

Integra NeuroSciences
Special 510(k): Device Modification
Hermetic Plus™ External CSF Drainage Systems

Confidential

K030289

**Hermetic Plus™
External CSF Drainage System**

510(k) SUMMARY

FEB 26 2003

Submitter's name and address:

Integra LifeSciences Corporation
Integra NeuroSciences
311 Enterprise Drive
Plainsboro, NJ 08536

Contact person and telephone number:

Donna R. Wallace
Director, Regulatory Affairs
(609) 275-0500

Date summary was prepared:

January 24, 2003

Name of the device:

Proprietary Name: Hermetic Plus™ External CSF Drainage System
Common Name: External CSF Drainage System
Classification Name: Central Nervous System Shunt and Components JXG

Substantial Equivalence:

The Hermetic Plus™ External CSF Drainage System is substantially equivalent in function and intended use to the unmodified External CSF Drainage and Management Systems which has been cleared to market under Premarket Notification 510(k) K972994.

Intended use:

The Hermetic Plus™ External CSF Drainage System is indicated for draining and monitoring of cerebrospinal fluid (CSF) from the lateral ventricles of the brain or lumbar subarachnoid space in selected patients to reduce intracranial pressure (ICP), monitor intracranial pressure, to monitor cerebrospinal fluid, and provide temporary CSF drainage for patients with infected hydrocephalic shunts.

Device Description:

The Hermetic Plus™ External Drainage Systems are designed to externally drain cerebrospinal fluid (CSF) from the lateral ventricles of the brain or the lumbar subarachnoid space to a drainage bag in selected patients. The systems connect to a ventricular or lumbar catheter via a luer connection to a patient line and ultimately to a drainage bag. The patient line is connected to a graduated burette that is then connected to the drainage bag. CSF can be collected and measured in the burette and subsequently emptied into the drainage bag by opening the stopcock placed in line between the burette and the drainage bag. An antimicrobial vent is included in the burette cap. This antimicrobial vent allows air to enter the burette to facilitate drainage from the burette to the drainage bag while protecting the system from microbial contamination. The

antimicrobial vent used on the Hermetic Plus™ systems will allow better drainage of the CSF to the drainage bag and will resist occlusion after contact with CSF without the need for clamping the burette vent tube.

The Safety Locking Knob of the Hermetic Plus™ system will now contain a titanium screw component and the cord lock of the suspension cord has been changed to an all plastic component.

Safety

The Hermetic Plus™ External CSF Drainage Systems have been demonstrated to be MR safe* when used in the Magnetic Resonance (MR) environment.

*MRI safe is defined by the CDRH Magnetic Resonance Working Group (Feb. 7, 1997) draft document A Primer on Medical Device Interactions with MRI Systems as “The device, when used in the MRI environment, has been demonstrated to present no additional risk to the patient or other individuals, but may affect the quality of the diagnostic information.”

Testing has shown that the antimicrobial vent is resistant to occlusion after 30 minutes of exposure to fluids with high protein levels. The systems have been tested for strength of bonded components, leakage, drainage, and package integrity. Additionally, the needleless sampling sites were designed to reduce needlestick injuries and subsequent exposure to infected fluids.

Conclusion

The Hermetic Plus™ External CSF Drainage System is substantially equivalent to the unmodified External CSF Drainage Management Systems. The modifications do not affect the intended use, the fundamental scientific technology of the device, and do not raise new issues of safety and effectiveness.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

FEB 26 2003

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Integra LifeSciences Corporation
Donna R. Wallace
Director, Regulatory Affairs
311 Enterprise Drive
Plainsboro, New Jersey 08536

Re: K030289

Trade/Device Name: Hermetic Plus™ External CSF Drainage Systems
Regulation Number: 882.5550
Regulation Name: Central nervous system fluid shunt and components
Regulatory Class: Class II
Product Code: JXG
Dated: January 27, 2003
Received: January 28, 2003

Dear Ms. Wallace:

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

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

Page 2 – Ms. Donna R. Wallace

(21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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

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

Sincerely yours,



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

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number: K030289

Device Name: Hermetic Plus™ External CSF Drainage System

Indications for Use:

The Hermetic Plus™ External CSF Drainage System is indicated for draining and monitoring of Cerebrospinal Fluid (CSF) flow from the lateral ventricles of the brain or lumbar subarachnoid space in selected patients to reduce intracranial pressure (ICP), monitor intracranial pressure (ICP), monitor cerebrospinal fluid (CSF), and provide temporary CSF drainage for patients with infected hydrocephalic shunts.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
 (Per 21 CFR 801.109)

Or

Over-the-Counter Use

Optional Format 1-2-96)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K030289



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

FEB 26 2003

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Integra LifeSciences Corporation
Donna R. Wallace
Director, Regulatory Affairs
311 Enterprise Drive
Plainsboro, New Jersey 08536

Re: K030289

Trade/Device Name: Hermetic Plus™ External CSF Drainage Systems
Regulation Number: 882.5550
Regulation Name: Central nervous system fluid shunt and components
Regulatory Class: Class II
Product Code: JXG
Dated: January 27, 2003
Received: January 28, 2003

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Page 2 – Ms. Donna R. Wallace

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

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<http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



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

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number: K030289

Device Name: Hermetic Plus™ External CSF Drainage System

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
 (Per 21 CFR 801.109)

Or

Over-the-Counter Use

Optional Format 1-2-96)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K030289

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

January 28, 2003

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

INTEGRA LIFESCIENCES CORP.
 311 ENTERPRISE DRIVE
 PLAINSBORO, NJ 08536
 ATTN: DONNA WALLACE

510(k) Number: K030289
 Received: 28-JAN-2003
 Product: HERMETIC PLUS
 EXTERNAL CSF
 DRAINAGE SYSTEMS,
 INS-8301, INS-8302, IN

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

As a reminder, we would like to mention that FDA requires all 510(k) submitters to provide an indications for use statement on a separate page. If you have not included this indications for use statement in addition to your 510(k) summary (807.92), or a 510(k) statement (807.93), and your Truthful and Accurate statement, please do so as soon as possible. If the above mentioned requirements have been submitted, please do not submit them again. There may be other regulations or requirements affecting your device such as Postmarket Surveillance (Section 522(a)(1) of the Act) and the Device Tracking regulation (21 CFR Part 821). Please contact the Division of Small Manufacturers, International and Consumer Assistance (DSMICA) at the telephone or web site below for more information.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC)(HFZ-401) at the above letterhead address. Correspondence sent to any address other than the DMC will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

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

Sincerely yours,

Marjorie Shulman
 Consumer Safety Officer
 Premarket Notification Staff
 Office of Device Evaluation



311C Enterprise Drive • Plainsboro, NJ 08536 • (609) 275-0500 • Fax: (609) 275-3684 • <http://www.Integra-LS.com>
Via Federal Express

January 27, 2003

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

RE: Special 510(k): Device Modification

Original Reference: Premarket Notification 510(k) K972994
External CSF Drainage Management Systems
Date of Concurrence: November 3, 1997

RECEIVED
2003 JAN 28 A 10:58
FDA/CDRH/OCE/P110

This notification is submitted pursuant to Section 510(k) of the Federal Food, Drug and Cosmetic Act and Code of Federal Regulations, Title 21, Part 807. Integra LifeSciences is submitting this **Special 510(k): Device Modification** as a notification of intent to market a modified device known as the Hermetic Plus™ External CSF Drainage System. The modified Hermetic Plus™ system is substantially equivalent to the commercially available External CSF Drainage Systems, 510(k) K972994 that has been recommended for classification as Class II by the Neurology Panel of the Food and Drug Administration.

