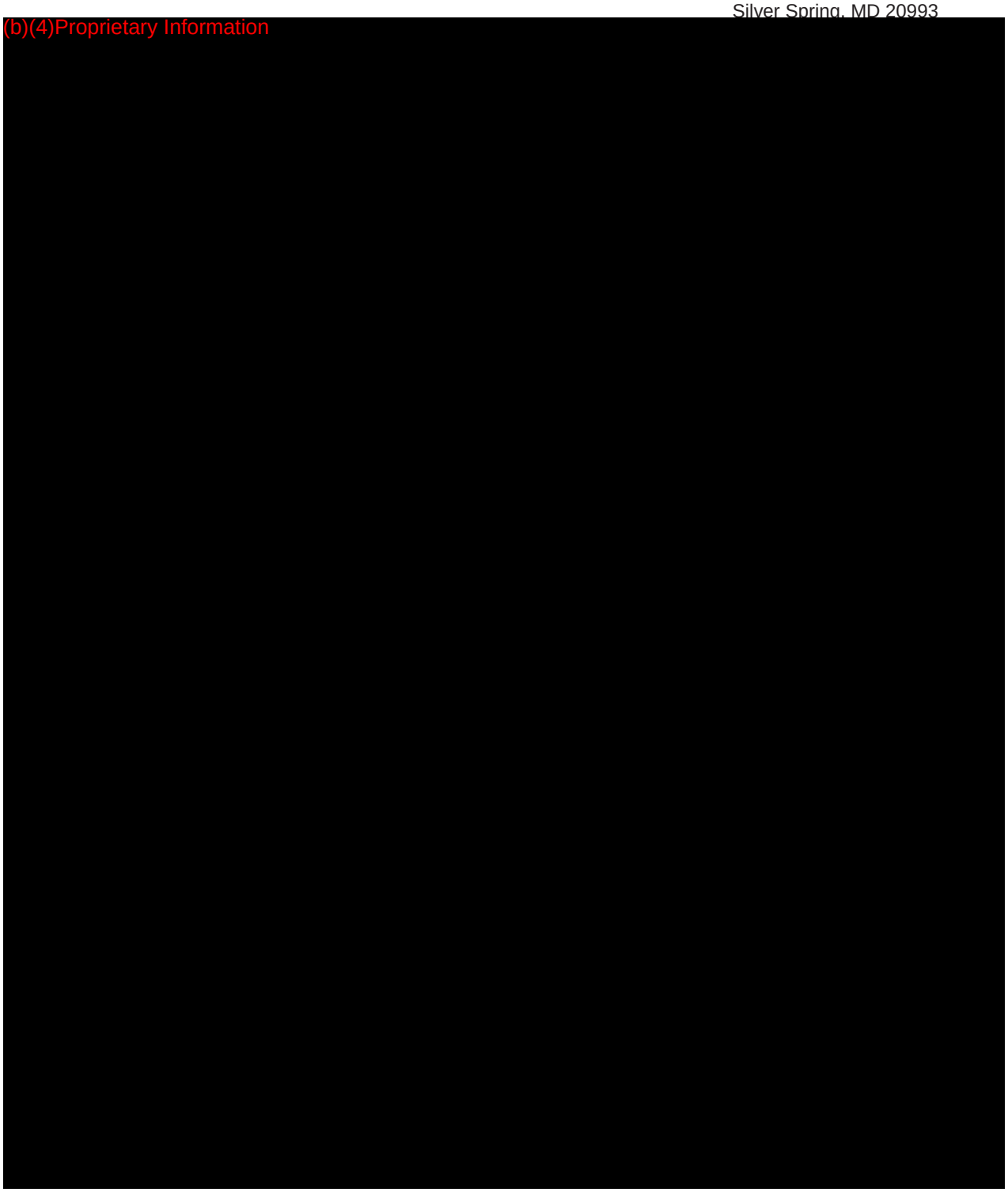
Food and Drug Administration
Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993

(b)(4)Proprietary Information

[redacted]

Food and Drug Administration
Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993

(b)(4)Proprietary Information



Food and Drug Administration
Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993

(b)(4)Proprietary Information

IX. Specific Questions from Lead Reviewer

(b)(4)Proprietary Information

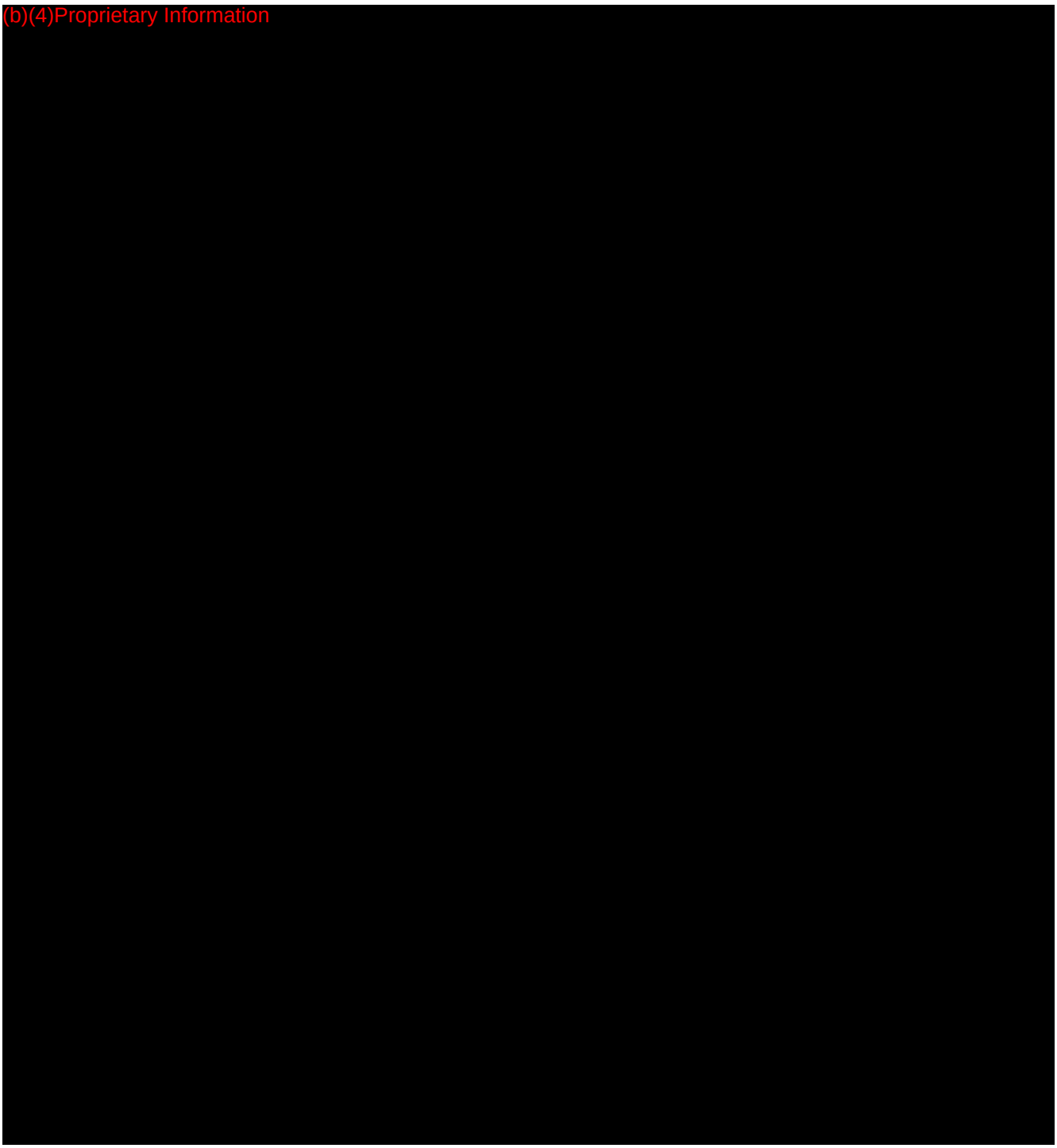
X. Deficiencies

(b)(4)Proprietary Information

DEPARTMENT OF HEALTH AND HUMAN SERVICES MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993

(b)(4)Proprietary Information



DEPARTMENT OF HEALTH AND HUMAN SERVICES MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993

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Food and Drug Administration
Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993

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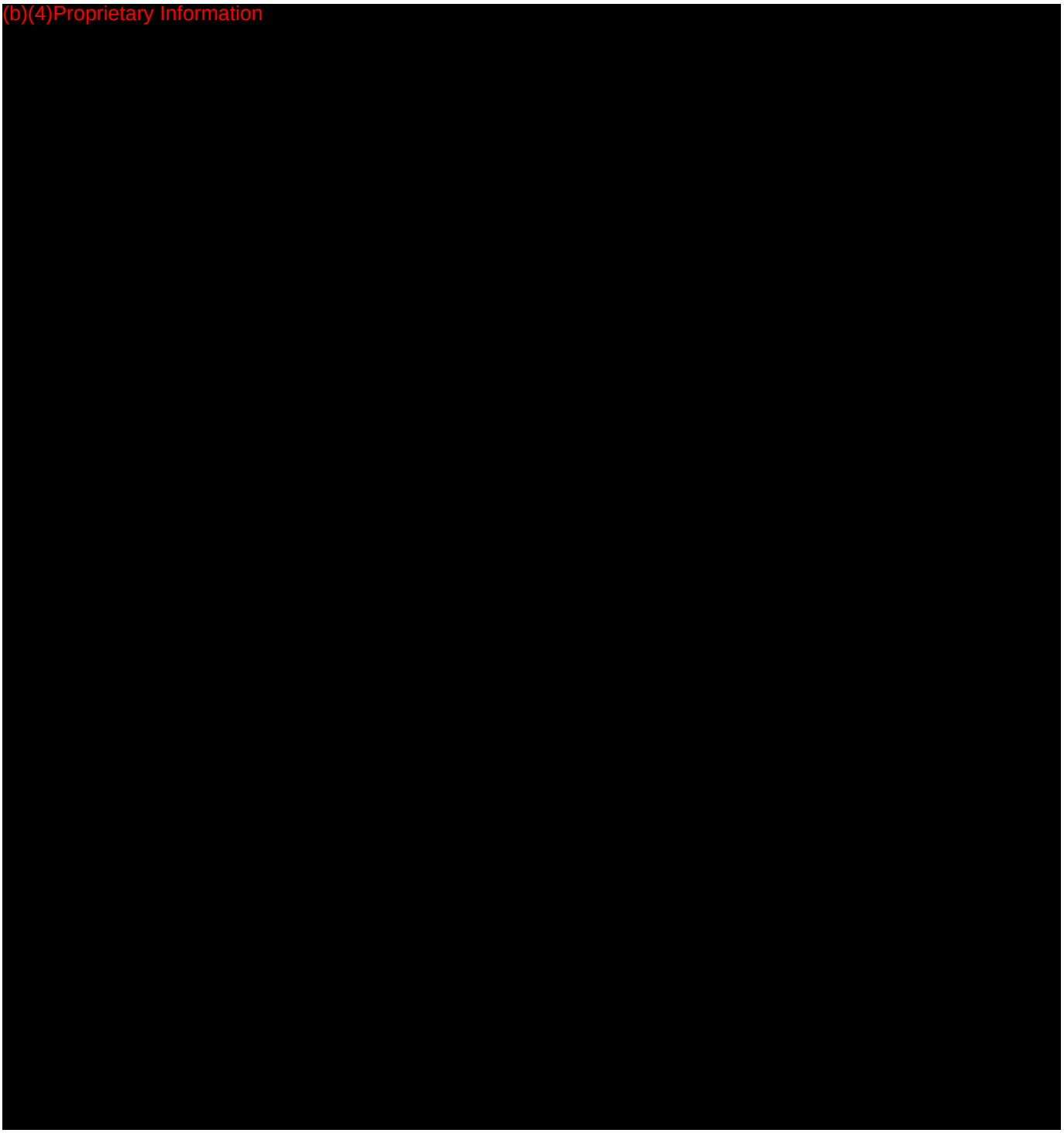

Food and Drug Administration
Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993

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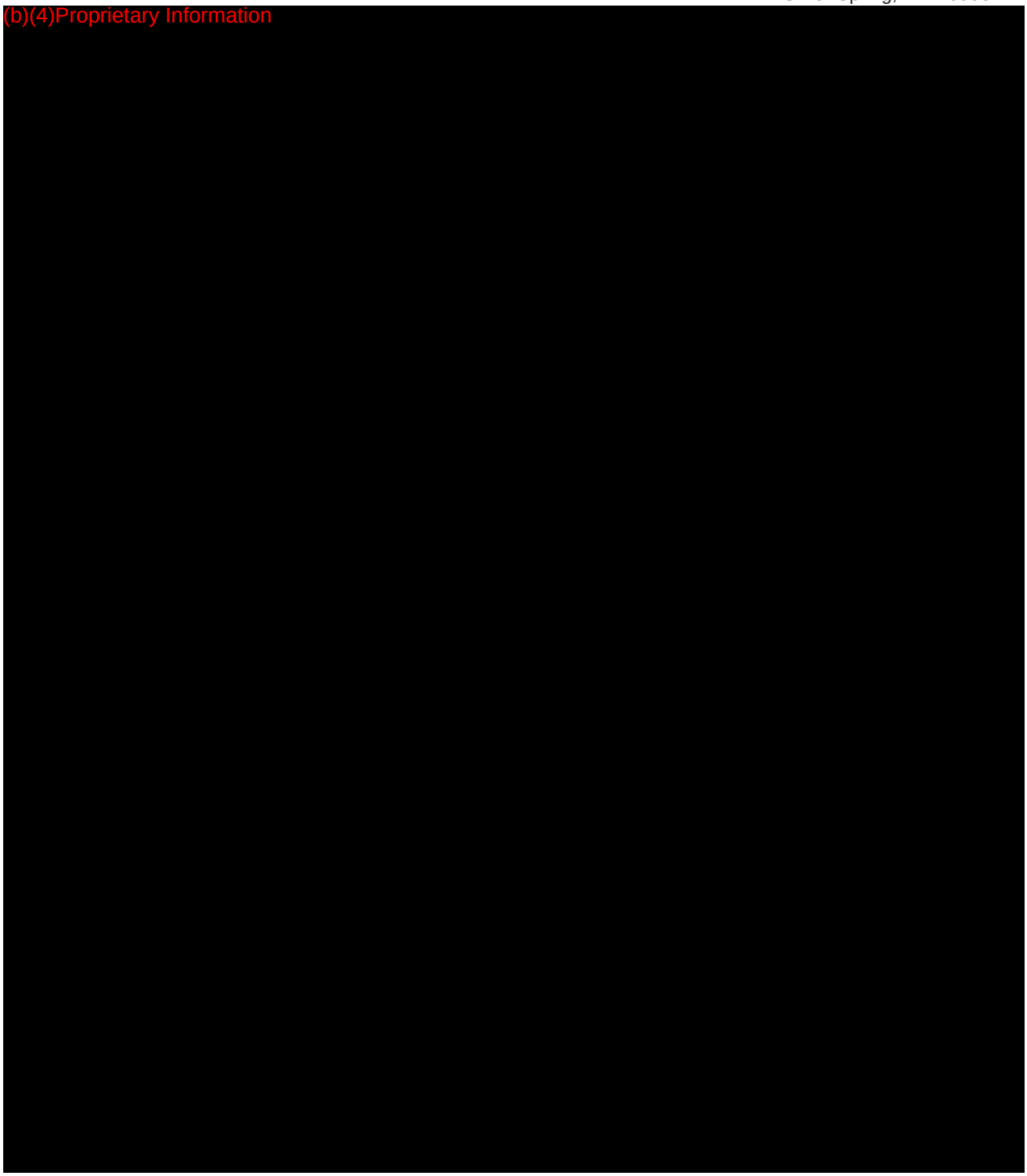

Food and Drug Administration
Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993