The Hermetic Plus™ External CSF Drainage System is undergoing modifications to change the materials of certain components and to change the design of the antimicrobial vent of the graduated burette. MRI safety testing was performed on the modified Hermetic Plus™ External Drainage System and information on its use in a MR environment is included in the product's labeling. We believe these modifications are eligible for the Special 510(k) process since they have the same fundamental scientific technology, the same intended use as the predicate device and do not raise new issues of safety and effectiveness.

Integra LifeSciences Corporation considers its intent to market this device as confidential commercial information and requests that the Food and Drug Administration hold as confidential all such information in this submission. The intent to market the device has not been disclosed to anyone except employees of, or paid consultants of Integra LifeSciences Corporation.

Thank you in advance for your consideration of our application. If you have further questions or if you need additional information, please do not hesitate to contact me at (609) 936-2397, by facsimile at (609)-275-9445 or by email at dwallace@integra-ls.com.

Sincerely,

Donna R. Wallace, RAC
Director, Regulatory Affairs

5158
NE
II 21

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

Premarket Submission Cover Sheet

Date of Submission:
January 27, 2003

FDA Document Number:

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

Section B1 Reason for Submission - 510(k)s Only		
<input type="checkbox"/> New device	<input type="checkbox"/> Additional or expanded indications	<input checked="" type="checkbox"/> Change in technology, design, materials, or manufacturing process
<input type="checkbox"/> Other reason (specify): <i>Comment section</i>		

Section B2 Reason for Submission - PMAs Only		
<input type="checkbox"/> New device	<input type="checkbox"/> Change in design, component, or specifications:	<input type="checkbox"/> Location change:
<input type="checkbox"/> Withdrawal	<input type="checkbox"/> Software	<input type="checkbox"/> Manufacturer
<input type="checkbox"/> Additional or expanded indications	<input type="checkbox"/> Color additive	<input type="checkbox"/> Sterilizer
<input type="checkbox"/> Licensing agreement	<input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Packager
<input type="checkbox"/> Labeling change:	<input type="checkbox"/> Process change:	<input type="checkbox"/> Report submission:
<input type="checkbox"/> Indications	<input type="checkbox"/> Manufacturer	<input type="checkbox"/> Annual or periodic
<input type="checkbox"/> Instructions	<input type="checkbox"/> Sterilizer	<input type="checkbox"/> Post-approval study
<input type="checkbox"/> Performance Characteristics	<input type="checkbox"/> Packager	<input type="checkbox"/> Adverse reaction
<input type="checkbox"/> Shelf life		<input type="checkbox"/> Device defect
<input type="checkbox"/> Trade name	<input type="checkbox"/> Response to FDA correspondence (specify below)	<input type="checkbox"/> Amendment
<input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Request for applicant hold	
<input type="checkbox"/> Change in ownership	<input type="checkbox"/> Request for removal of applicant hold	
<input type="checkbox"/> Change in correspondent	<input type="checkbox"/> Request for extension	
<input type="checkbox"/> Other reason (specify):	<input type="checkbox"/> Request to remove or add manufacturing site	

Section B3 Reason for Submission - IDEs Only		
<input type="checkbox"/> New device	<input type="checkbox"/> Change in:	<input type="checkbox"/> Response to FDA letter concerning:
<input type="checkbox"/> Addition of institution	<input type="checkbox"/> Correspondent	<input type="checkbox"/> Conditional approval
<input type="checkbox"/> Expansion/extension of study	<input type="checkbox"/> Design	<input type="checkbox"/> Deemed approved
<input type="checkbox"/> IRB certification	<input type="checkbox"/> Informed consent	<input type="checkbox"/> Deficient final report
<input type="checkbox"/> Request hearing	<input type="checkbox"/> Manufacturer	<input type="checkbox"/> Deficient progress report
<input type="checkbox"/> Request waiver	<input type="checkbox"/> Manufacturing	<input type="checkbox"/> Deficient investigator report
<input type="checkbox"/> Termination of study	<input type="checkbox"/> Protocol - feasibility	<input type="checkbox"/> Request of extension of time to respond to FDA
<input type="checkbox"/> Unanticipated adverse effect	<input type="checkbox"/> Sponsor	<input type="checkbox"/> Request meeting
<input type="checkbox"/> Emergency use:	<input type="checkbox"/> Report submission:	<input type="checkbox"/> IOL submissions only:
<input type="checkbox"/> Notification of emergency use	<input type="checkbox"/> Current investigator	<input type="checkbox"/> Change in IOL style
<input type="checkbox"/> Additional information	<input type="checkbox"/> Annual progress	<input type="checkbox"/> Request for protocol waiver
<input type="checkbox"/> Other reason (specify):	<input type="checkbox"/> Site waiver limit reached	
	<input type="checkbox"/> Final	

22

				FDA Document Number:	
Section C Product Classification					
Product code: JXG		C.F.R. Section: 21 CFR 882.5550		Device class: <input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified	
Classification Panel: Neurology					
Section D Information on 510(k) Submissions					
Product codes of devices to which equivalence is claimed:				Summary of, or statement concerning, safety and effectiveness data:	
1 JXG	2	3	4	<input checked="" type="checkbox"/> 510(k) summary attached <input type="checkbox"/> 510(k) statement	
5	6	7	8		
Information on devices to which substantial equivalence is claimed:					
510(k) Number	Trade or proprietary or model name			Manufacturer	
1 K972994	1. External CSF Drainage Management Systems			1 Integra NeuroSciences	
2	2			2	
3	3			3	
4	4			4	
Section E Product Information - Applicable to All Applications					
Common or usual name or classification name: Common: External CSF Drainage Systems Classification Name: Central Nervous System Shunts and Components					
Trade or proprietary or model name				Model number	
1	Hermetic Plus™ External CSF Drainage Systems			1 INS-8301	
2				2 INS-8302	
3				3 INS-8700	
4				4 NL850-8305N	
5				5	
6				6	
7				7	
8				8	
9				9	
10				10	
11				11	
12				12	
FDA document numbers of all prior related submissions (regardless of outcome): None					
1	2	3	4	5	6
7	8	9	10	11	12
Data included in submission: <input checked="" type="checkbox"/> Laboratory testing <input type="checkbox"/> Animal trials <input type="checkbox"/> Human trials					
Indications (from labeling): Drainage and monitoring of cerebrospinal fluid (CSF) flow from the lateral ventricles of the brain or lumbar subarachnoid space is indicated in selected patients to reduce intracranial pressure (ICP) monitor intracranial pressure (ICP), monitor cerebrospinal fluid (CSF) and provide temporary CSF drainage for patients with infected hydrocephalic shunts.					

23

		FDA Document Number:	
Section F: Manufacturing/Packaging/Sterilization Sites			
<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	FDA establishment registration number: 2648988	<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract manufacturer	<input type="checkbox"/> Contract sterilizer <input type="checkbox"/> Repackager / relabeler
Company / Institution name: Integra NeuroSciences PR, Inc.			
Division name (if applicable):		Phone number (include area code): 787-826-2329	
Street address: State Road 402, Km 1.2		Fax number (include area code): 787-826-2772	
City: Anasco	State / Province: Puerto Rico	Country: USA	ZIP / Postal Code: 00610
Contact name: Donna Wallace			
Contact title: Director, Regulatory Affairs			
<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	FDA establishment registration number: 2648045	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract manufacturer	<input checked="" type="checkbox"/> Contract sterilizer <input type="checkbox"/> Repackager / relabeler
<i>(b)(4)</i>			
<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	FDA establishment registration number:	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract manufacturer	<input type="checkbox"/> Contract sterilizer <input type="checkbox"/> Repackager / relabeler
Company / Institution name:			
Division name (if applicable):		Phone number (include area code):	
Street address:		Fax number (include area code):	
City:	State / Province:	Country:	ZIP / Postal Code: D
Contact name:			
Contact title:			

24

		FDA Document Number:	
Section G Applicant or sponsor:			
Company / Institution name: Integra LifeSciences Corporation		FDA establishment registration number: 1121308	
Division name (if applicable): Integra NeuroSciences		Phone number (include area code): 609-275-0500	
Street address: 311 Enterprise Drive		Fax number (include area code): 609-275-9445	
City: Plainsboro	State / Province: NJ	Country: USA	ZIP / Postal Code: 08536
Signature: <i>Donna Wallace</i>			
Name: Donna Wallace			
Title Director, Regulatory Affairs			
Section H Submission correspondent (if different from above)			
Company / Institution name: Integra LifeSciences Corporation		FDA establishment registration number: 1121308	
Division name (if applicable):		Phone number (include area code): 609-936-2397	
Street address: 311 Enterprise Drive		Fax number (include area code): 609-275-3684	
City: Plainsboro	State / Province: New Jersey	Country: USA	ZIP / Postal Code: 08536
Signature: <i>Donna Wallace</i>			
Name: Donna Wallace			
Title Director, Regulatory Affairs			

25



311C Enterprise Drive • Plainsboro, NJ 08536 • (609) 275-0500 • Fax: (609) 275-3684 • <http://www.Integra-LS.com>
Via Federal Express

January 27, 2003

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

RE: Special 510(k): Device Modification

Original Reference: Premarket Notification 510(k) K972994
External CSF Drainage Management Systems
Date of Concurrence: November 3, 1997

*Integra Life Sciences
2003-01-27
Donna R. Wallace*

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Director, Regulatory Affairs

26

Integra NeuroSciences
Special 510(k): Device Modification
Hermetic Plus™ External CSF Drainage Systems

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TABLE OF CONTENTS

I. DEVICE NAME.....1

II. COMPANY NAME, ADDRESS, AND MANUFACTURING FACILITY.....1

III. ESTABLISHMENT REGISTRATION NUMBER1

IV. CLASSIFICATION OF DEVICE1

V. PREDICATE DEVICE INFORMATION2

VI. PROPOSED LABELING AND INTENDED USE.....2

VII. DEVICE DESCRIPTION AND COMPARISON2

VIII. SUBSTANTIAL EQUIVALENCE.....4

IX. 510(K) SUMMARY10

X. LITERATURE REFERENCES10

XI. SUMMARY OF DESIGN CONTROL ACTIVITIES10

XII. CONCLUSION14

XIII. TRUTHFUL AND ACCURATE STATEMENT15

27

Integra NeuroSciences
Special 510(k): Device Modification
Hermetic Plus™ External CSF Drainage Systems

Confidential

APPENDICES

- A. DRAFT LABELS AND INSTRUCTIONS FOR USE – HERMETIC PLUS EXTERNAL CSF DRAINAGE SYSTEM**
- B. INSTRUCTIONS FOR USE- CURRENT HERMETIC PLUS EXTERNAL CSF DRAINAGE SYSTEM**
- C. INDICATIONS FOR USE – HERMETIC PLUS EXTERNAL CSF DRAINAGE SYSTEM**
- D. PHOTOGRAPH**
- E. PRODUCT DRAWINGS**
- F. MRI SAFETY TESTING**
- G. INTERVENE™ & PSI FILTERS**
- H. ANTIMICROBIAL VENT VERIFICATION TEST REPORT**
- I. 510(K) SUMMARY**
- J. LITERATURE REFERENCES**
- K. DECLARATION OF CONFORMITY WITH DESIGN CONTROLS**

SPECIAL 510(k): DEVICE MODIFICATION

for

Hermetic Plus™ External CSF Drainage Systems

Reference:

510(k) K972994

Date of Concurrence: November 3, 1997

January 27, 2003

**Integra LifeSciences Corporation
Integra NeuroSciences
311 Enterprise Drive
Plainsboro, New Jersey 08536
Tel: 609-275-0500
Fax: 609-275-9445**

29

Integra NeuroSciences
Special 510(k): Device Modification
Hermetic Plus™ External CSF Drainage Systems

Confidential

I. DEVICE NAME

Proprietary Name
a. Modified: Hermetic Plus™ External CSF Drainage System
b. Unmodified: External CSF Drainage Management Systems
Common Name: External CSF Drainage Systems
Classification Name: Central Nervous System Shunts and Components JXG
Classification Panel: Neurology

II. Company Name, Address, and Manufacturing Facility

Integra LifeSciences Corporation
Integra NeuroSciences
311 Enterprise Drive
Plainsboro, NJ 08536
Telephone: 609-275-0500
Facsimile: 609-275-9445

A. Contact person and telephone number:

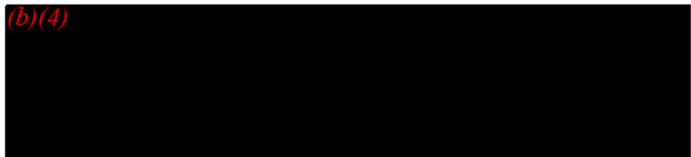
Donna R. Wallace, RAC
Director, Regulatory Affairs
Integra LifeSciences Corporation
311 Enterprise Drive
Plainsboro, NJ 08536
Telephone: 609-936-2397
Fax: 609-275-9445
e-mail: dwallace@integra-ls.com

III. ESTABLISHMENT REGISTRATION NUMBER

A. Manufacturing Site:

Integra NeuroSciences PR, Inc.
State Road 402, Km 1.2
P.O. Box 167
Anasco, PR 00610
Telephone: 787-826-2329
Facsimile: 787-826-2772
Establishment Registration Number: 2648988

B. Sterilization Site:

(b)(4)


IV. Classification of Device

The United States Food and Drug Administration has classified Central Nervous System Shunts and Components as Class II by the Neurology Panel.

30

V. PREDICATE DEVICE INFORMATION

External CSF Drainage Management Systems
510(k) K972994
Date of Concurrence: November 3, 1997

VI. PROPOSED LABELING AND INTENDED USE

Draft labels and Instructions for Use for the modified Hermetic Plus™ External CSF Drainage System are provided in **Appendix A**. The Instructions for Use for the currently marketed Hermetic External CSF Drainage systems are also provided for ease of review in **Appendix B**. The intended use of the device has not been changed.

The Hermetic Plus™ External CSF Drainage System is indicated for draining and monitoring of cerebrospinal fluid (CSF) flow from the lateral ventricles of the brain or lumbar subarachnoid space in selected patients to reduce intracranial pressure (ICP), monitor intracranial pressure (ICP), monitor cerebrospinal fluid (CSF), and provide temporary CSF drainage for patients with infected hydrocephalic shunts

The “Indications for Use” statement for the Hermetic Plus™ External CSF Drainage System is provided on a separate page in **Appendix C**.