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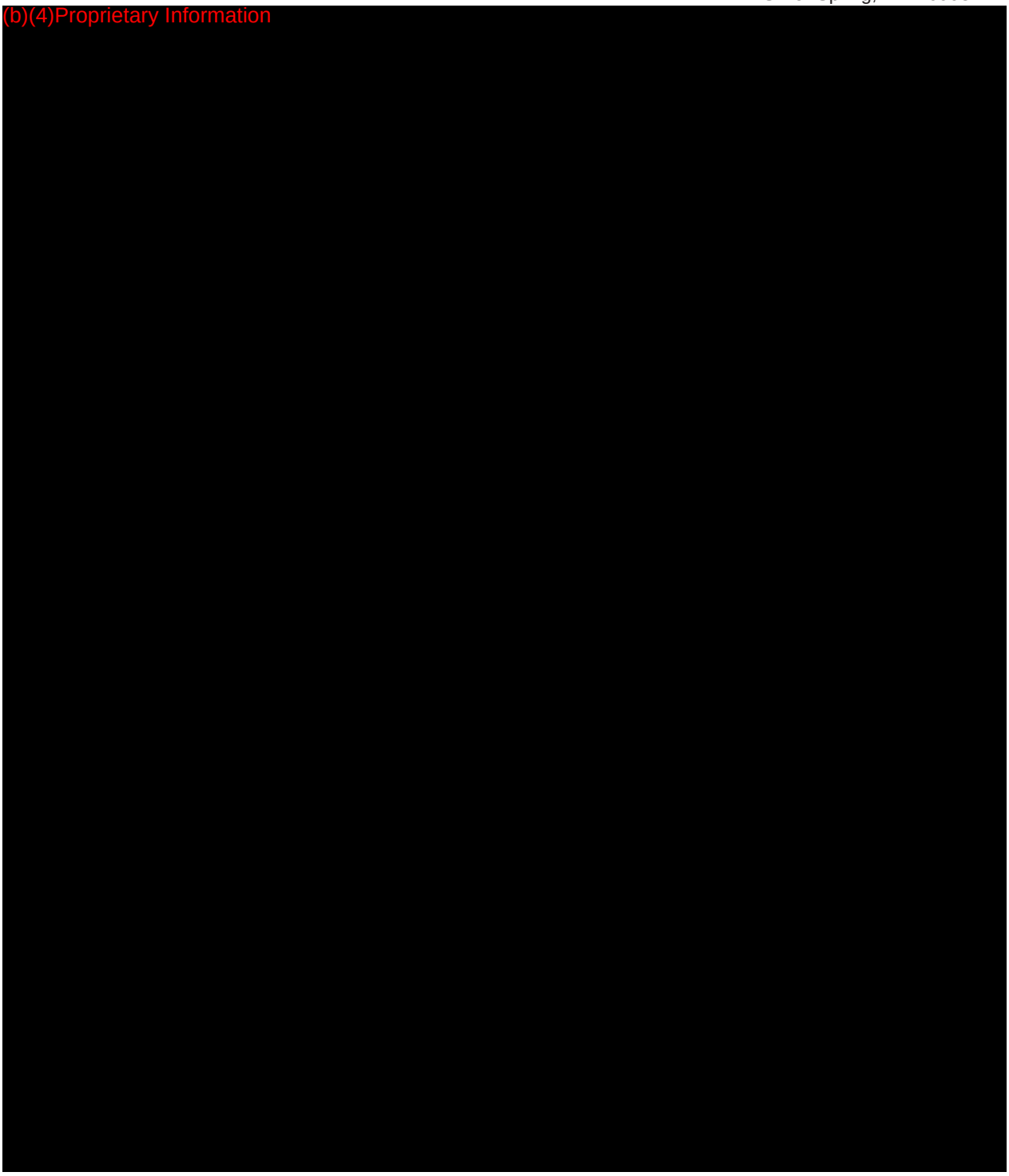

Food and Drug Administration
Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993

(b)(4)Proprietary Information

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XI. Interactive Review

(b)(4)Proprietary Information

[redacted]

Food and Drug Administration
Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993

Digital Signature Concurrence Table	
Reviewer Sign-Off	Cindy Cheng -S 2015.04.22 11:52:12 -04'00'
Branch Chief Sign-Off	

DEPARTMENT OF HEALTH AND HUMAN SERVICES MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993

K142646/S003 ENG-MECH Review

Date: April 7, 2015
To: Chris Dugard, M.S., Lead Reviewer (CDRH/ODE/DSD/PRSB2)
From: Cindy Cheng, Ph.D., Biomedical Engineer (CDRH/ODE/DSD/PRSB2)

Sponsor: Genadyne Biotechnologies
Device: XLR8 White Foam Dressing Kit
Consult due date: April 20, 2015

Table of Contents

I. ENG-MECH Recommendation

(b)(4)Proprietary Information

[redacted]

Food and Drug Administration
Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993

II. Review Scope

(b)(4)Proprietary Information

[redacted]

III. Regulatory History

(b)(4)Proprietary Information

[redacted]

IV. Indications for Use

Genadyne XLR8 White Foam Dressing Kit is intended to be used in conjunction with the Genadyne A4 Wound Vacuum System (K082676) as well as the Genadyne A4-XLR8 Wound Vacuum System (K090638) to deliver negative pressure to the wound. Genadyne A4 & A4-XLR8 Wound Vacuum System is indicated for patients who would benefit from a suction device particularly as the device may promote wound healing by the removal of excess exudates, infectious material and tissue debris.

V. Device Description

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VI. Predicate Device

Genadyne A4-XLR8 Foam Dressing (K092992)

VII. Original Deficiency

(b)(4)Proprietary Information

[redacted]

Food and Drug Administration
Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993

(b)(4)Proprietary Information

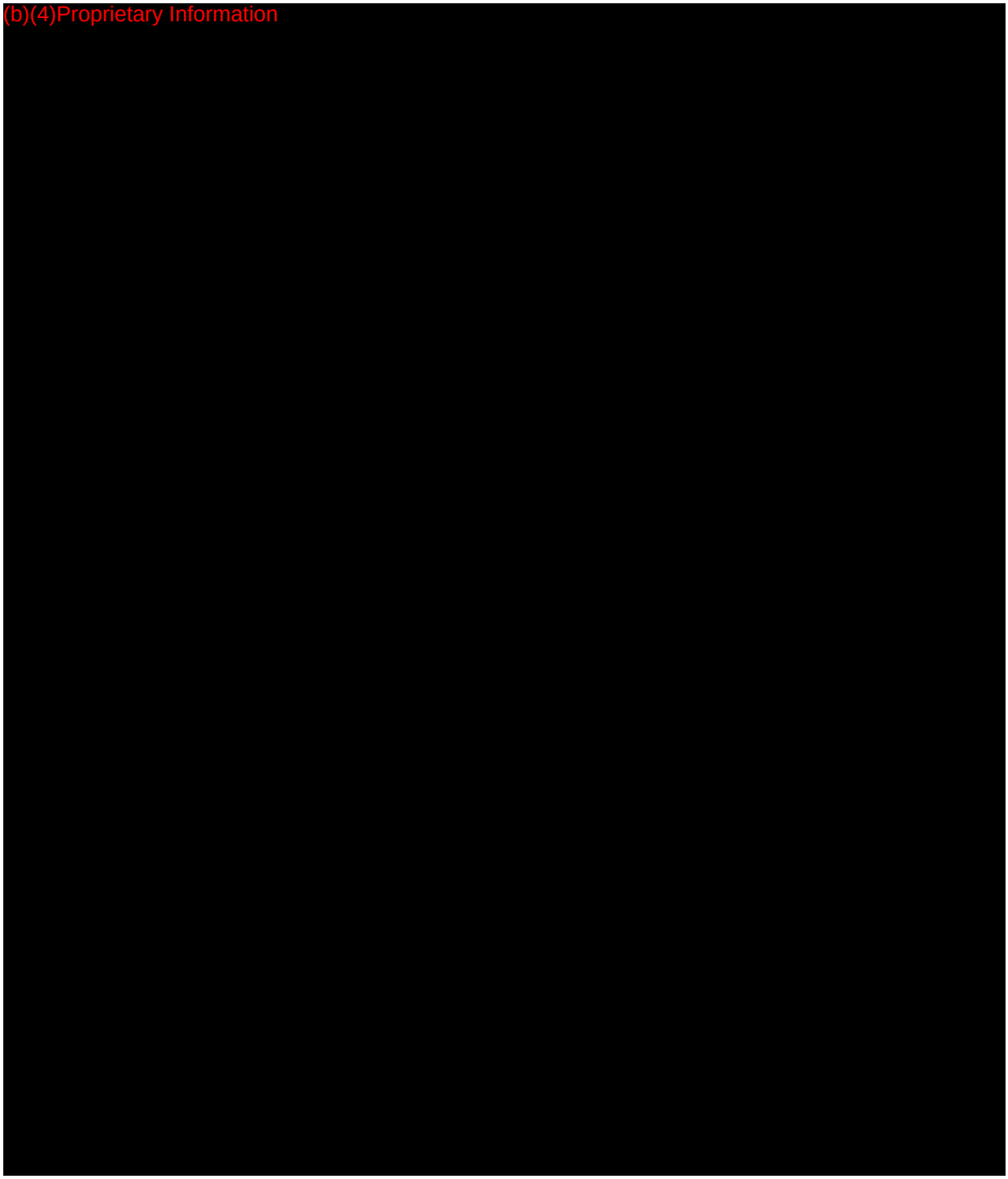
VIII. Sponsor's Response to Deficiency and Summary of Testing

(b)(4)Proprietary Information

DEPARTMENT OF HEALTH AND HUMAN SERVICES MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993

(b)(4)Proprietary Information



DEPARTMENT OF HEALTH AND HUMAN SERVICES MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993

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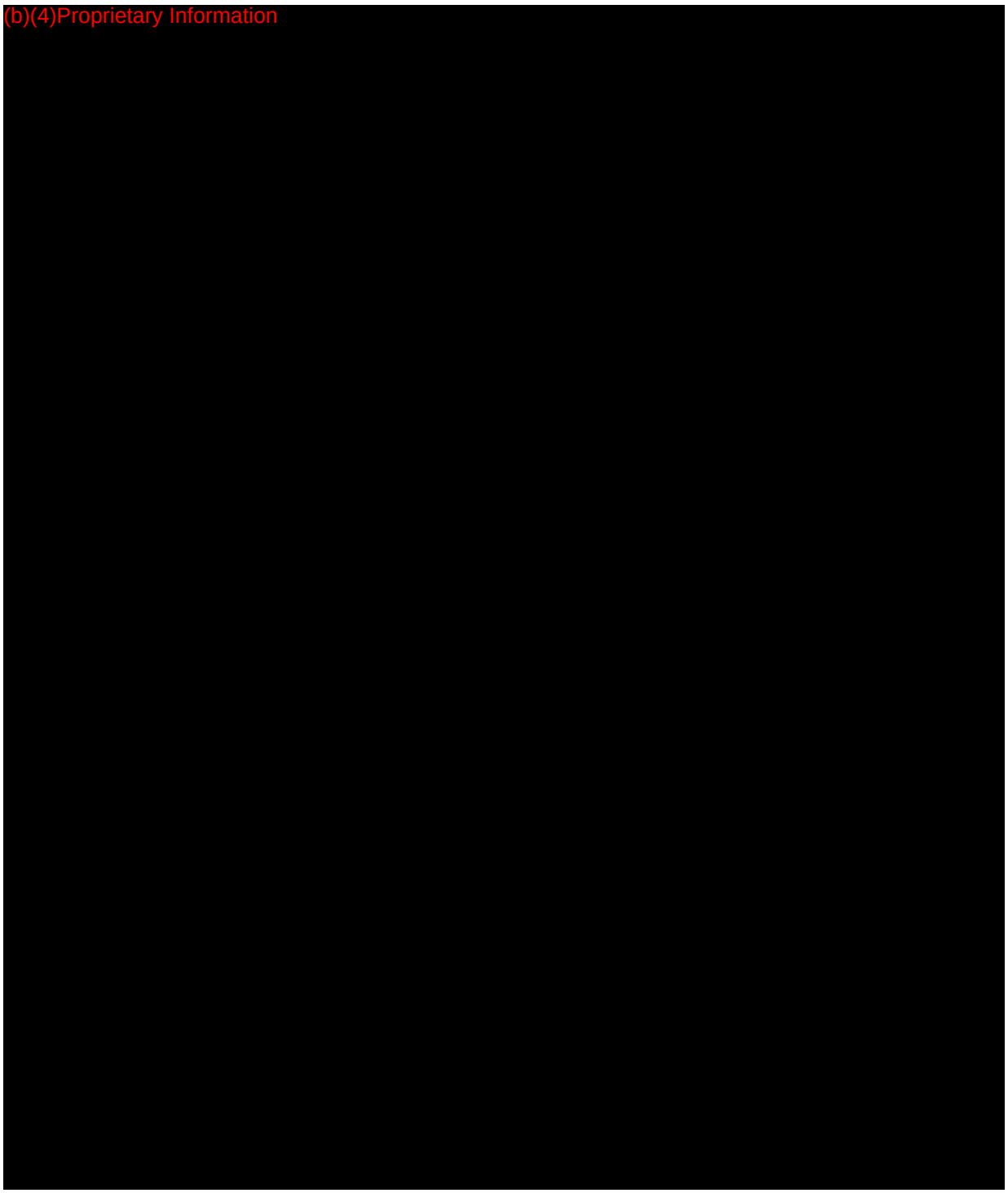

DEPARTMENT OF HEALTH AND HUMAN SERVICES MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993

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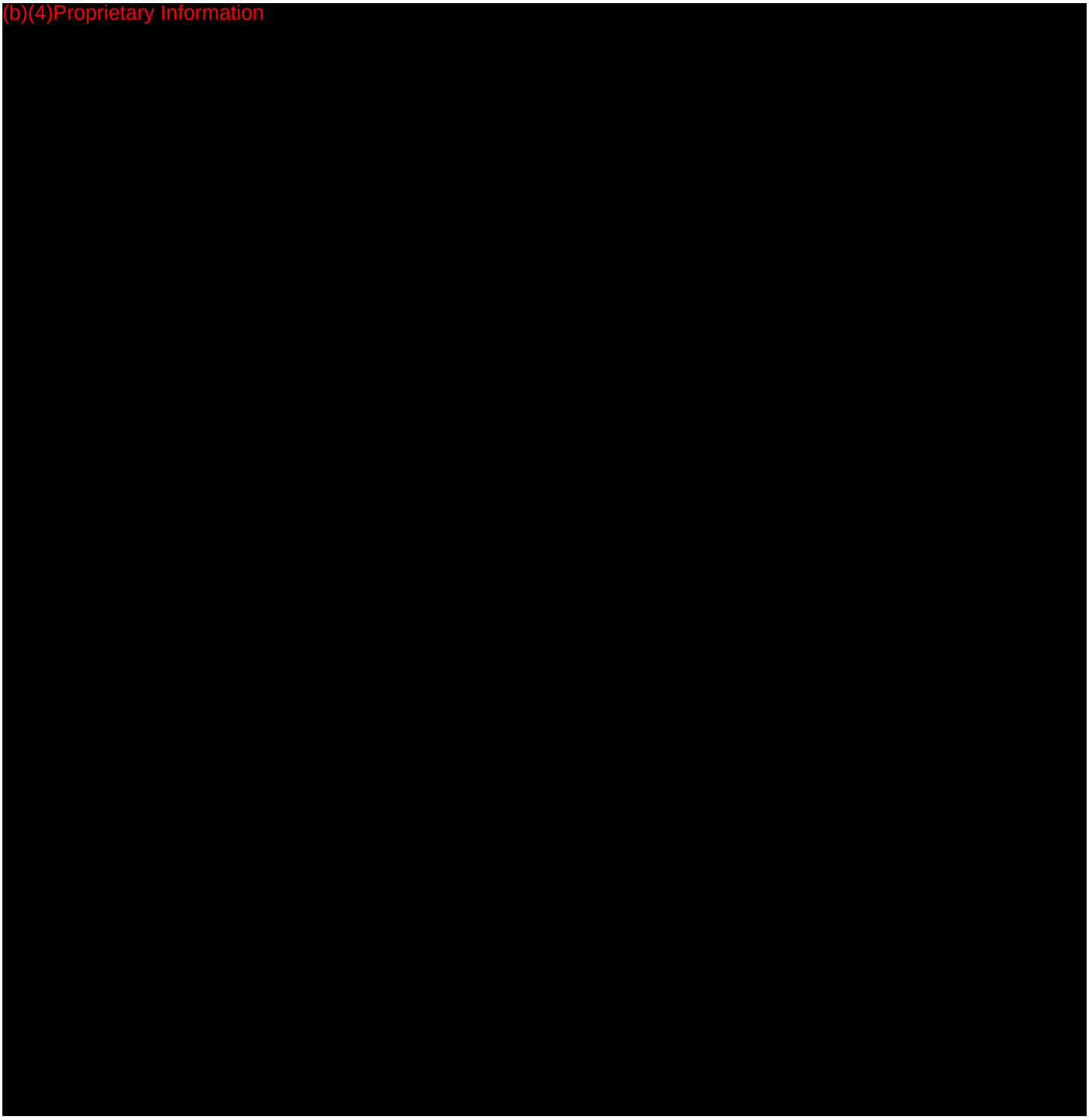

DEPARTMENT OF HEALTH AND HUMAN SERVICES MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993

(b)(4)Proprietary Information

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Digital Signature Concurrence Table	
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Branch Chief Sign-Off	

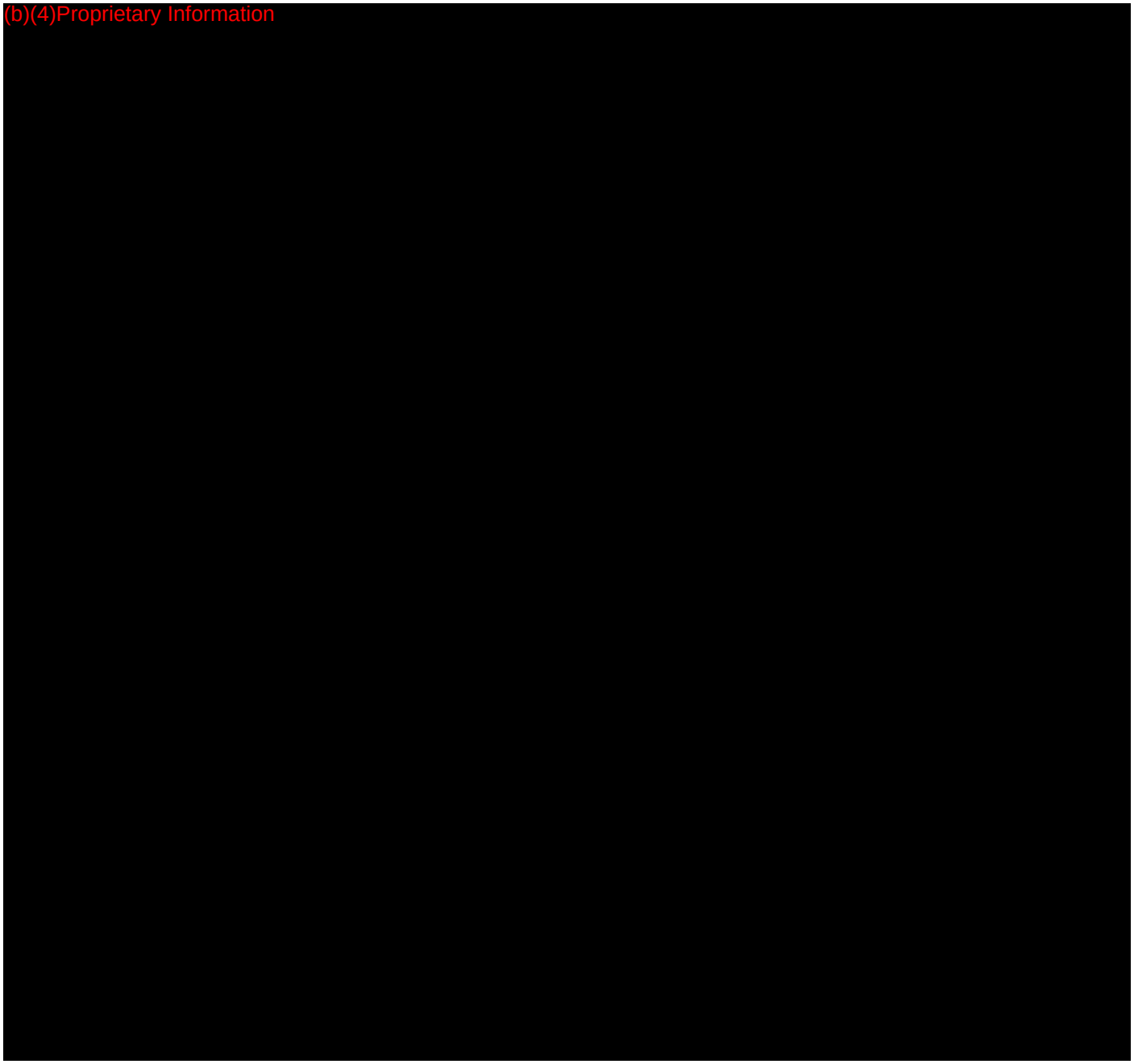
DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

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

K142646/S002
510(k) HOLDER COMPANY: Genadyne Biotechnologies, Inc.
Trade Name: XLR8 White Foam Dressing Kit

We have reviewed your Section 510(k) premarket notification of intent to market the device (K142646). We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission, we require that you address the following deficiencies.