VII. DEVICE DESCRIPTION AND COMPARISON

The modified Hermetic Plus™ External CSF Drainage Systems were designed to be very similar and are substantially equivalent to the unmodified Hermetic External CSF Drainage Systems. The modifications do not change the intended use or fundamental scientific technology of the device.

The External CSF Drainage Management Systems now known as the Hermetic External CSF Drainage Systems were cleared to market via 510(k) K972994 on November 3, 1997. Three configurations of the drainage systems were described in 510(k) K972994. Configuration B is equivalent to the currently marketed Hermetic Plus™ External CSF Drainage System. The Hermetic Plus™ system was first marketed in 2001 with some minor modifications from the External CSF Drainage Management System (Configuration B) as described in 510(k) K972994.

(b)(4)



31

(b)(4)



This Special 510(k) will compare the combination of these modifications to the original External CSF Drainage Management System (Configuration B) of 510(k) K972994.

Both the original External CSF Drainage Management System (Configuration B) and the modified Hermetic Plus™ External CSF Drainage Systems are designed to externally drain cerebrospinal fluid (CSF) from the lateral ventricles of the brain or the lumbar subarachnoid space to a drainage bag. Both systems connect to a ventricular or lumbar catheter via a luer connection to a patient line. The patient line connects to a graduated burette and ultimately to a drainage bag. The ventricular and lumbar catheters are provided separately from the Hermetic Plus™ External CSF Drainage System and are not the subject of this Special 510(k) submission.

Two models of the Hermetic Plus™ system are available. One contains an anti-reflux valve in the patient line and one does not. The Hermetic Plus™ systems may be suspended from an intravenous (IV) pole using the suspension cord with the cord locking mechanism. Velcro® straps are also supplied for more secure attachment to the IV pole.

Striped pressure tubing is used in both the modified and unmodified systems. The Hermetic Plus™ system includes 150 cm of green striped pressure tubing from the catheter connection to the panel mounted stopcock, while the External CSF Drainage Management System (Configuration B) contained 200 cm of white striped pressure tubing. The green stripe on the tubing aids in identifying this portion of the patient line as pressure tubing since it connects to the panel mounted stopcock that can be used as a transducer port.

In both systems the graduated burette is attached to a panel assembly and may be moved up and down to change positioning of the burette by loosening and then re-tightening the Safety Locking Knob located on the sliding panel. CSF can be collected and measured in the graduated burette and subsequently emptied to the drainage bag by opening the stopcock placed in-line between the burette and the drainage bag. The Hermetic Plus™ systems may be used with Integra NeuroSciences' replacement drainage bags that are available both with and without an anti-reflux valve and a drain port in the bottom of the bag. Both the current and modified Hermetic Plus™ systems include needleless access sites and stopcocks to permit CSF sampling and attachment of fluid filled transducers for intracranial pressure (ICP) monitoring.

An antimicrobial vent is included in the burette cap of both the modified and the unmodified systems. This antimicrobial vent allows air to enter the burette to facilitate drainage from the burette to the drainage bag while protecting the system from microbial contamination. The antimicrobial vent used on the current Hermetic Plus™ system is being replaced with a vent that will better resist occlusion after contact with CSF. The current vent requires that the slider clamp (Vent Tube Lock) supplied on the burette vent

¹ Velcro® is a registered trademark of Velcro Industries, LLC.

tube be closed prior to transport of the patient to prevent CSF from contacting the antimicrobial vent. The Vent Tube Lock must then be opened after patient transport to re-establish CSF drainage. To eliminate the need for the slider clamp on the burette tubing, the housing of the vent has been enlarged and a hydrophobic antimicrobial filter media composed of (b)(4) materials

To assure that the Hermetic Plus™ External Drainage System is safe when used in an MR environment, the (b)(4) materials portion of the Safety Locking Knob is being replaced with a (b)(4) materials and the current cord lock on the suspension cord is being changed to a totally (b)(4) materials.

The Hermetic Plus™ External CSF Drainage System will continue to be sterilized to a (b)(4) sterilization using the existing validated (b)(4) sterilization sterilization cycle. Determination of bacterial endotoxins will continue to be performed using the Gel-Clot Limulus Amebocyte Lysate (LAL) method previously validated by Integra NeuroSciences PR, Inc. The pass/fail criteria for pyrogen testing for the Hermetic Plus™ system is equal to or less than 0.06 EU/ml. The Hermetic Plus™ External CSF Drainage System will be packaged in the same packaging as the currently marketed systems.

A photograph of the Hermetic Plus™ External CSF Drainage System and product drawing are provided in **Appendix D** and **Appendix E** respectively.

VIII. SUBSTANTIAL EQUIVALENCE

The modified Hermetic Plus™ External CSF Drainage System is substantially equivalent in function and intended use to the currently marketed Hermetic Plus™ system and the unmodified External Drainage Management System (Configuration B).

The modified Hermetic Plus™ External CSF Drainage System differs from the unmodified External CSF Drainage Management System in the following manner:

MRI Safety Testing

Magnetic Resonance Imaging (MRI) scanning has become a commonly used diagnostic tool which can be especially useful when images of the brain are needed. This is due to its ability to distinguish between white and gray matter of the brain and because Magnetic Resonance (MR) images are unobstructed by bone.² There are no claims regarding MRI safety made for the unmodified Hermetic Plus™ system. Since use of MR imaging has become so commonly used, testing has been performed on the modified Hermetic Plus™ system to assure that the modified Hermetic Plus™ system is MRI safe when tested in a MR environment. MRI Safety is defined as, "The device, when used in the MRI environment, has been demonstrated to present no additional risk to the patient or other individuals, but may affect the quality of the diagnostic information."²

The currently marketed Hermetic Plus™ was evaluated to determine if any components of the system contain ferrous metal materials that could possibly be attracted by the strong magnetic field of a MR scanner. The screw and nut components of the Safety Locking Knob, the cord lock of the suspension cord, and the leveling device accessory were identified as potential sources of Magnetic Resonance incompatibility. The

² *A Primer on Medical Device Interactions with Magnetic Resonance Imaging Systems*, Draft Document, CDRH Magnetic Resonance Working Group, February 7, 1997.

Integra NeuroSciences
 Special 510(k): Device Modification
 Hermetic Plus™ External CSF Drainage Systems

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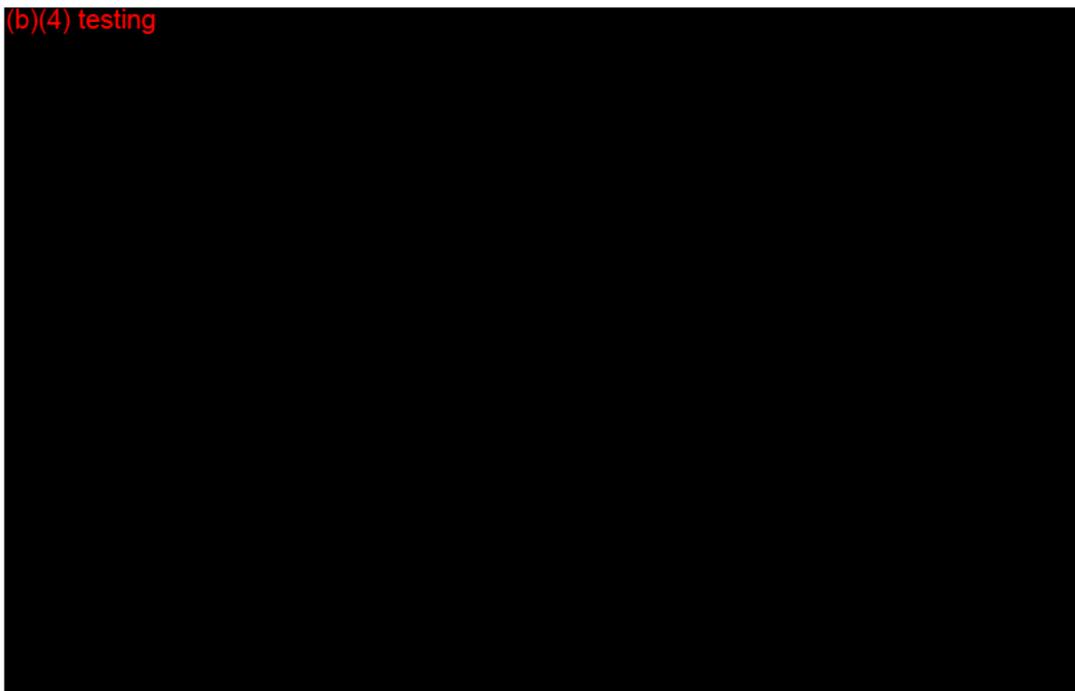
identified components were tested for MRI safety. Please note, there have been no adverse events reported relative to the use of the Hermetic Plus™ System in a MR environment.

Testing was performed with the current Hermetic Plus™ system containing the (b) (b)(4) materials component of the Safety Locking Knob, as well as the cord lock containing a (b) spring. The components identified above were tested for deflection and heating in a MR environment. Testing was also performed to determine if the level of the graduated burette could change in the magnetic field causing the drainage system to operate in a manner other than intended.

A (b)(4) version of the screw component was also tested. All tests were conducted in the "worst-case" MRI environment that could be generated in a commercial (b)(4) (b)(4) testing. While the (b) (b)(4) and (b) combination exhibited acceptable heating test results and the assembled screw and nut together did not exhibit movement of the burette chamber while in the MR field, deflection of greater than 45 degrees was seen with the individual steel screw component. It was determined that the (b)(4) screw be used along with the (b) (b) since there was no displacement seen with the (b)(4) materials and only a small amount of deflection (between (b)(4) degrees) was seen with the (b)(4). Additionally, the cord lock was replaced with one made entirely of (b)(4) (b)(4) materials. Heating and deflection testing of the leveling device was also performed. The acceptable heating and deflection results obtained support the use of the leveling device in the defined MR environment.

Further deflection and heating testing confirmed that the modified Hermetic Plus™ External CSF Drainage System containing the (b)(4) screw and (b)(4) nut component of the Safety Locking Knob, the all (b)(4) cord lock, and the leveling device was MRI safe² when tested in the following MR environment:

(b)(4) testing



²A Primer on Medical Device Interactions with Magnetic Resonance Imaging Systems, Draft Document, CDRH Magnetic Resonance Working Group, February 7, 1997.

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 Special 510(k): Device Modification
 Hermetic Plus™ External CSF Drainage Systems

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(b)(4) testing

A copy of the test report which includes MRI safety testing of the modified Hermetic Plus™ System is provided in **Appendix F**.

A label has been added to the support panel of the modified Hermetic™ Plus system and the Instructions for Use have been updated to reflect that the device has been demonstrated to present no additional risk to the patient or other users when used in the described MR environment. A copy of the draft label and Instruction For Use are provided in **Appendix A**.

Change to (b)(4) materials (component of the Safety Locking Knob)

Testing was performed to assure that the Safety Locking Knob with the (b)(4) materials and the (b)(4) is capable of holding the sliding panel in its desired position during use. No slippage of the sliding panel was observed when tested over a period of (b) days. The results also showed that the sliding panel is capable of holding a weight of (b) grams which is greater than that expected during use when the graduated burette is completely filled.

Change to an all (b)(4) materials

Testing of the new (b)(4) materials cord lock on the suspension cord was performed which showed that the cord lock could be opened and closed by a compression force equal to or less than (b) pounds, which is equivalent to the force on the current cord lock. Testing also showed that the cord lock when suspended by the two (b) inch cords was capable of holding the weight of the system with a filled graduated (b) burette and a filled drainage bag.

Antimicrobial Vent

Both the current and modified Hermetic Plus™ External CSF Drainage Systems contain an antimicrobial vent. The filter media used in the current antimicrobial vent is made of (b)(4) which is an (b)(4) materials. The Hermetic Plus™ system will now incorporate an antimicrobial vent composed of a (b)(4) materials. The new (b)(4) media has been qualified by the vendor as an antimicrobial barrier using an aerosol challenge method. The (b)(4) media was subjected to an (b)(4) testing with (b)(4) testing.

The design and materials of the antimicrobial vent have been modified to further resist occlusion by CSF in the event that the system is laid down during patient transport without first emptying the burette. This modification eliminates the need for the slider clamp (Vent Tube Lock) on the burette vent tube. The (b)(4) material was chosen as the antimicrobial media for the vent due to its ability to resist occlusion while allowing increased airflow, and its history of use in other medical devices. The same antimicrobial

vent using the (b)(4) materials is used in Integra NeuroSciences, MoniTorr ICP™ External CSF Drainage and Monitoring System (K022554) and for other medical applications such as transducer protection, moisture barriers, small volume venting, sterile air/gas delivery, pump protection, and as hydrophobic barriers. Other examples of filters that are available with (b)(4) filter media are the Intervene™ Filters manufactured by Pall Medical, and the medical filter line manufactured by Performance Systematrix (PSI). Literature on the Intervene™ filters and the PSI filters is provided in **Appendix G**.

The housing design of the new antimicrobial vent reduces the probability of fluid entering the vent while allowing sufficient air to enter the system, thus improving the drainage of CSF from the burette. Testing has shown that even under worst case conditions where fluid with high protein levels is in contact with the antimicrobial media for up to 30 minutes, the system drained faster than drainage systems with the current antimicrobial vent. A copy of the verification testing report is provided in **Appendix H**.

Change in Type of Needleless Sampling Sites

Both the unmodified External CSF Drainage Management System (Configuration B) system and the Hermetic Plus™ systems contain needleless access sites for sampling CSF. In place of the needleless sampling sites with the tethered cap described in the unmodified External CSF Drainage Management System (Configuration B), the Smart Site®³ needleless system (K960280) which does not require a cap, is being used in the modified Hermetic Plus™ system.

Needleless sites are designed to prevent needlestick injuries and subsequent exposure to infected fluids in compliance with the Needlestick Safety and Prevention Act, H.R.5178. The Smart Site® needleless system resists bacterial contamination through the valve by maintaining a closed system when not activated. The needleless valve is activated with any standard luer lock or luer slip syringe. The valve opens when a luer end is inserted into the valve and reseals when removed, thus preventing fluid flow after sampling the CSF. The flush, flat top of the needleless sampling site facilitates swabbing for disinfection. The Smart Site® needleless systems are also used on Integra NeuroSciences MoniTorr ICP™ External CSF Drainage and Monitoring System (K022554).

To aid in the identification of the needleless sampling site, the modified Hermetic Plus™ system will be labeled with yellow CSF Access labels placed on the patient line on either side of the needleless site.

Mount Transducer Port on Support Panel

Both the Hermetic Plus™ system and the unmodified External CSF Drainage Management System (Configuration B) contain a transducer port (stopcock) in the patient line. In the Hermetic Plus™ system, this stopcock was mounted on the support panel to facilitate the placement of a fluid filled transducer at the system zero reference that is now labeled in red.