(b)(4)Proprietary Information



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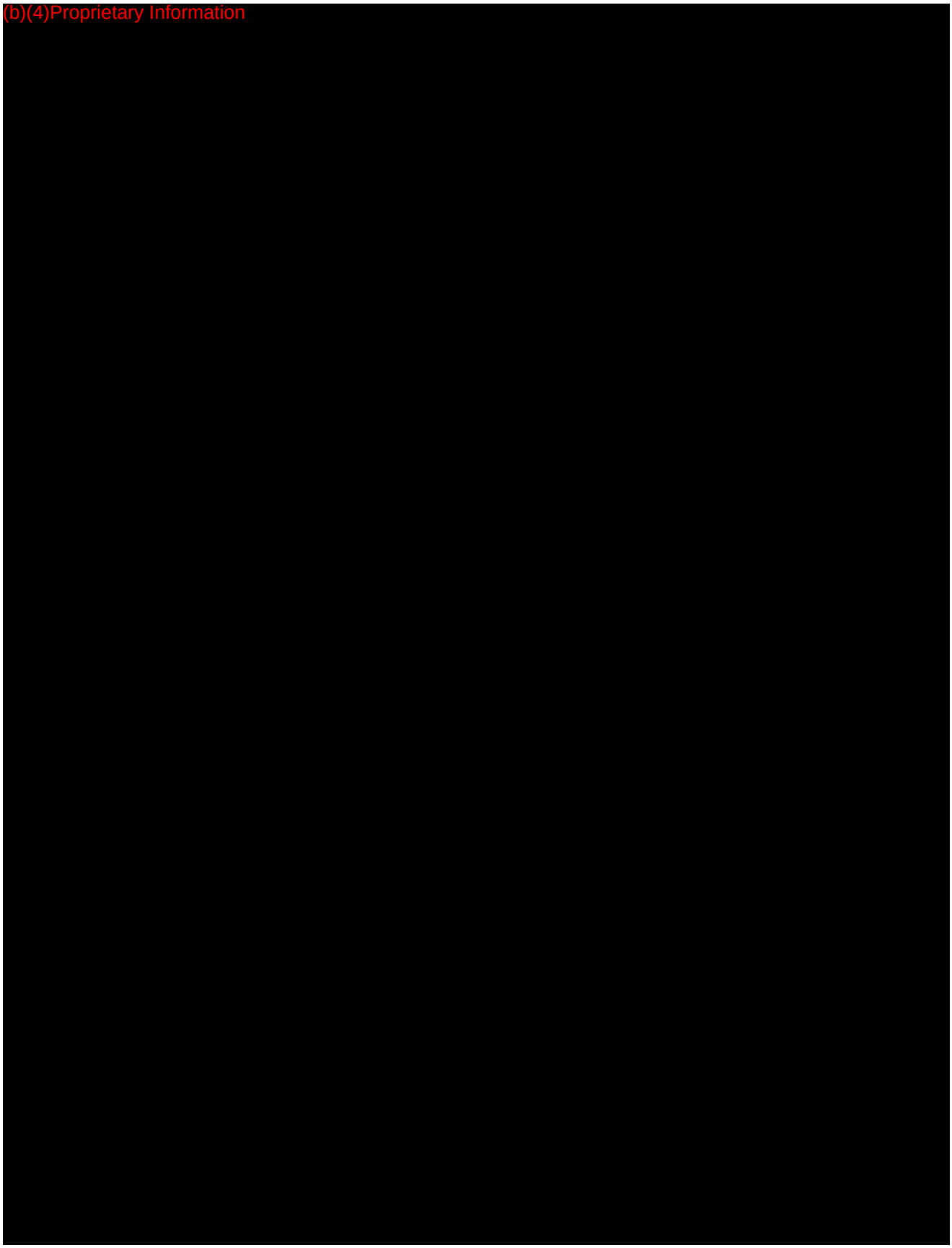

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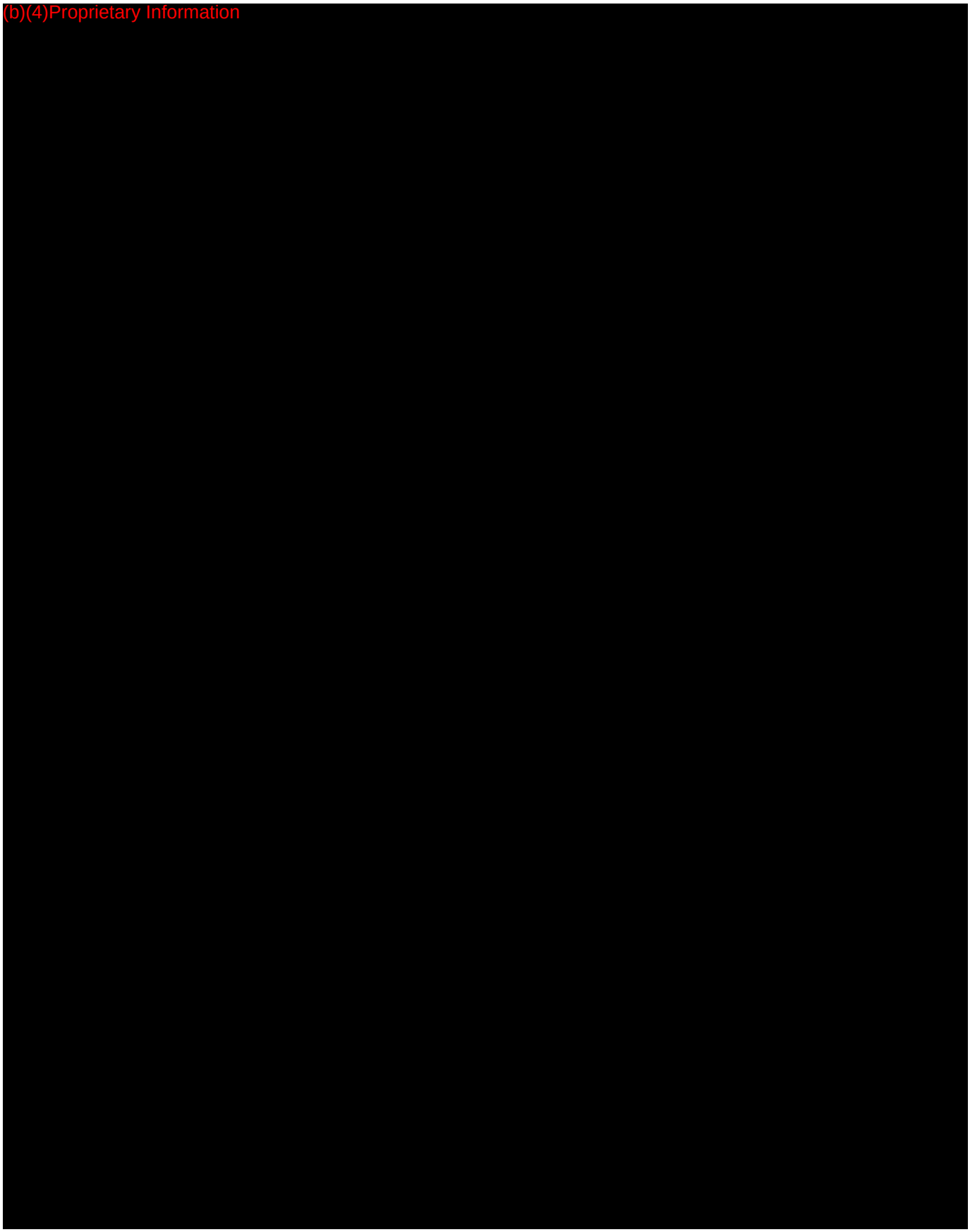

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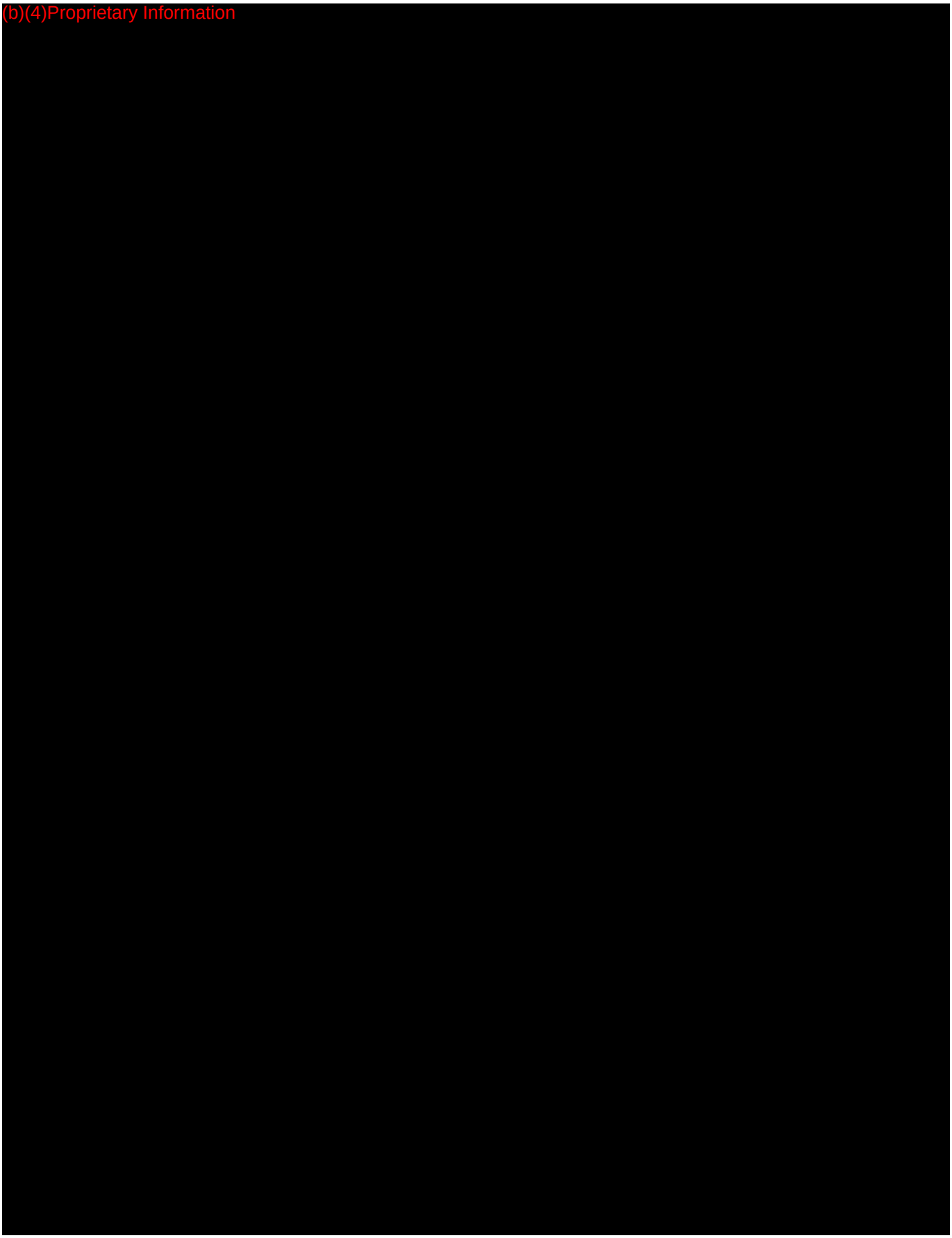

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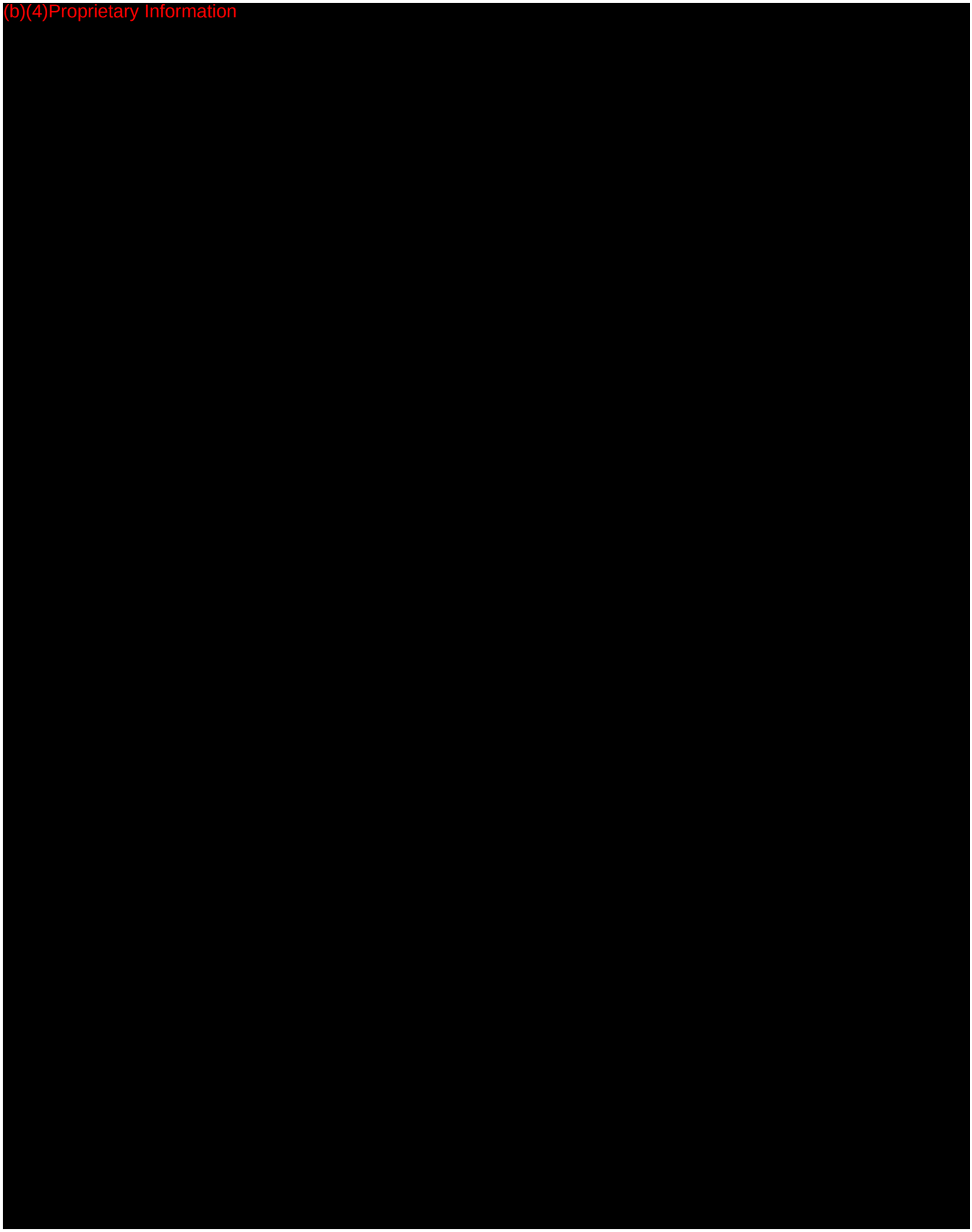