³SmartSite® is a registered trademark of ALARIS Medical Systems, Inc.

Leveling Device Accessory

A leveling device is supplied as a convenience item with the Hermetic Plus™ systems to assist the healthcare professional in leveling the zero reference of the drainage system to the patient's Foramen of Monro or the exit level of the lumbar catheter. The leveling device supplied with the Hermetic Plus™ system, known as a line level, contains a bubble level in an (b)(4) materials. The level may be attached to the slit provided in the support panel of the Hermetic Plus™ system.

There have been no changes in the basic design, the intended use, or sterility assurance level of the device. The Instructions for Use have been revised to reflect the changes described above.

A feature comparison chart between the modified Hermetic™ Plus External CSF Drainage System and the predicate device, the unmodified External CSF Drainage Management System (Configuration B) (K972994) is presented in Table 1.

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 Special 510(k): Device Modification
 Hermetic Plus™ External CSF Drainage Systems

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Table 1: Feature Comparison Chart

Feature	Modified Hermetic™ Plus External CSF Drainage System	Predicate External CSF Drainage Management system (Configuration B) K972994
Intended Use	Drainage and monitoring of cerebrospinal fluid (CSF) flow from the lateral ventricles of the brain or lumbar subarachnoid space in selected patients	Same
Incorporates the same basic design and utilizes the same operating principle	Drains CSF externally to a drainage bag	Same
	Luer connection to external ventricular or lumbar catheters	Same
	Closed system vented with hydrophobic microbiological barrier filter	Same
	Panel mounted system with a sliding panel secured by a Safety Locking Knob	Same
	50 ml graduated burette mounted on a sliding panel	Same
	700ml graduated drainage bag with or without anti reflux valve and drain port in the bottom of the bag	700ml graduated drainage bag
	Red Marker at zero reference on sliding panel	Clear marker at zero reference on sliding panel
	Needleless sites for sampling CSF included.	Same
	Transducer stopcock integral to the patient line and mounted on the support panel at the zero reference mark	Transducer stopcock integral to patient line, not mounted onto support panel
	CSF access site on the patient line is identified by yellow labels on either side of the access site	CSF access site not labeled
	Two methods of secure attachment to the IV pole (Suspension Cord with cord lock and Velcro® straps) provided	Same
Supplied with a leveling device	No leveling device supplied	
Performance Specifications	MRI Safe ²	No claims made
Materials	Antimicrobial vent consists of (b) media in a (b)(4) which does not require clamping during patient transport	Antimicrobial vent consists of an (b)(4) testing on a (b)(4) testing support in an (b)(4) testing which requires clamping during patient transport
	Safety Locking Knob with a (b)(4) and (b)(4) materials	Safety Locking Knob with at (b)(4) materials (b)(4)
	Cord lock composed of (b)(4) materials (b))	Cord lock composed of (b)(4) (b)(4) mat (b)(4) materials

²A Primer on Medical Device Interactions with Magnetic Resonance Imaging Systems, Draft Document, CDRH Magnetic Resonance Working Group, February 7, 1997.

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 Hermetic Plus™ External CSF Drainage Systems

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Sterilization Process / Sterility Assurance Level (SAL)	(b)(4) [redacted]	(b)(4) [redacted]
Biocompatible	Yes	Yes
Non-pyrogenic	Yes	Yes
Packaging	Packaged in a mylar/Tyvek pouch and an outer cardboard box	Same

In summary, the modified Hermetic Plus™ External CSF Drainage System, which is described in this submission, is substantially equivalent to the current Hermetic Plus™ External CSF Drainage System and the unmodified External CSF Drainage Management System (Configuration B) (K972994).

IX. 510(K) SUMMARY

As required by the Safe Medical Device Act of 1990, Section 513(i)(3)(A), a Premarket Notification 510(k) Summary for the Hermetic Plus™ External CSF Drainage System is included in **Appendix I**.

X. LITERATURE REFERENCES

The following references supporting the use of the PTFE antimicrobial media and the Smart Site™ needleless sampling sites have been included in **Appendix J**.

1. Alter, Jason M., Ph.D., *Hydrophobic Through and Not Through*, Industrial Design & Development, January 1998.
2. Rogers, W., Fitzgerald, E., RN, BSN, *Contamination and Decontamination Study For The IVAC® SmartSite™ Needleless System*, ALARIS™ Medical Systems.
3. Leising, K., PE, Fitzgerald, E., RN, BSN, *Chemical Compatibility and The Alaris™ Medical Systems SmartSite™ Needleless Valve*, ALARIS™ Medical Systems, 1998.

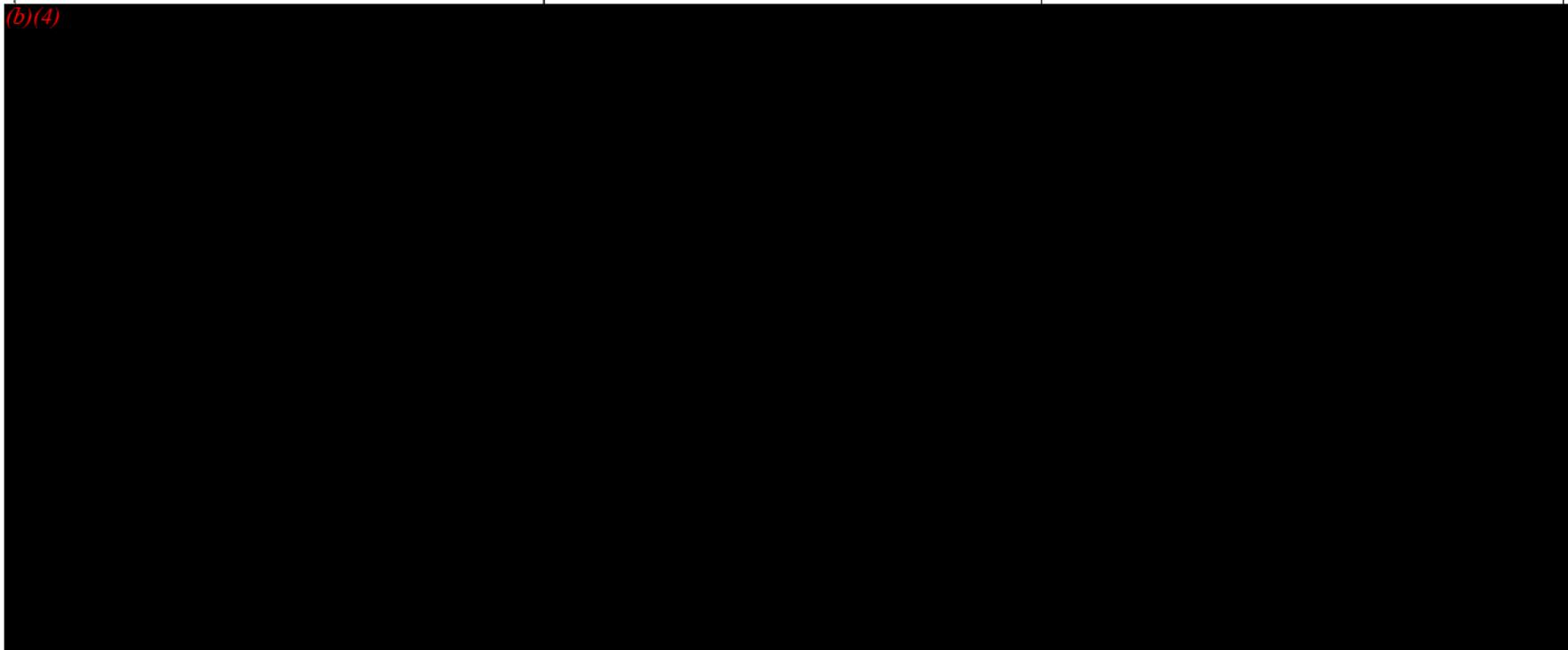
XI. SUMMARY OF DESIGN CONTROL ACTIVITIES

(b)(4) testing [redacted]

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Special 510(k): Device Modification
Hermetic Plus™ External CSF Drainage System

Table 2: Verification Tests

Modifications	Test Performed	Acceptance Criteria
<i>(b)(4)</i> 		

40

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(b)(4)

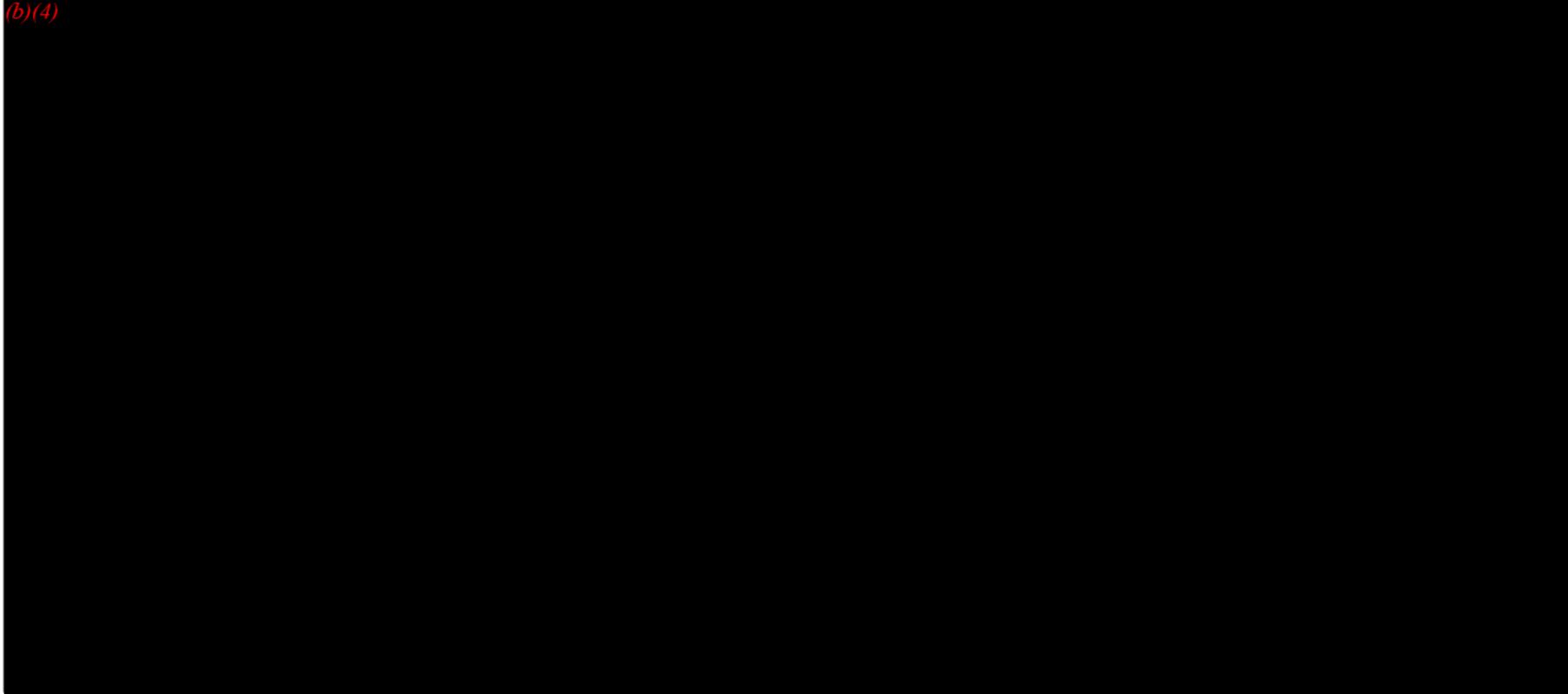


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(b)(4)



Verification and validation activities, as identified by the risk analysis, for the modifications were performed. **A Declaration of Conformity with Design Controls** is provided in **Appendix K**.

XII. CONCLUSION

The modified Hermetic Plus™ External CSF Drainage System is substantially equivalent to the current Hermetic Plus™ External CSF Drainage System and the unmodified External CSF Drainage Management System (Configuration B). The modifications, as described in this submission, do not affect the intended use, the fundamental scientific technology of the device, and do not raise new issues of safety and effectiveness.

43

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Special 510(k): Device Modification
Hermetic Plus™ External CSF Drainage System

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XIII. TRUTHFUL AND ACCURATE STATEMENT

I, Donna R. Wallace, hereby certify, that to the best of my knowledge, as Director of Regulatory Affairs for Integra LifeSciences Corporation, that all data and information submitted in this Premarket Notification for the Hermetic Plus™ External CSF Drainage System is truthful and accurate and that no material fact has been omitted.

Signature Donna R. Wallace Date January 27, 2003
Donna R. Wallace
Director, Regulatory Affairs

44

REF INS-8301

LOT

DRAFT LABELING



Hermetic Plus™ External CSF Drainage System with Anti-Reflex Valve and Needleless Injection Sites
Système de drainage LCR externe Hermetic Plus™ avec valve anti-reflux et sites d'injection sans aiguille
Hermetic Plus™ Externes Liquor-Drainagesystem mit Antirefluxventil und kanülenlosen Injektionsstellen
Sistema di drenaggio del fluido cerebrospinale esterno Hermetic Plus™ con valvola antiriflusso e siti di iniezione senza ago
Sistema Hermetic Plus™ de drenaje externo de LCR con válvula antirreflujo y sitios de inyección sin aguja

STERILE EO



STERILE EO

REF INS-8301

Hermetic Plus™ External CSF Drainage System with Anti-Reflex Valve and Needleless Injection Sites

Contains: One Hermetic Plus External CSF Drainage System with Anti-Reflex Valve and Needleless Injection Sites: 700ml drainage bag, 50ml burette, 130cm green striped tubing line with anti-reflux valve and needleless injection sites, pole mounted support panel. One leveling device (supplied non-sterile).

Contient : un système de drainage LCR externe Hermetic Plus avec valve anti-reflux et sites d'injection sans aiguille : poche de drainage 700 ml ; burette 50 ml ; tubulure verte rayée 130 cm avec valve anti-reflux et sites d'injection sans aiguille ; panneau de soutien pour montage sur pied. Un dispositif de nivellement (fourni non stérile).

Read entire product insert prior to use. Sterile for single use only.

Lire l'intégralité de la notice du produit avant utilisation. Stérile et à usage unique.

Inhalt: Ein Hermetic Plus Externes Liquor-Drainagesystem mit Antirefluxventil und kanülenlosen Injektionsstellen: Drainagebeutel (700 ml), Burette (50 ml), grün gestreifter Schlauch (130 cm) mit Antirefluxventil und kanülenlosen Injektionsstellen, Stützplatte zur Stangenmontierung. Eine Nivelliervorrichtung (nicht-steril beigelegt).