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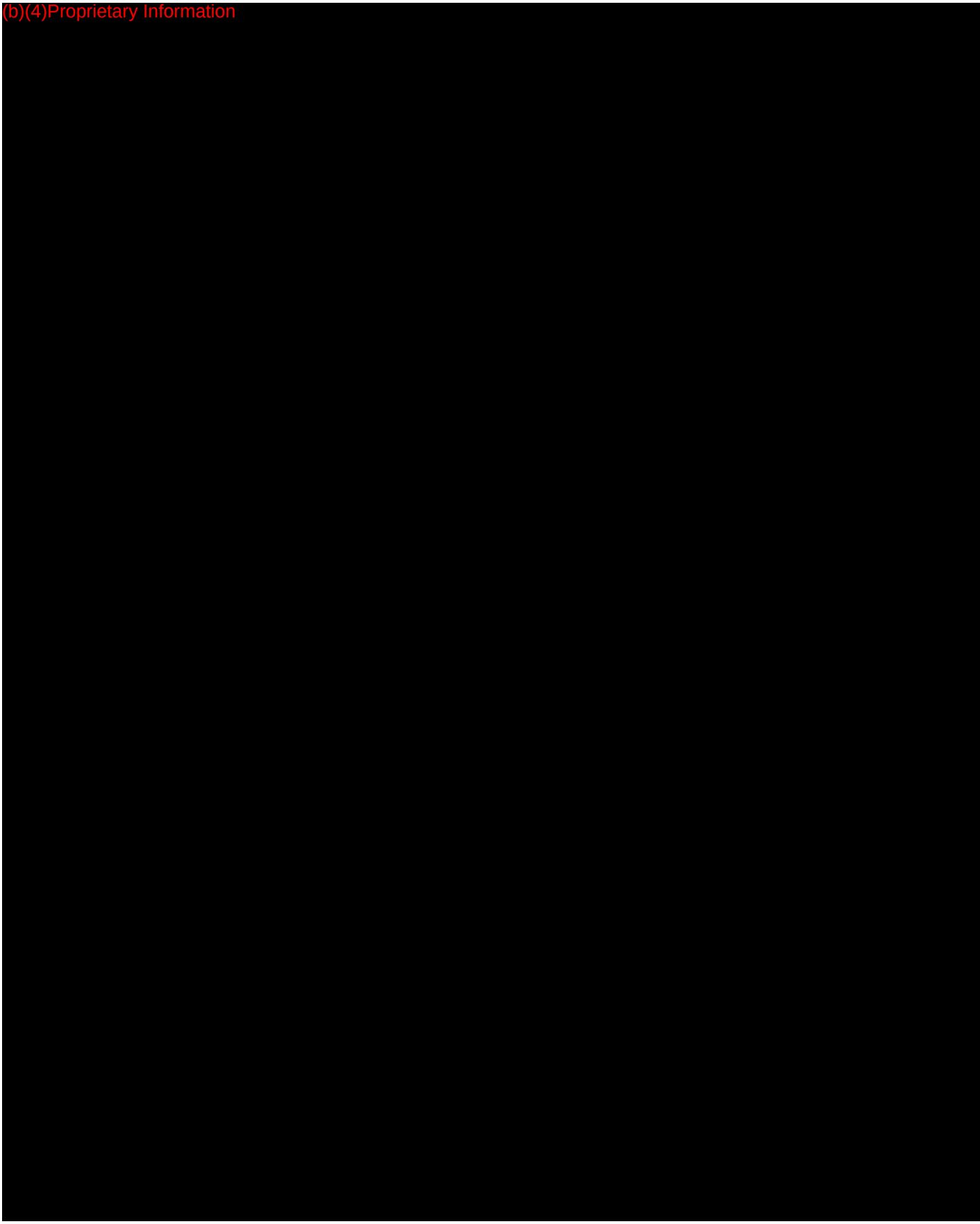

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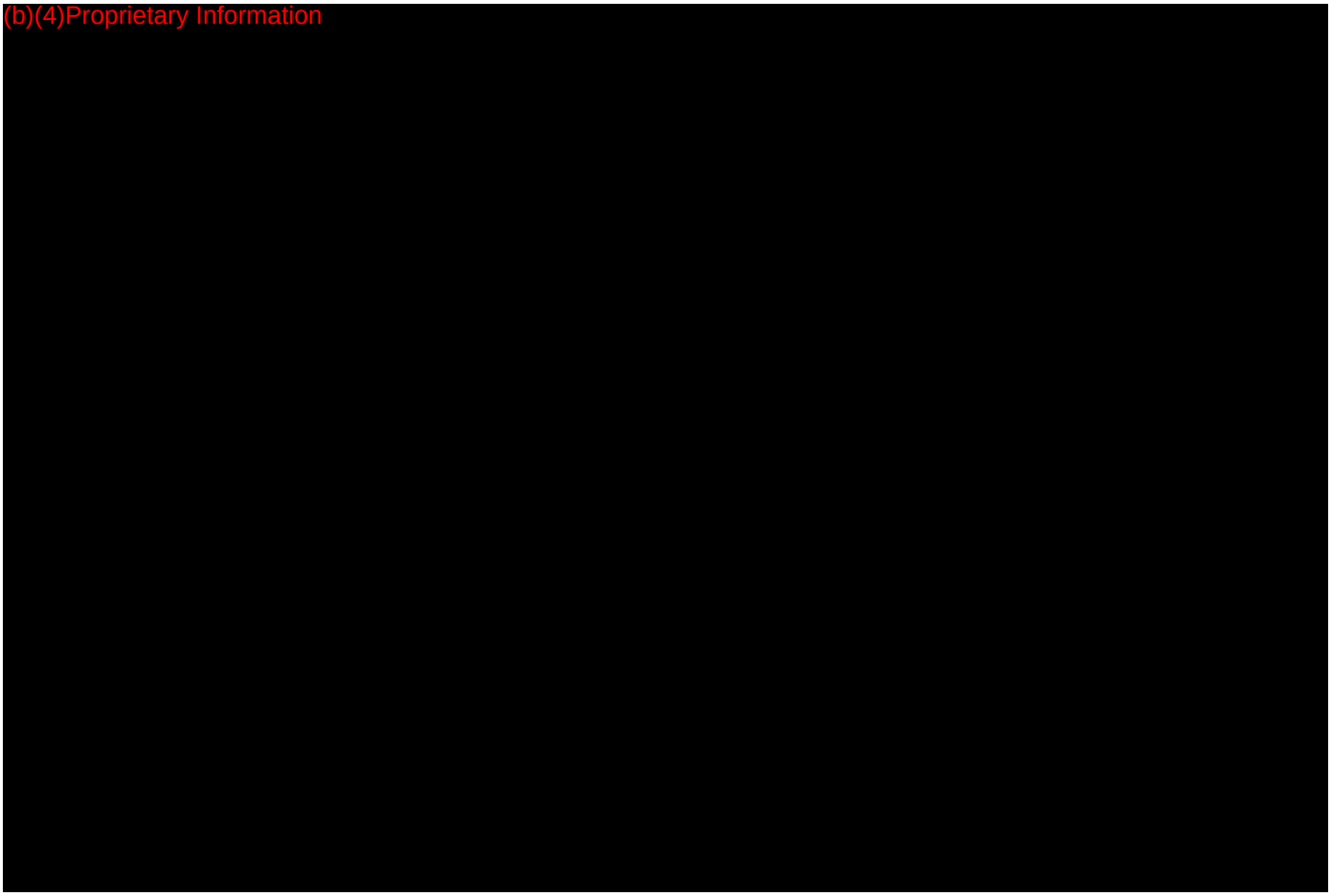


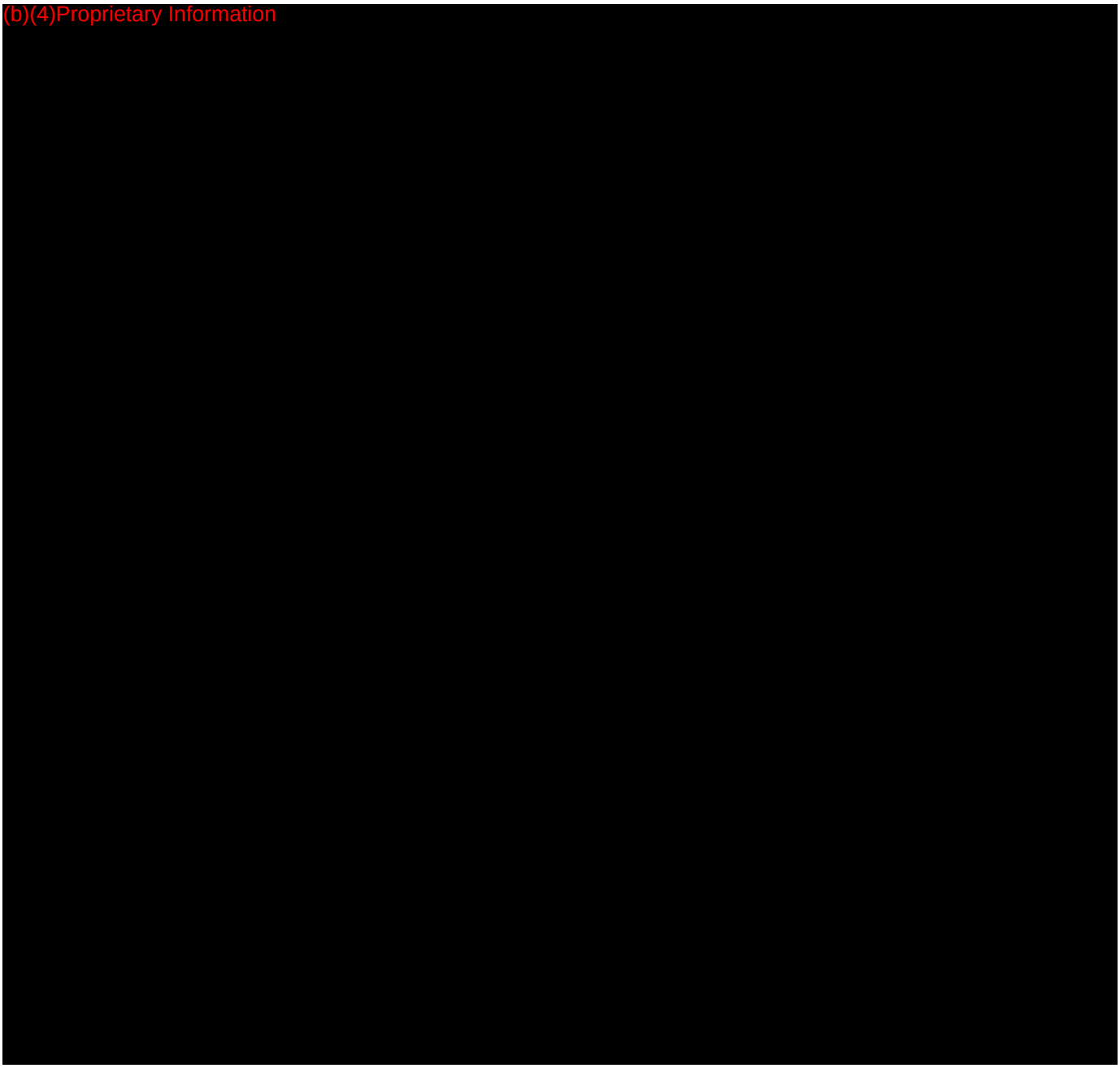
DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

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

K142646/S002
510(k) HOLDER COMPANY: Genadyne Biotechnologies, Inc.
Trade Name: XLR8 White Foam Dressing Kit

We have reviewed your Section 510(k) premarket notification of intent to market the device (K142646). We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission, we require that you address the following deficiencies.

(b)(4)Proprietary Information



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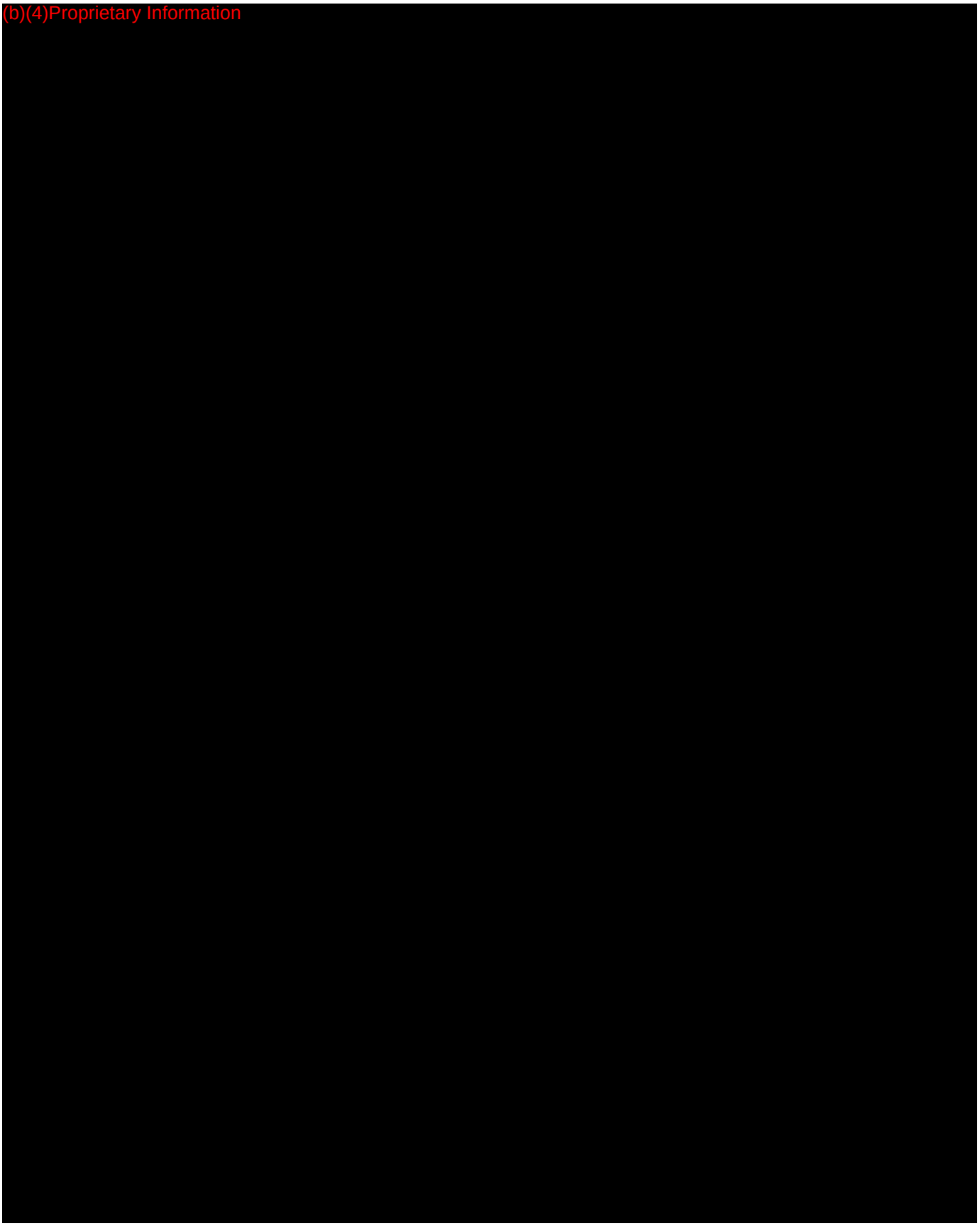

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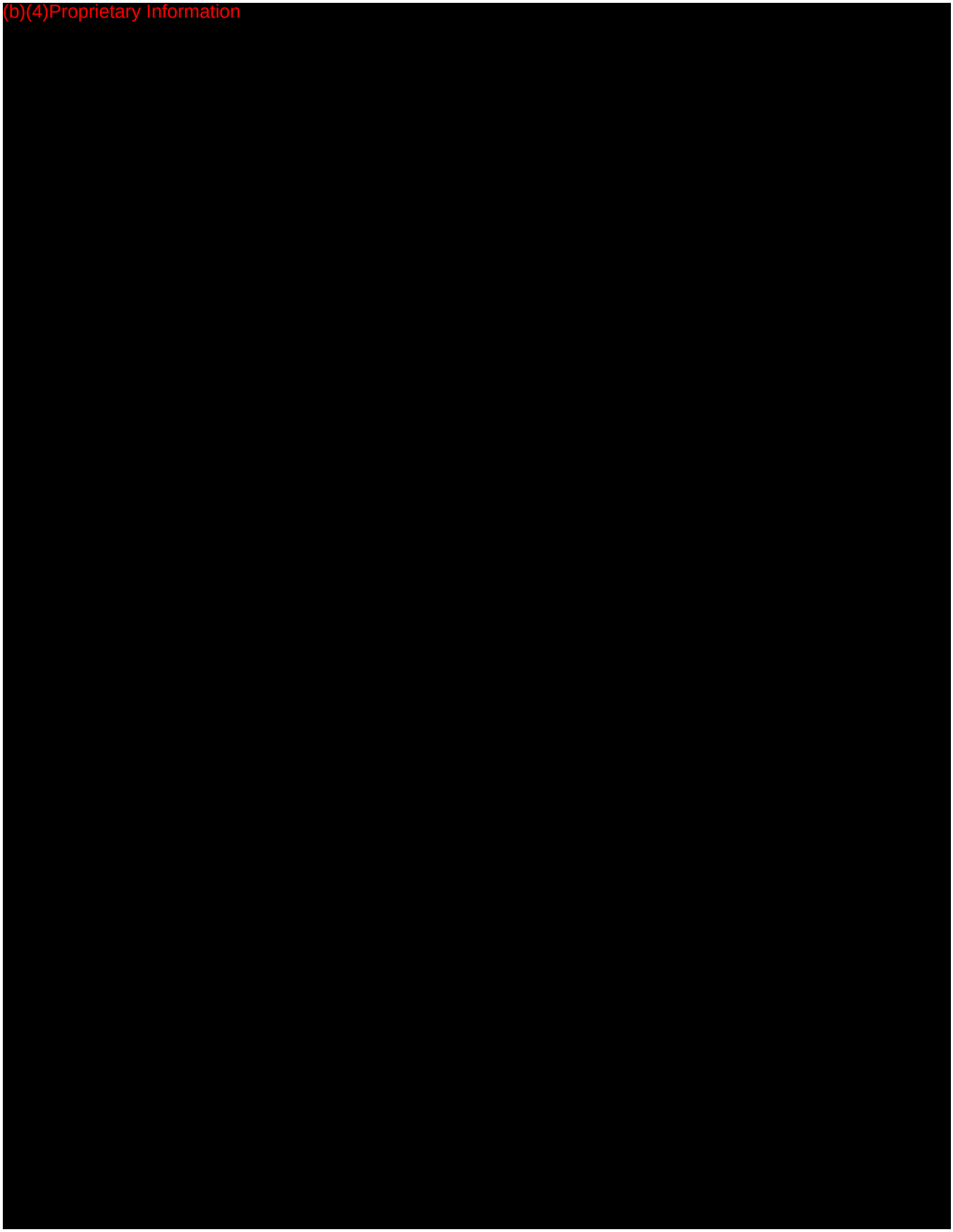

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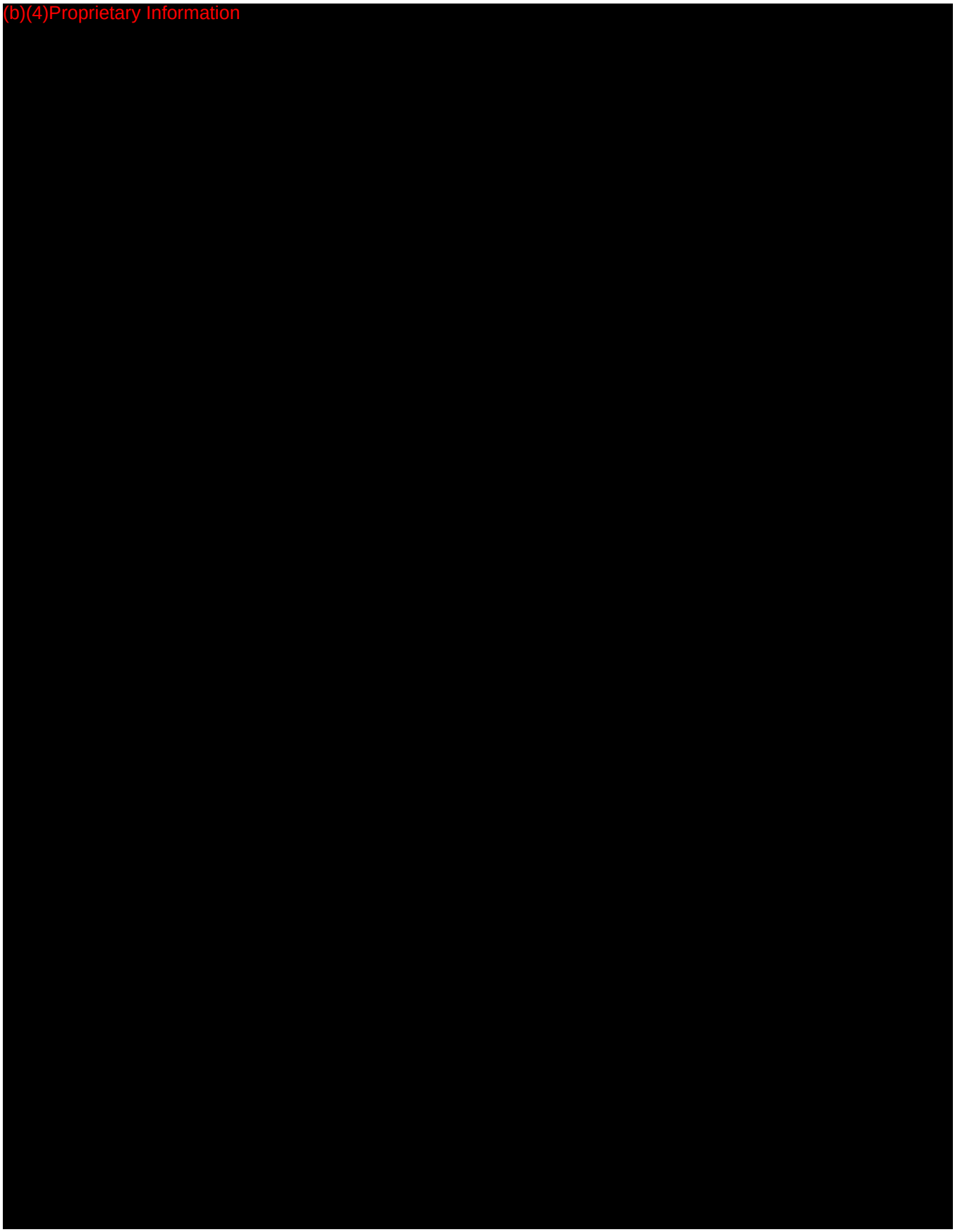

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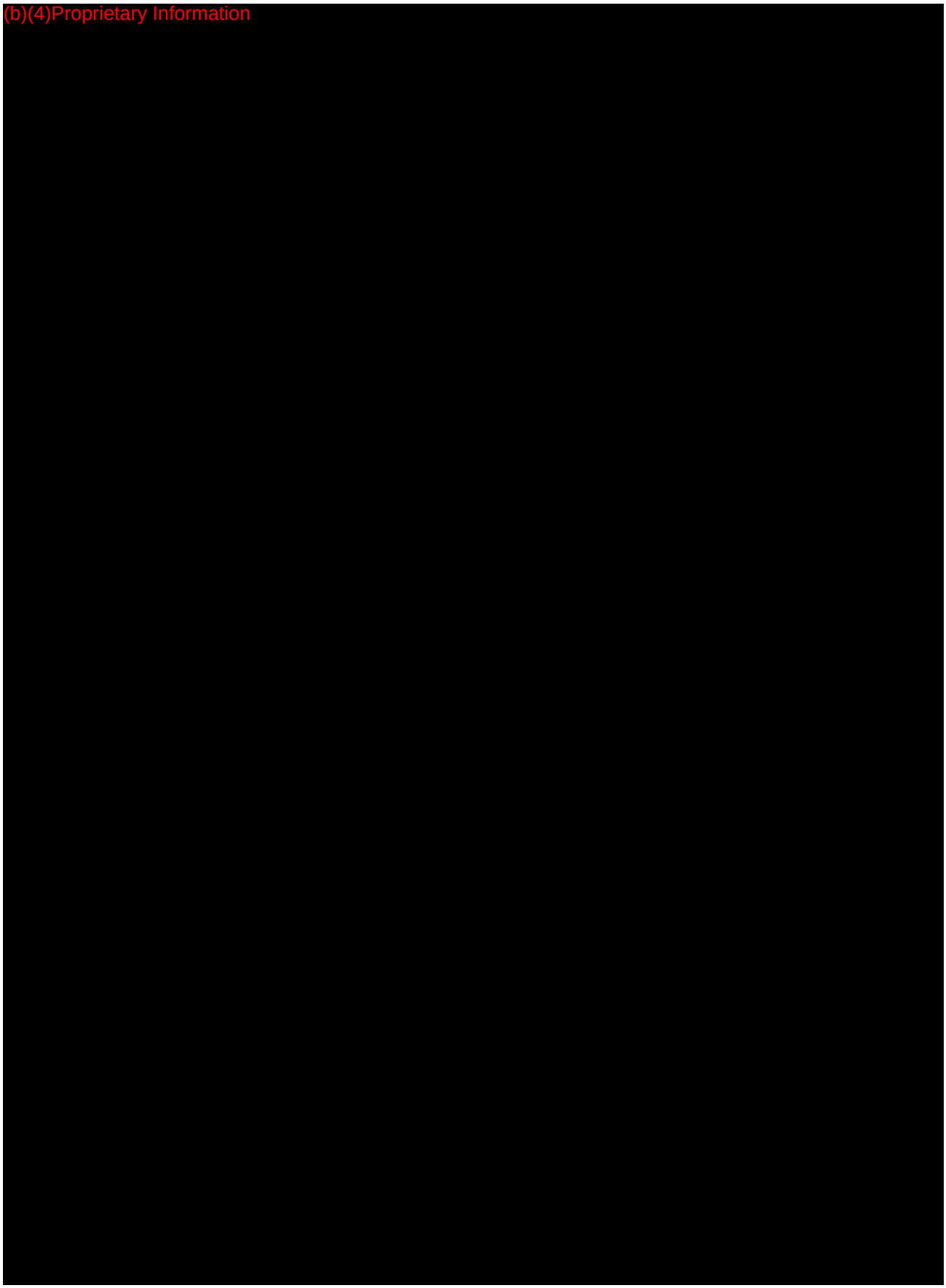

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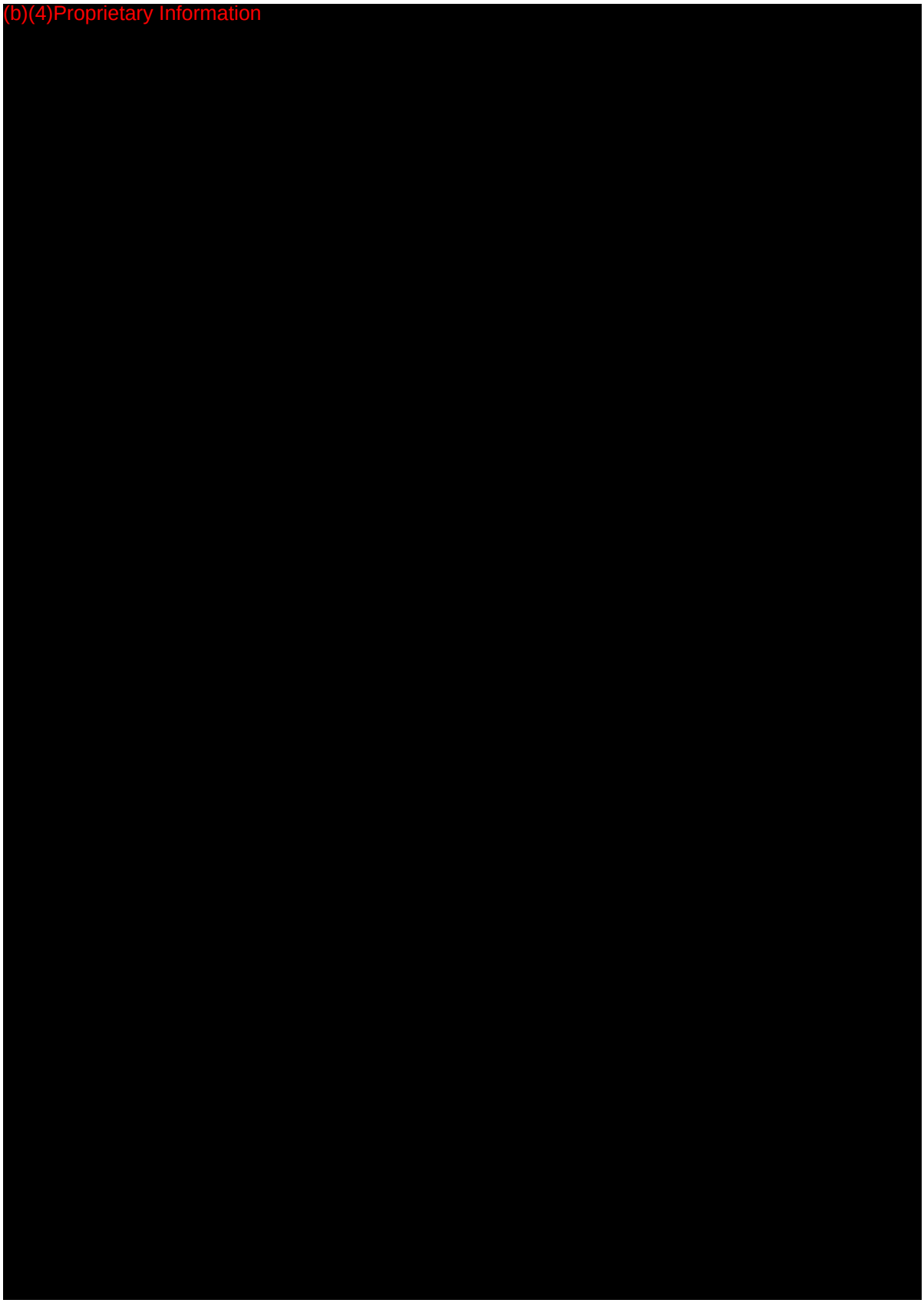

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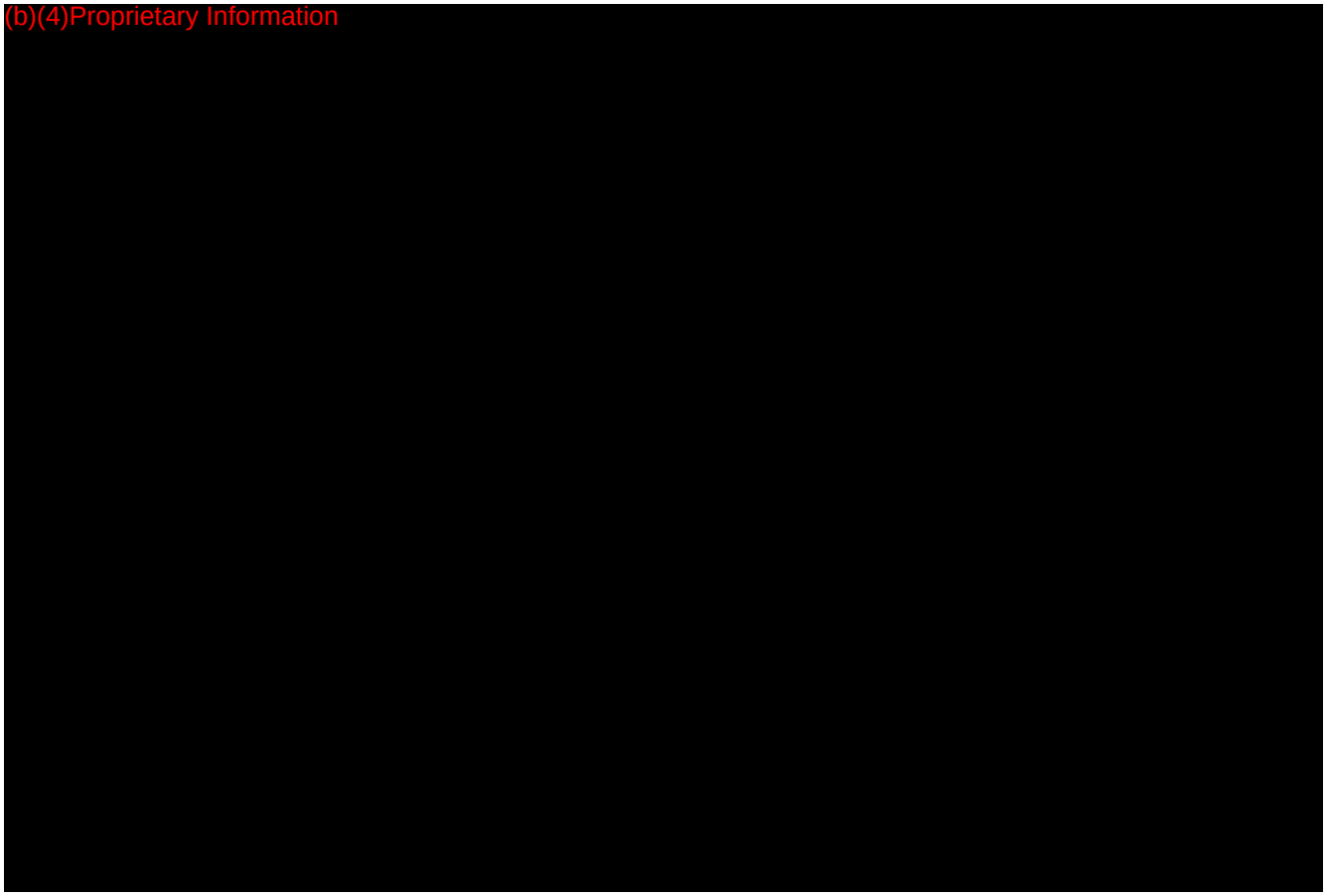


Consult Memorandum
K142646/CON1424018

To: Jiyoung Dang, Ph.D.
CDRH/ODE/DSD/PRSB2

From: Lixin Liu, Ph.D.
CDRH/ODE/DSD/PRSB2

Date: December 20, 2014

Device: Genadyne XLR8 White Foam Dressing Kit

Sponsor: Genadyne Biotechnologies, Inc.

Consult: Biocompatibility Consult for K142646/S002

Introduction

(b)(4)Proprietary Information

[redacted]

Recommendation

(b)(4)Proprietary Information

[redacted]

Indications for Use

Genadyne XLR8 White Foam Dressing kit is intended to be used in conjunction with the Genadyne A4-XLR8 Wound Vacuum System (K090638) to deliver negative pressure wound

therapy to the wound. Genadyne A4-XLR8 Wound Vacuum System is indicated for patients who would benefit from a suction device particularly as the device may promote wound healing.

XLR8 White Foam Dressing is appropriate for use on the following wounds:

- Pressure ulcers
- Diabetic/Neuropathic Ulcers
- Venous insufficiency ulcers
- Traumatic wounds
- Post-operative and dehisced surgical wounds
- Skin flap and grafts

Device Description

Original, attachment D, page 1

> Genadyne XLR8 White Foam Dressing Kit consist of a rectangular shape foam manufactured using a polyvinyl alcohol foam material (**Figure 1**), a silicone port tubing (**Figure 2**), and a transparent adhesive film dressing (**Figure 3**). This single-use dressing kit is housed in a Tyvek/Mylar Peel Pouch. Each product is sterilized individually.

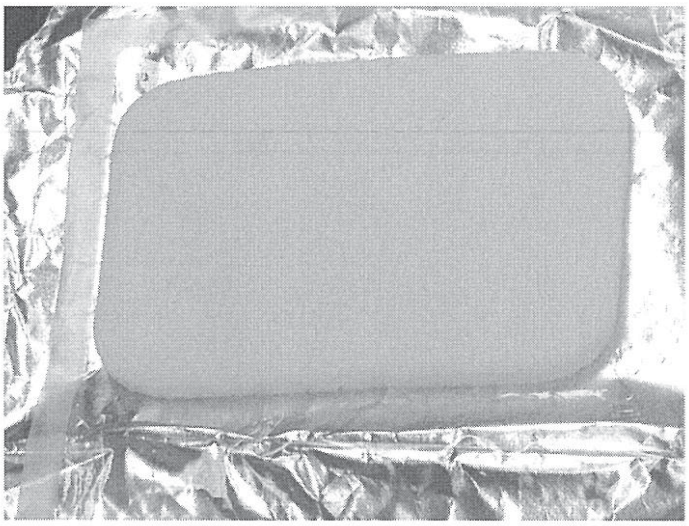
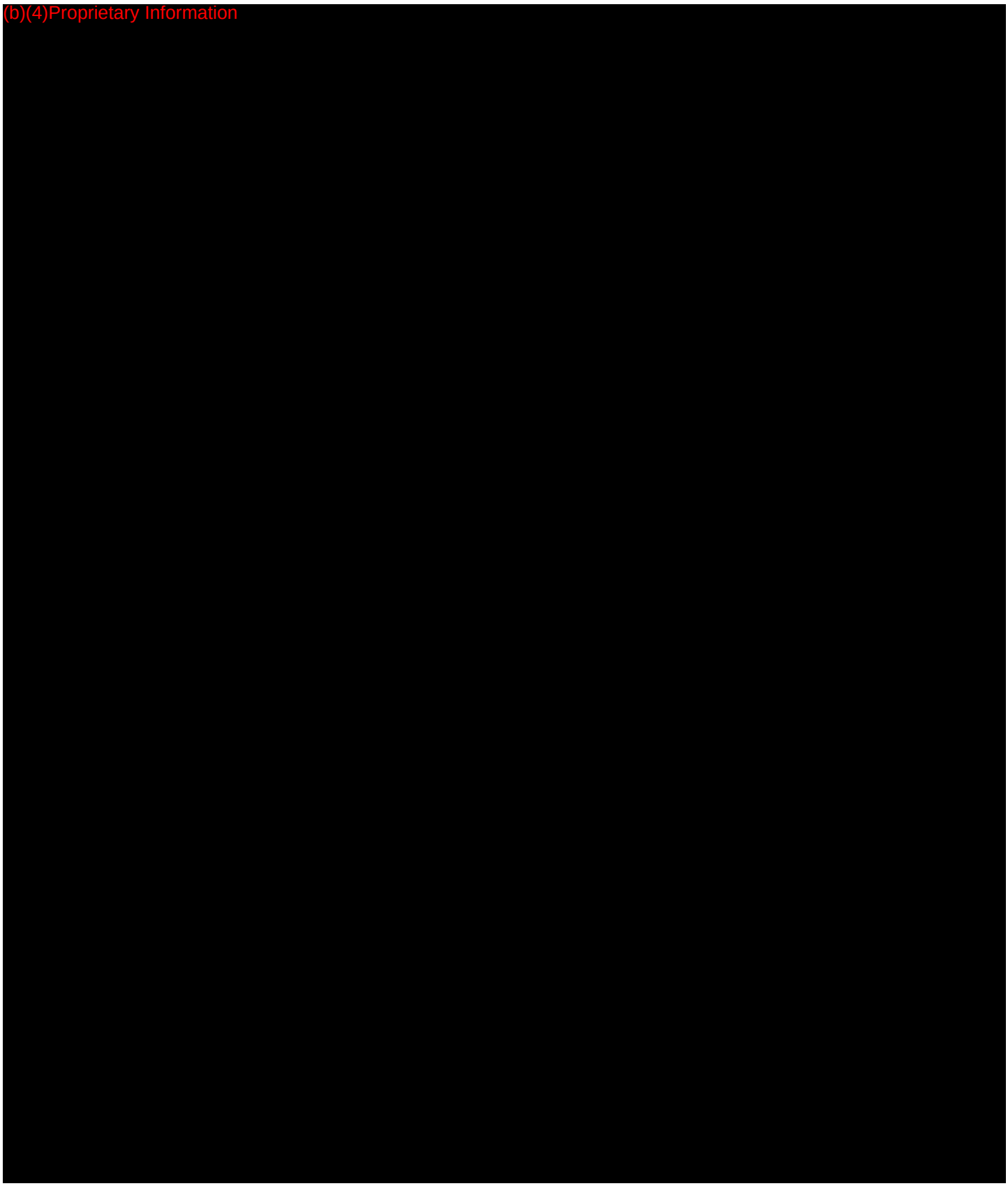


Figure 1

Reviewer comments

I checked with Dr. Charles White, the previous lead reviewer about which part of the subject device is different from the predicate. Dr. White said that only the rectangular shape foam part of subject device shown in figure 1 above is different from that of predicate. Therefore, my review of biocompatibility tests will focus on the foam part of the device.

(b)(4)Proprietary Information



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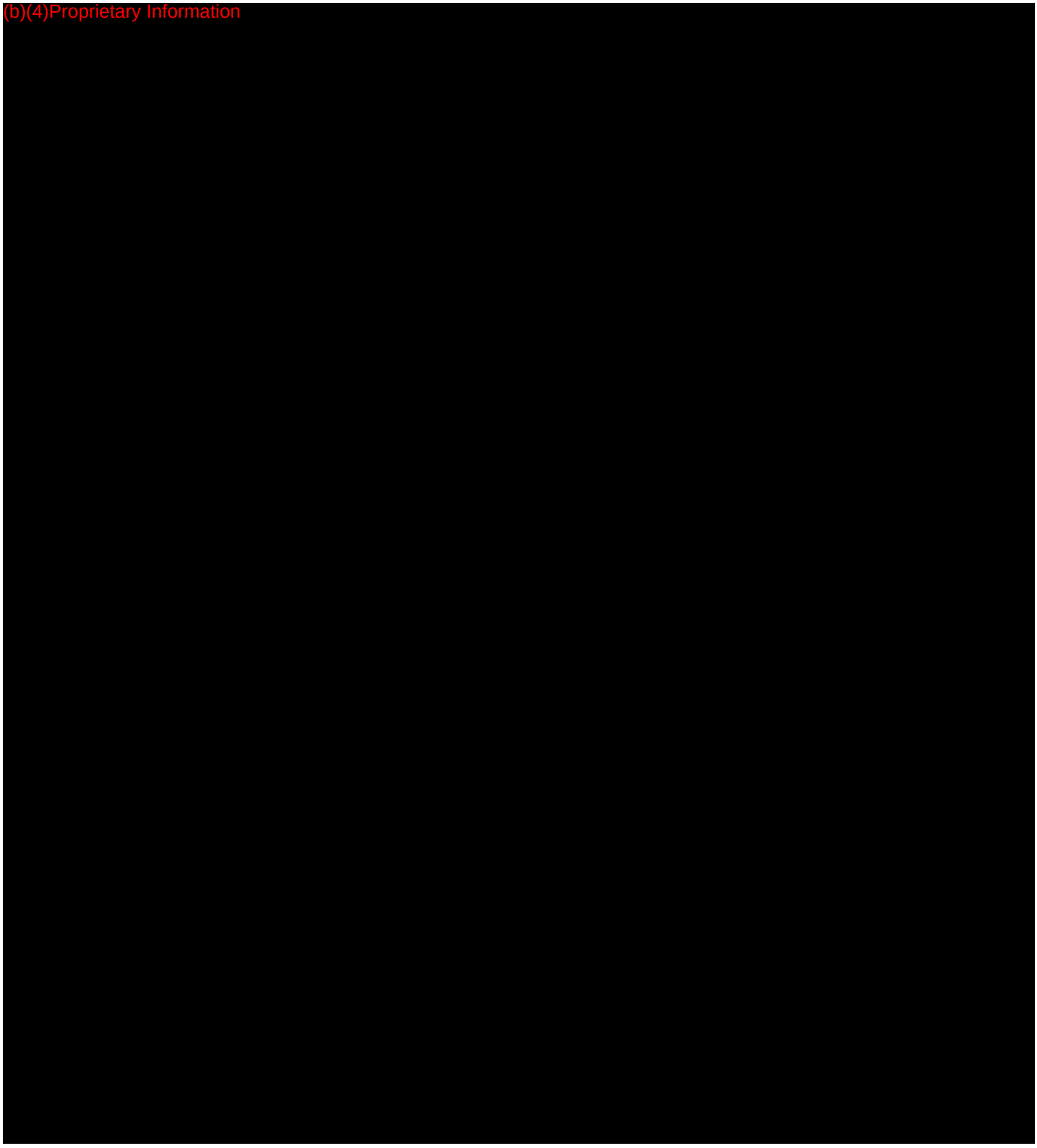

Digital Signature Concurrence Table	
Reviewer Sign-Off	Lixin Liu -S 2015.01.02 09:21:41 -05'00'
Branch Chief Sign-Off (optional)	
Division Sign-Off (optional)	

DEPARTMENT OF HEALTH AND HUMAN SERVICES M E M O R A N D U M

Food and Drug Administration
Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Premarket Notification [510(k)] Review

Traditional

K142646

Date:
To: The Record
From: Jiyoung M. Dang, Ph.D. (Branch chief, Biomedical engineer)
Branch: Plastic and Reconstructive Surgery Branch II
Division: Division of Surgical Devices
Office: Office of Device Evaluation

Digital Signature Concurrence Table	
Branch Chief Sign-Off	Jiyoung Dang -S 2015.01.01 21:41:10 -05'00'

Device Name: XLR8 White Foam Dressing Kit
510(k) Holder: Genadyne Biotechnologies, Inc.
Address: 16 Midland Ave
Hicksville, NY 11801
Establishment Registration Number: 2435947
Contact: Chien Ming Goh
Vice President, Regulatory Affairs
Phone: (516) 487-8787
Fax: (516) 977-8974
Email: andrew@genadyne.com

TABLE OF CONTENTS

I. Purpose of Submission

(b)(4)Proprietary Information

II. Document History

(b)(4)Proprietary Information

III. Recommendation

Request for additional information – (b)(4)Proprietary

Regulation Number:
Regulation Name:
Regulatory Class:

Product Code:

IV. Document Summary

V. Administrative Requirements

	YES	NO	N/	MISC
Indications for Use page (Indicate if: Prescription or OTC)	x			Rx only
Truthful and Accurate Statement	x			Attachment B
510(k) Summary or 510(k) Statement	x			Summary Attachment A)
ClinicalTrials.gov Form FDA-3874	x			(a)
Standards Form	x			

(b)(4)Proprietary Information

[redacted]

VI. Device Description

	YES	NO	N/A
Is the device life-supporting or life sustaining?		x	
Is the device an implant (implanted longer than 30 days)?		x	
Does the device design use software?		x	
Is the device sterile?	x		
Is the device reusable (not reprocessed single use)?		x	

	YES	NO	N/A
Are “cleaning” instructions included for the end user?			x

(b)(4)Proprietary Information

[redacted]

VII. Indications for Use

Genadyne XLR8 White Foam Dressing Kit is intended to be used in conjunction with the Genadyne A4-XLR8 Wound Vacuum System (K090638) to deliver negative pressure to the wound. Genadyne Z4-XLR8 Wound Vacuum System is indicated for patients

who would benefit from a suction device particularly as the device may promote wound healing.

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- Venous insufficiency ulcers
- Traumatic wounds
- Post-operative and dehisced surgical wounds
- Skin flap and grafts

(b)(4)Proprietary Information

(b)(4)Proprietary Information

VIII. Predicate Device Comparison

(b)(4)Proprietary Information

IX. Labeling

(b)(4)Proprietary Information

(b)(4)Proprietary Information

[redacted]

(b)(4)Proprietary Information

[redacted]

X. Sterilization/Reuse

Review Template for Sterile Devices

1. Sterilant:	YES	NO
a. **Sterilization method** description (e.g., Steam, EtO, Radiation):		
b. **Dose**, for radiation (e.g., 25 – 50 kGy):		
c. **Sterilant residuals** remaining on the device: For EO, the maximum levels of residuals of EO and ethylene chlorhydrin that remain on the device (note: not to include ethylene glycol residual level because the recognized standard, "ANSI/AAMI/ISO 10993-7:1995 Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide sterilization residuals," does not include measurement of ethylene glycol residuals);		
2. A description of the Validation Method for the sterilization cycle (not data): (Full citation of an FDA recognized standard is recommended		

(e.g., ANSI/AAMI/ISO 11135))		
3. Sterility assurance level (SAL): (e.g., 10^{-6} for all devices (except 10^{-3} for devices that contact intact skin))		
4. Is it labeled "Pyrogen Free"?		
If so, a description of the method: (e.g., LAL (*Limulus* Amebocyte Lysate test))		
5. A description of the packaging (not including package integrity test data):		

(b)(4)Proprietary Information

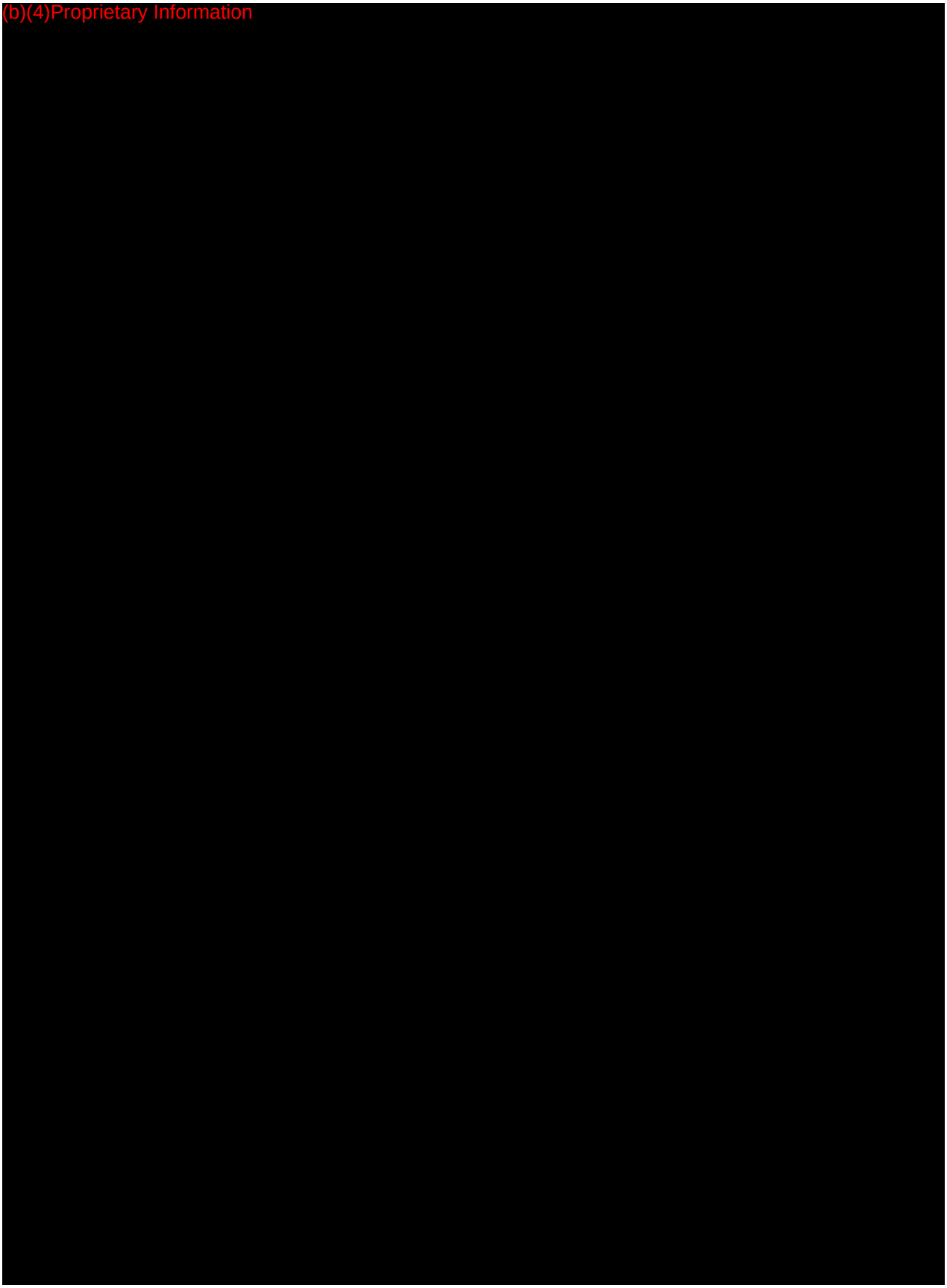
[redacted]

XI. Shelf Life/Stability Testing

(b)(4)Proprietary Information

[redacted]

(b)(4)Proprietary Information

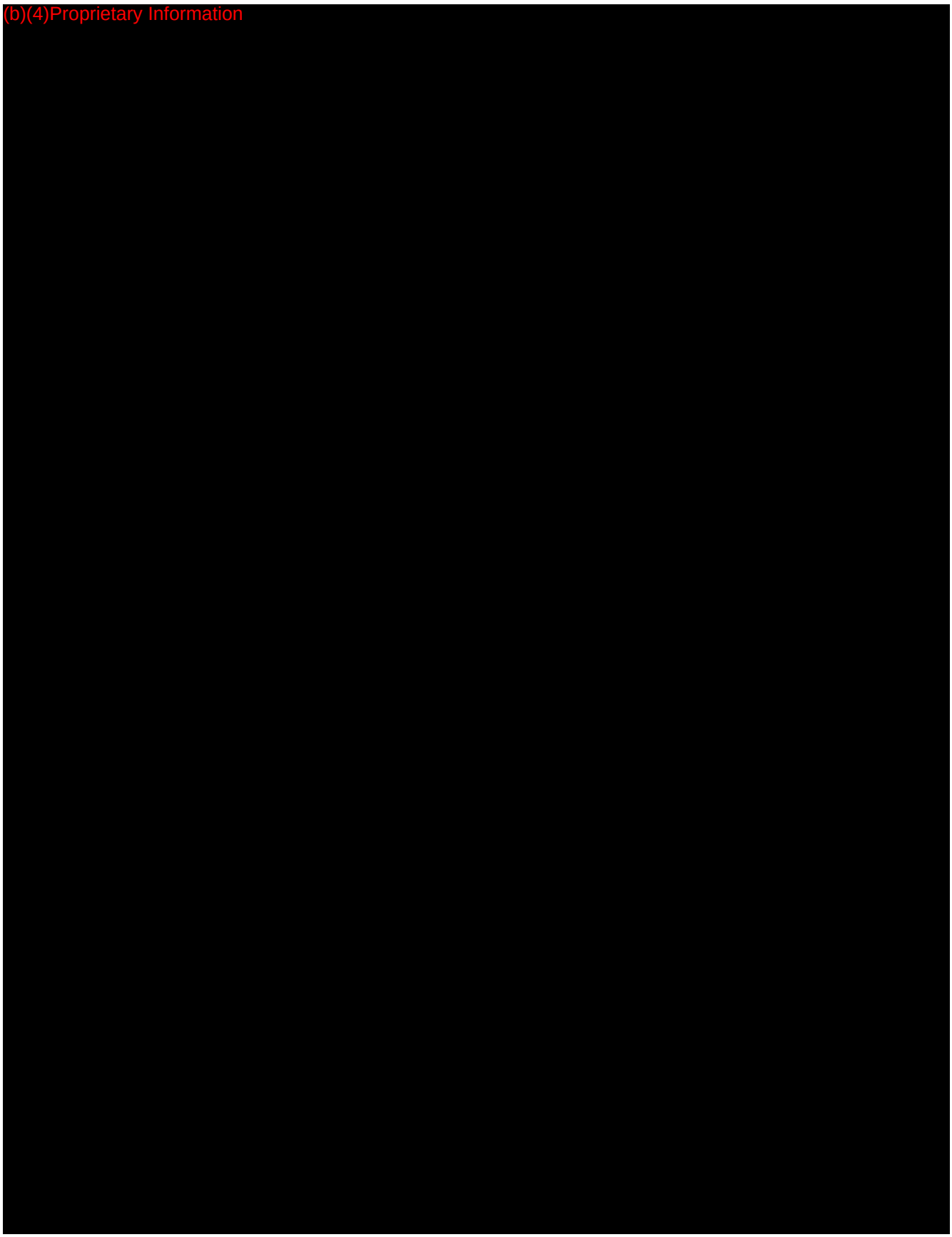


(b)(4)Proprietary Information

[redacted]

XII. Biocompatibility

(b)(4)Proprietary Information



(b)(4)Proprietary Information

[redacted]

XIII. Software

Not applicable.

XIV. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

Not applicable.

XV. Performance Testing – Bench

(b)(4)Proprietary Information

[redacted]

XVI. Performance Testing – Animal

Animal testing is not needed to determine substantial equivalence

XVII. Performance Testing – Clinical

Animal testing is not needed to determine substantial equivalence

XVIII. Substantial Equivalence Discussion

Note: Use the 510(k) Decision Tree to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

	YES	NO	
1. Same Indication Statement?	x		If YES = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If YES = Stop NSE
3. Same Technological Characteristics?	x		If YES = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 6
5. Descriptive Characteristics Precise Enough?		x	If NO = Go To 8

			If YES = Stop SE
6. New Types Of Safety Or Effectiveness Questions?			If YES = Stop NSE
7. Accepted Scientific Methods Exist?			If NO = Stop NSE
8. Performance Data Available?		x	If NO = Request Data
9. Data Demonstrate Equivalence?			Final Decision:

1. Explain how the new indication differs from the predicate device's indication:
2. Explain why there is or is not a new effect or safety or effectiveness issue:
3. Describe the new technological characteristics:
4. Explain how new characteristics could or could not affect safety or effectiveness:
5. Explain how descriptive characteristics are not precise enough:

Testing is needed to demonstrate substantial equivalence in safety (through biocompatibility testing, labeling content) and performance (through simulated wound testing, stability testing).

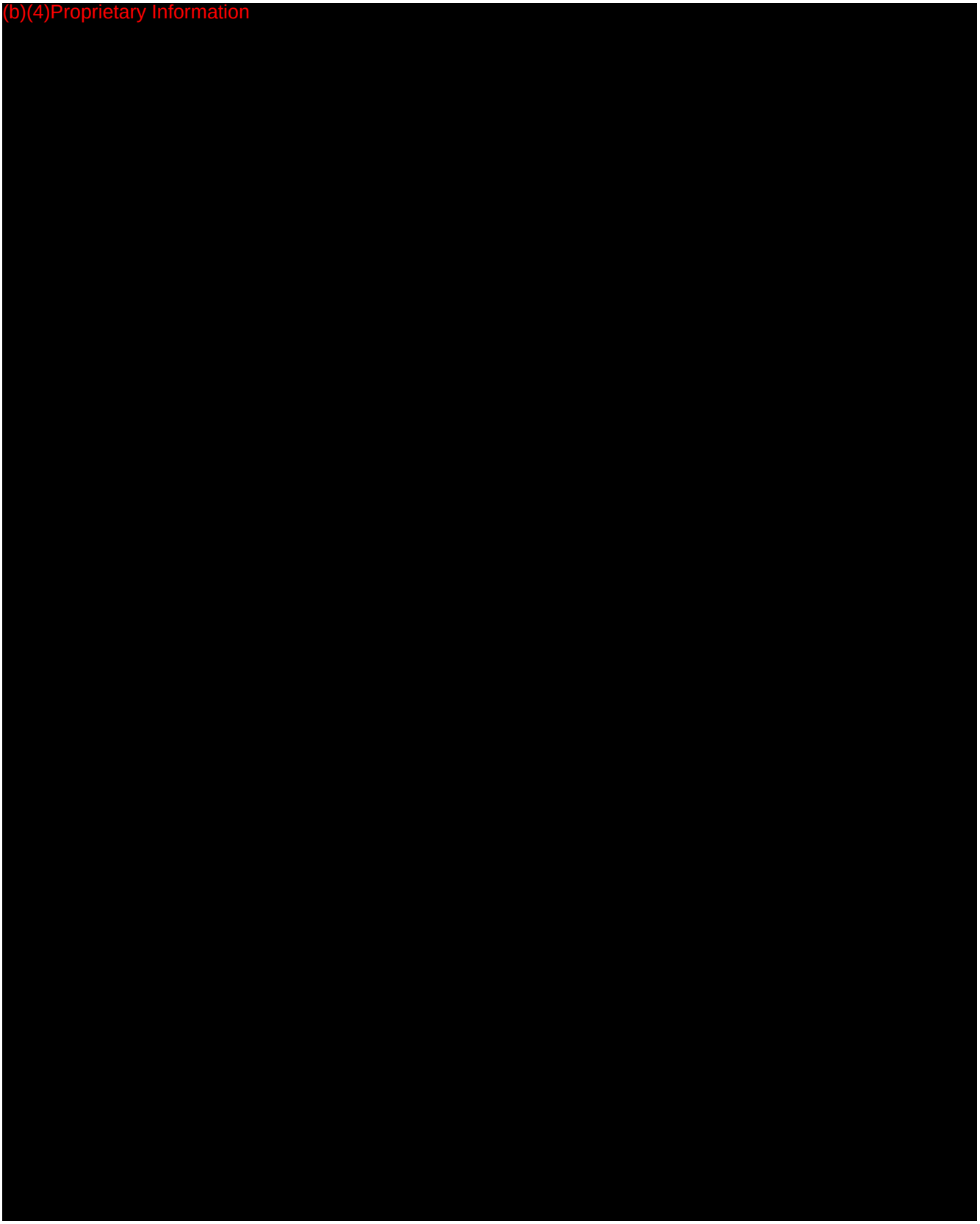
6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:
7. Explain why existing scientific methods can not be used:
8. Explain what performance data is needed:

Bench testing is needed to demonstrate performance; most of the test reports provided require further clarification to understand whether the subject device was evaluated and whether the test methods used are appropriate – see deficiencies below for further details

9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

XIX. Deficiencies

(b)(4)Proprietary Information



(b)(4)Proprietary Information

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(b)(4)Proprietary Information

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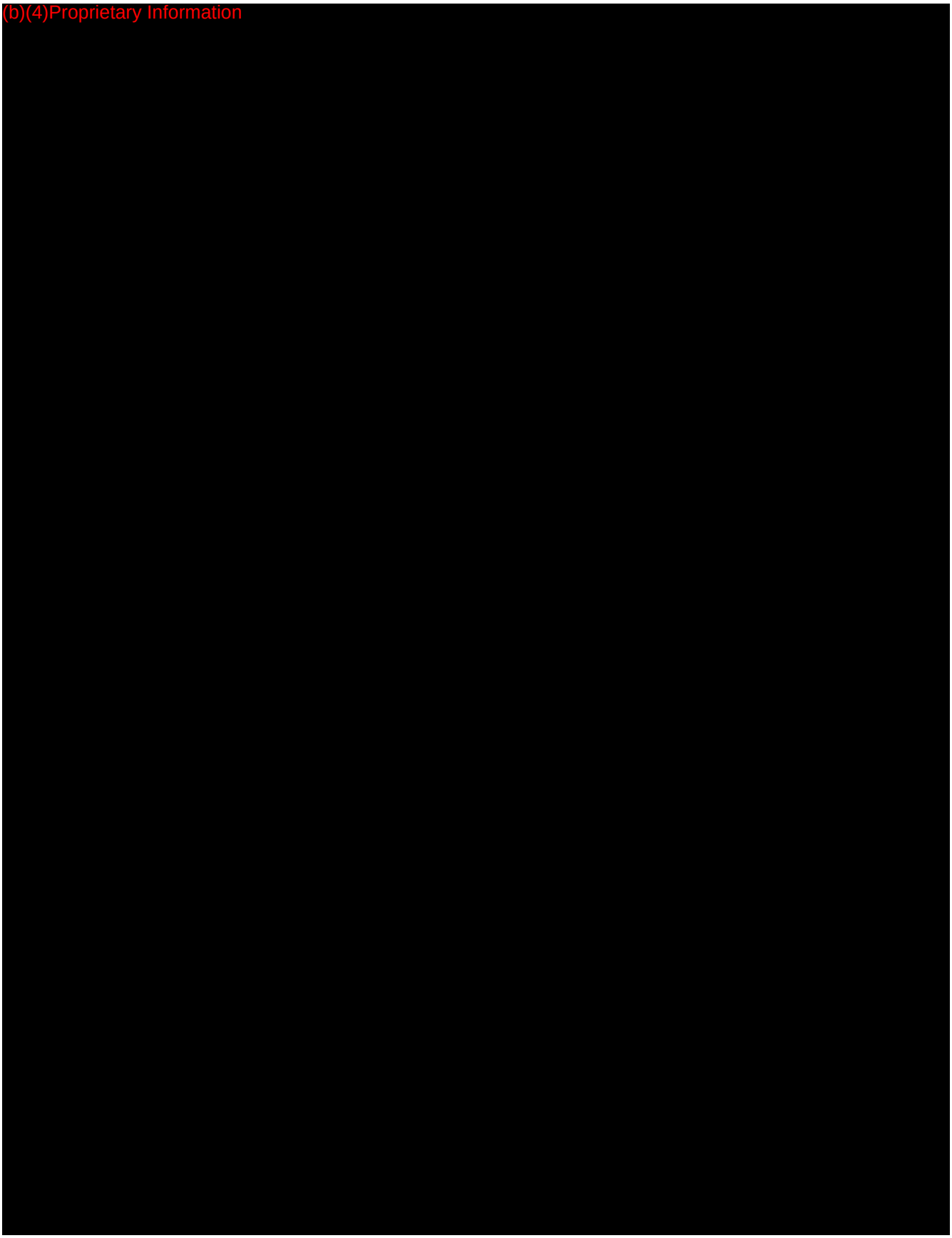
(b)(4)Proprietary Information



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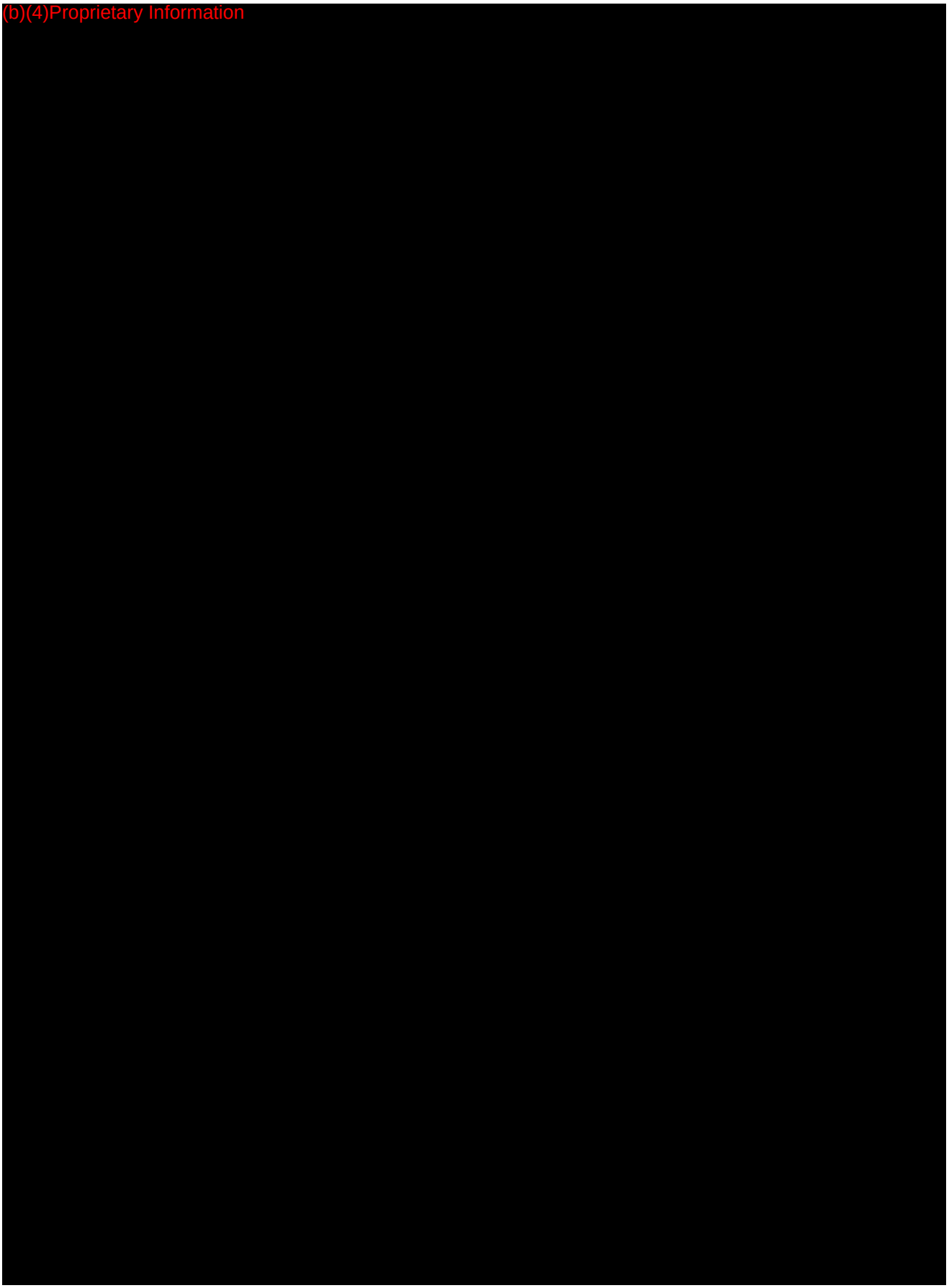

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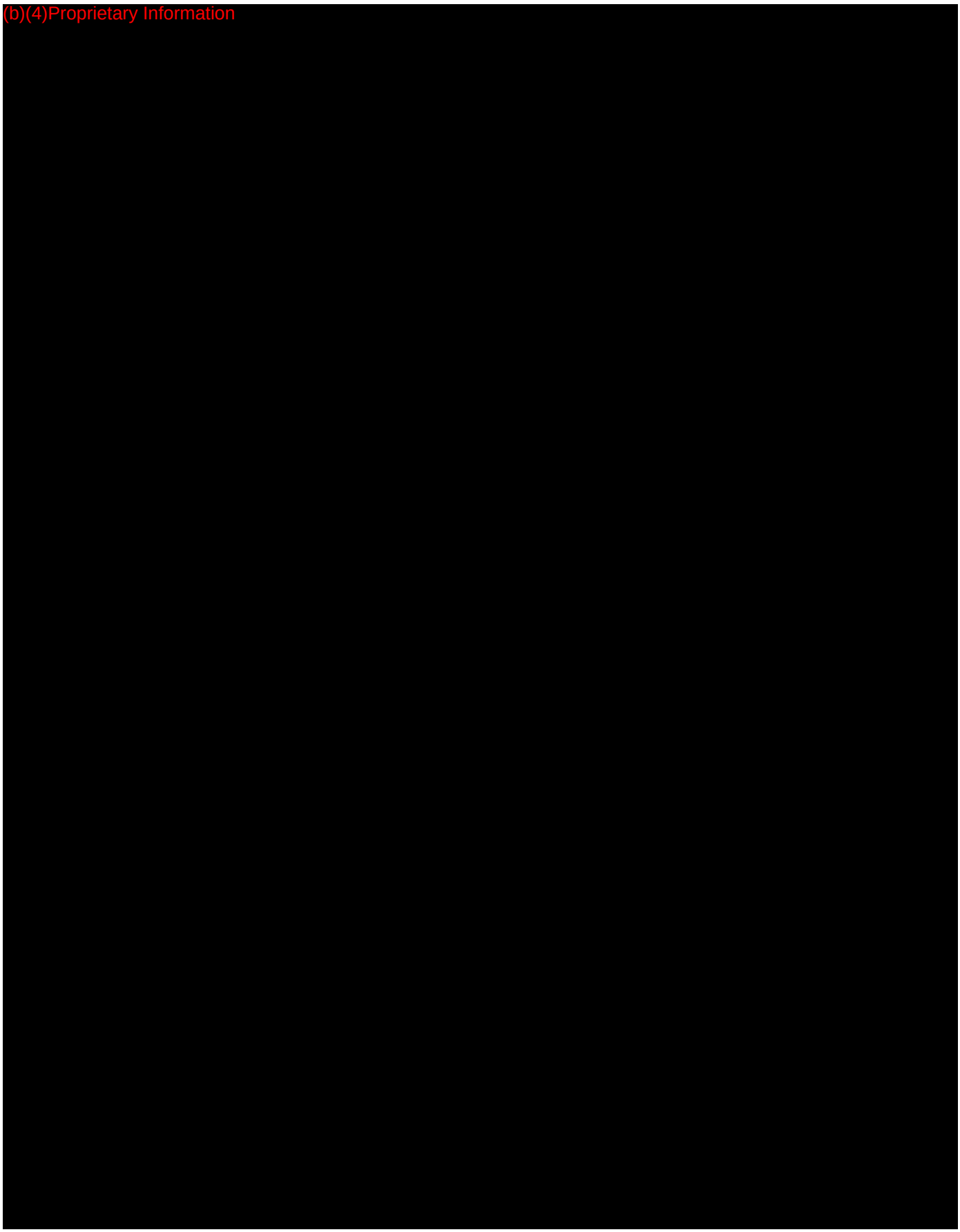

(b)(4)Proprietary Information

XX. Contact History

(b)(4)Proprietary Information

From: Cheng, Cindy
To: Dugard, Christopher; Nielsen, Joseph A. (CDRH)
Subject: ENG consult K142646
Date: Friday, April 10, 2015 10:31:59 AM
Attachments: K142646-(b) .ENG-MECH.Consult.pdf

Hi Chris –

Here is my consult for Genadyne's XLR8 white foam dressing kit. (b)(4)Proprietary information [redacted]

Thanks!
Cindy

From: CDRH Center Tracking System
To: Dugard, Christopher
Subject: CTS Assignment Notification: K142646/S003 has been assigned to you
Date: Tuesday, March 31, 2015 8:56:30 AM

March 31, 2015

This document has been assigned to you in the Center Tracking System (CTS).

Document # :	K142646/S003
Document Type :	510(k)
Workflow State :	Requires Recommendation
Assignor :	Joseph Nielsen [JAN4]

You may visit the Center Tracking System (CTS) at: (b)(4)Proprietary Information [redacted]

Please contact Joseph Nielsen [JAN4] at joseph.nielsen@fda.hhs.gov or at 240-276-3621 if you have any questions or comments.

If you would like NOT to receive these messages in the future, please uncheck 'Receive Assignment Email Notification' checkbox in the User Preferences section of your CTS user profile, accessible through the toolbar in CTS.

*** This is a system-generated email notification ***

Contains Nonbinding Recommendations

Print Form

Acceptance Checklist for Traditional 510(k)s

(Should be completed within 15 days of DCC receipt)

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

510(k) #: K142646 Date Received by DCC: Sep 17, 2014

Lead Reviewer: Charles J. White

Branch: PRSB2 Division: DSD Center/Office: CDRH/ODE

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

Preliminary Questions

Answers in the shaded blocks indicate consultations with Center advisor is needed	Yes	No
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)? 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. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If the product does not appear to be a device or such a combination product, mark "No."	X	
Comments?		
2. Is the application with the appropriate Center? 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. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If application should not be reviewed by your Center mark "No."	X	
Comments?		
3) If a Request for Designation was submitted for the device or combination product with a device constituent part and assigned to your center, identify the RFD # and confirm the following: a) Is the device or combination product the same (e.g., design, formulation) as that presented in the RFD submission? 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 ? 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. Provide summary of Jurisdictional Officer's/Liaison's determination. If the answer to either question is no, mark "No." If there was no RFD, skip this question.		
Comments?		
4) Is this device type eligible for a 510(k) submission? 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."	X	
Comments?		

5) Is there a pending PMA for the same device with the same indications for use? If yes, consult division management and the CDRH 510(k) Program Director or appropriate CBER staff to determine the appropriate action.		X
Comments?		
6) If clinical studies have been submitted, is the submitter the subject of an Application Integrity Policy (AIP)? If yes, consult with the CDRH Office of Compliance/Division of Bioresearch Monitoring (OC/DBM - BIMO) or CBER Office of Compliance and Biologics Quality/Division of Inspections and Surveillance/Bioresearch Monitoring Branch (OCBQ/DIS/BMB) to determine the appropriate action. Check on web at http://www.fda.gov/ICECI/EnforcementActions/ApplicationIntegrityPolicy/ucm134453.htm		
Comments?		

If the answer to 1 or 2 appears to be "No," then stop review of the 510(k) and issue the "Original Jurisdictional Product" letter.
If the answer to 3a or 3b appears to be "No," then stop the review and contact the CDRH Jurisdictional Officer or CBER Office of Jurisdiction Liaison.
If the answer to 4 is "No," the lead reviewer should consult division management and other Center resources to determine the appropriate action.
If the answer to 5 is "Yes," then stop review of the 510(k), contact the CDRH 510(k) Staff and PMA Staff, or appropriate CBER staff.
If the answer to 6 is "Yes," then contact CDRH/OC/DBM-BIMO or CBER/OCBQ/DIS/BMB, provide a summary of the discussion with the BIMO Staff, and indicate BIMO's recommendation/action.

Organizational Elements

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

	Yes	No
1) Submission contains a Table of Contents	X	
2) Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)	X	
3) All pages of the submission are numbered.		X
4) Type of 510(k) is identified (i.e., traditional, abbreviated, or special)	X	
Comments? We recommend that all pages in the submission are numbered.		

Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

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A. Administrative				
1) All content used to support the submission is written in English (including translations of test reports, literature articles, etc.)	X			
2) Submission identifies the following (such as in CDRH Premarket Review Submission Cover Sheet (Form 3514) or 510(k) cover letter):	X			
a) Device trade name or proprietary name	X			
b) Device common name	X			
c) Device class and panel or Classification regulation or Statement that device has not been classified with rationale for that conclusion	X			
3) Submission contains Indications for Use Statement with Rx and/or OTC designation (see also 21 CFR 801.109).	X			
4) Submission contains 510(k) Summary or 510(k) Statement	X			
a) Summary contains all elements per 21 CFR 807.92 *(See also* 510(k) Summary Checklist*)*	X			
b) Statement contains all elements per 21 CFR 807.93			X	
5) Submission contains Truthful and Accuracy Statement per 21 CFR 807.87(k) *See recommended* format.	X			
6) Submission contains Class III Summary and Certification. *See recommended* content.			X	
7) Submission contains clinical data			X	
8) If submission references use of a national or international standard as part of demonstration of substantial equivalence, submission contains Standards Data Report for 510(k)s (Form 3654) or includes detailed information about how and the extent to which the standard has been followed.	X			
9) The submission identifies prior submissions for the same device for which FDA provided feedback related to the data or information needed to support substantial equivalence (e.g., submission numbers for Pre-Submission, IDE, prior not substantially equivalent (NSE) determination, prior 510(k) that was deleted or withdrawn) or states that there were no prior submissions for the subject device.		X		X
a) If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence outlined in prior communications are addressed. For additional information regarding the Pre-Submission process, please refer to the Draft Guidance "Medical Devices: The Pre-Submission Program and Meetings with FDA Staff." Once finalized, this guidance will represent the Agency's current thinking on this topic.			X	
Comments? Please state if there are any prior submissions for this device.				
B. Device Description				
10)				

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a) If there are requirements regarding the device description, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes device description information to establish that the submitter has followed the device-specific requirement.			X	
b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes device description information to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.			X	
11) Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling), including:				
a) A description of the principle of operation and mechanism of action for achieving the intended effect.	X			
b) A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.	X			
c) A list and description of each device for which clearance is requested.	X			
12) Submission contains representative engineering drawing(s), schematics, illustrations and/or figures of the device that are clear, legible, labeled, and include dimensions.		X		X
Comments? Please include the dimensions for the length and width of the adhesive film dressing.				
13) If device is intended to be marketed with multiple components, accessories, and/or as part of a system				
a) Submission includes a list of all components and accessories to be marketed with the subject device.	X			
b) Submission includes a description (as detailed in item 11(a) and (b) and 12 above) of each component or accessory.	X			
c) A 510(k) number is provided for each component or accessory that received a prior 510(k) clearance.			X	
C. Substantial Equivalence Discussion				
14) Submitter has identified a predicate device.	X			
a) Predicate's 510(k) number, trade name, and model number (if applicable) provided. For predicates that are preamendments devices, information is provided to document preamendments status. *Information regarding* documenting preamendment status *is available online.*	X			
b) The identified predicate(s) is consistent throughout the submission (i.e., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing.	X			
15) Submission includes a comparison of the following for the predicate(s) and subject device				
a) Indications for Use	X			
b) Technology, including features, materials, and principles of operation	X			

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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))		X		X
Comments? Please discuss the differences in between the predicate device and the subject device, specifically the foam dressing material and the differences in foam dressing material dimensions and thickness, and how these differences affect the performance, safety and effectiveness of the foam dressing material, and equivalence of the subject device with the predicate.				
D. Proposed Labeling (see also 21 CFR part 801)				
If *in vitro* diagnostic (IVD) device, criteria 17 & 19 may be omitted.				
17) Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual) that include a description of the device, its intended use, and the directions for use.	X			X
a) Indications for use are stated in labeling and are identical to Indications for Use form and 510(k) Summary (if 510(k) Summary provided).	X			
b) Submission includes directions for use that - include statements of all conditions, purposes or uses for which the device is intended (e.g., hazards, warnings, precautions, contraindications) AND - includes directions for layperson (see 21 CFR 801.5) OR submission states that device qualifies for exemption per 21 CFR 801 Subpart D		X		
Comments? Please include directions for use for the subject device include statements of all conditions, purposes or uses for which the device is intended (e.g., hazards, warnings, precautions, contraindications)				
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]	X			
19) General labeling provisions				
a) Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1).	X			
b) Labeling includes device common or usual name. (21 CFR 801.61)	X			
20)				
a) If there are requirements regarding labeling, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes labeling to establish that the submitter has followed the device-specific requirement.			X	
b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes labeling to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.			X	

Elements of a Complete Submission (RTA Items)

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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.

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c) If there is a special controls document applicable to the device, the submission includes labeling to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness.			X	
21) If the device is an in vitro diagnostic device, provided labeling includes all applicable information required per 21 CFR 809.10.			X	
E. Sterilization				
If IVD device and sterilization is not applicable, select "N/A" and criteria below will be omitted from checklist.				
Submission states that the device and/or accessories are: (one of the below must be checked)				
X provided sterile				
provided non-sterile but sterilized by the end user				
non-sterile when used				
Information regarding the sterility status of the device is not provided.				
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.				
22) Assessment of the need for sterilization information				
a) Identification of device, and/or accessories, and/or components that are provided sterile.	X			
b) Identification of device, and/or accessories, and/or components that are end user sterilized.			X	
c) Identification of device, and/or accessories, and/or components that are reusable and cleaning /disinfection instructions are provided.			X	
23) If the device, and/or accessory, and/or a component is provided sterile:				X
a) Sterilization method is stated for each component (including parameters such as dry time for steam sterilization, radiation dose, etc.).		X		
b) A description of method to validate the sterilization parameters (e.g., half-cycle method and full citation of FDA-recognized standard, including date) is provided for each proposed sterilization method. *Note, the sterilization validation report is not required.*		X		
c) For devices sterilized using chemical sterilants such as ethylene oxide (EO) and hydrogen peroxide, submission states maximum levels of sterilant residuals remaining on the device and sterilant residual limits.			X	
d) Submission includes description of packaging and packaging contents (e.g., if multiple devices are included within the same package, Tyvek packaging, etc.)	X			
e) Sterility Assurance Level (SAL) is stated.		X		
Comments? You have provided the sterilization report for the Fuzhou Foreking Medical PVA White Foam.				

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Please clarify if the Fuzhou Foreking Medical PVA White Foam refers to the subject device (XLR8 White Foam). Also, please provide Sterilization method for the other components of the kit that are provided sterile. Please provide the Sterility Assurance Level (SAL).				
24) If the device, and/or accessory, and/or a component is end user sterilized:			X	
25)				
a) If there are requirements regarding sterility, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes sterility information to establish that the submitter has followed the device-specific requirement.			X	
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.			X	
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.			X	
F. Shelf Life				
26) Proposed shelf life/expiration date stated	X			
27) For sterile device, submission includes summary of methods used to establish that device will remain sterile through the proposed shelf life or a rationale for why testing to establish shelf life is not applicable.	X			
28) Submission includes summary of methods used to establish that device performance is not adversely affected by aging or includes a rationale for why the storage conditions are not expected to affect device safety or effectiveness.	X			
G. Biocompatibility				
If IVD device, select "N/A" and the below criteria will be omitted from checklist.				
Submission states that there: (one of the below must be checked)				
X are direct or indirect (e.g., through fluid infusion) patient-contacting components.				
are no direct or indirect (e.g., through fluid infusion) patient-contacting components.				
Information regarding the patient contact status of the device is not provided.				
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.				

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29) Submission includes list of patient-contacting device components and associated materials of construction, including identification of color additives, if present	X			
30) Submission identifies contact classification (e.g., surface-contacting, less then 24 hour duration, etc.)	X			
31) Biocompatibility assessment of patient-contacting components Submission includes: Test protocol (including identification and description of test article), methods, pass/fail criteria, and results provided for each completed test, OR a statement that biocompatibility testing is not needed with a rationale (e.g., materials and manufacturing/processing are identical to the predicate).	X			
H. Software				
Submission states that the device: (one of the below must be checked)				
does contain software/firmware.				
X does not contain software/firmware.				
Information regarding whether the device contains software is not provided.				
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.				
I. EMC and Electrical Safety				
Submission states that the device: (one of the below must be checked)				
does require EMC and Electrical Safety evaluation.				
X does not require EMC and Electrical Safety evaluation.				
Information regarding whether the device requires EMC and Electrical Safety evaluation is not provided.				
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.				
J. Performance Data - General If IVD device, select "N/A" and the below criteria will be omitted from checklist. Performance data criteria relating to IVD devices will be addressed in Section K.				
36) Full test report is provided for each completed test. A full test report includes: objective of the test, description of the test methods and procedures, study endpoint(s), pre-defined pass/fail criteria, results summary, conclusions, and an explanation of how the data generated from the test supports a finding of substantial equivalence.	X			
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.			X	

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b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes performance data to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.			X	
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.			X	
38) If literature is referenced in the submission, submission includes:			X	
39) For each completed nonclinical (i.e., animal) study conducted				
a) Submission includes a study protocol which includes all elements as outlined in 21 CFR 58.120.	X			
b) Submission includes final study report which includes all elements outlined in 21 CFR 58.185.	X			
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.	X			
K. Performance Characteristics - In Vitro Diagnostic Devices Only **(Also see 21 CFR 809.10(b)(12))**				
Submission states that the device: (one of the below must be checked)				
	is an in vitro diagnostic device.			
X	is not an in vitro diagnostic device.			

Decision: ○ Accept ◉ Refuse to Accept

If Accept, notify applicant.

If Refuse to Accept, notify applicant in writing and include a copy of this checklist.

Digital Signature Concurrence Table

Reviewer Sign-Off	Charles White -S 2014.10.01 15:41:56 -04'00'
Branch Chief Sign-Off (digital signature optional)*	Jiyoung Dang -S 2014.10.01 21:01:15 -04'00'
Division Sign-Off (digital signature optional)*	Binita S. Ashar -S 2014.10.01 21:56:27 -04'00'

* Branch and Division review of checklist and concurrence with decision required. Branch and Division digital signature optional.