Contiene: un sistema di drenaggio del fluido cerebrospinale esterno Hermetic Plus con valvola antiriflusso e siti di iniezione senza ago: sacca di drenaggio da 700ml, buretta da 50ml, tubo a righe verdi da 130cm con valvola antiriflusso e siti di iniezione senza ago, pannello di supporto montato su stativo. Un dispositivo di livellazione (fornito non sterile).

Vor Gebrauch das gesamte Beipackblatt lesen. Steril nur zum einmaligen Gebrauch.

Leggere l'intero foglietto illustrativo prima dell'uso. Sterile ed esclusivamente monouso.

Contiene: Un Sistema Hermetic Plus de drenaje externo de LCR con válvula antirreflujo y sitios de inyección sin aguja; bolsa de drenaje de 700ml; bureta de 50ml; tubo de 130cm con rayas verdes, válvulas antirreflujo y sitios de inyección sin aguja; panel protector montado en soporte. Un dispositivo nivelador (provisto sin esterilizar).

Lea todo el folleto informativo antes de usar el producto. Estéril para un solo uso.

DO NOT USE IF PACKAGE HAS BEEN OPENED OR DAMAGED.
 NE PAS UTILISER SI L'EMBALLAGE A ÉTÉ OUVERT OU ENDOMMAGÉ
 NICHT VERWENDEN, WENN PACKUNG GEÖFFNET ODER BESCHÄDIGT IST
 NON USARE SE LA CONFEZIONE È APERTA O DANNEGGIATA
 NO LO USE SI EL ENVASE ESTÁ ABIERTO O DAÑADO.

NOT RE-STERILIZABLE IF OPENED.
 NE PAS UTILISER LE MÉDICAMENT SI L'EMBALLAGE A ÉTÉ OUVERT
 GEÖFFNETES PACKUNG WIRD NICHT ZURÜCKGENOMMEN
 NON RESI RIFILIBILE UNA VOLTA APERTO
 NO RETORNABLE SI ESTÁ ABIERTO.

STERILE EO



STERILE AND NON-PYROGENIC UNLESS DAMAGED OR OPEN.
 STÉRILE ET APYROGÈNE, UNQUEMENT SI L'EMBALLAGE N'EST PAS OUVERT OU ENDOMMAGÉ.
 STERIL USE PROZEDURE. WENN UNBESCHÄDIGT ODER UNGEÖFFNET.
 STERILE E APPOGGIO A MENO CHE NON SIA DANNEGGIATO O APERTO.
 ESTERIL Y APROGADO A MENOS QUE ESTE DAÑADO O ABIERTO.

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
 Attention: Selon la Loi Médicale américaine, ce dispositif ne peut être vendu que par un médecin ou sur son ordonnance.
 Vorsicht: Das Bundesgesetz über den Verkauf von Medizinprodukten für die Anwendung oder im Auftrag eines Arztes.
 Attenzione: la legge federale (USA) limita la vendita di questo apparecchio a un medico o a detto prescrizione medica.
 Precaución: La ley federal de U.S. permite que la venta de este producto sólo sea efectuada por un médico o bajo su prescripción facultativa.

Integra NeuroSciences Plainsboro, NJ 08536 USA

10019-701-04

A001

45

REF INS-8302

LOT



DRAFT LABELING

Hermetic Plus™ External CSF Drainage System with Needleless Injection Sites

Système de drainage LCR externe Hermetic Plus™ avec sites d'injection sans aiguille

Hermetic Plus™ Externes Liquor-Drainagesystem mit kanülenlosen Injektionsstellen

Sistema di drenaggio del fluido cerebrospinale esterno Hermetic Plus™ con siti di iniezione senza ago

Sistema Hermetic Plus™ de drenaje externo de LCR con sitios de inyección sin aguja

STERILE EO



STERILE EO

REF INS-8302 **Hermetic Plus™ External CSF Drainage System with Needleless Injection Sites**

Contains: One Hermetic Plus External CSF Drainage System with Needleless Injection Sites: 700ml drainage bag, 50ml burette, 150cm green striped tubing line with needleless injection sites, pole mounted support panel. One leveling device (supplied non-sterile).

Read entire product insert prior to use. Sterile for single use only.

Contient : un système de drainage LCR externe Hermetic Plus avec sites d'injection sans aiguille : poche de drainage 700 ml ; burette 50 ml ; tubulure verte rayée 150 cm avec sites d'injection sans aiguille ; panneau de soutien pour montage sur pied. Un dispositif de nivellement (fourni non stérile).

Lire l'intégralité de la notice du produit avant utilisation. Stérile et à usage unique.

Inhalt: Ein Hermetic Plus Externes Liquor-Drainagesystem mit kanülenlosen Injektionsstellen: Drainagebeutel (700 ml), Burette (50 ml), grün gestreifter Schlauch (150 cm) mit kanülenlosen Injektionsstellen, Stützplatte zur Stangenmontierung. Eine Nivelliervorrichtung (nicht-steril beigelegt).

Vor Gebrauch das gesamte Beipackblatt lesen. Steril nur zum einmaligen Gebrauch.

Contiene: un sistema di drenaggio del fluido cerebrospinale esterno Hermetic Plus con siti di iniezione senza ago: sacca di drenaggio da 700ml, buretta da 50ml, tubo a righe verdi da 150cm con siti di iniezione senza ago, pannello di supporto montato su stativo. Un dispositivo di livellazione (fornito non sterile).

Leggere l'intero foglietto illustrativo prima dell'uso. Sterile ed esclusivamente monouso.

Contiene: Un Sistema Hermetic Plus de drenaje externo de LCR con sitios de inyección sin aguja: bolsa de drenaje de 700ml; bureta de 50ml; tubo de 150cm con rayas verdes y sitios de inyección sin aguja; panel protector montado en soporte. Un dispositivo nivelador (provisto sin esterilizar).

Lea todo el folleto informativo antes de usar el producto. Estéril para un solo uso.

DO NOT USE IF PACKAGE HAS BEEN OPENED OR DAMAGED. NE PAS UTILISER SI L'EMBALLAGE A ETE OUVERT OU ENDOMMAGE. NICHT VERWENDEN, WENN PACKUNG GEÖFFNET ODER BESCHÄDIGT IST. NON USARE SE LA CONFEZIONE È APERTA O DANNEGGIATA. NO LO USE SI EL ENVASE ESTÁ ABIERTO O DAÑADO.

NOT RETURNABLE IF OPENED. NE PEUT ÊTRE RENVOYÉ SI OUVERT. GEÖFFNETE PACKUNG WIRD NICHT ZURÜCKGENOMMEN. NON RESTITUIBILE UNA VOLTA APERTO. NO RETORNABLE SI ESTÁ ABIERTO.

STERILE EO



STERILE AND NON-PYROGENIC UNLESS DAMAGED OR OPEN. STÉRILE ET APYRÉNOGÈNE, UNMOUÏNEMENT SI L'EMBALLAGE N'EST PAS OUVERT OU ENDOMMAGÉ. STERIL UND PYROGENFREI, WENN UNBESCHÄDIGT ODER LANGGEÖFFNET. STERILE E APYROGENO A MENO CHE NON SIA DANNEGGIATO O APERTO. ESTÉRIL Y APIRÓGENO A MENOS QUE ESTÉ DAÑADO O ABIERTO.

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician. Attention: Selon la Loi fédérale américaine, ce dispositif ne peut être vendu que par un médecin ou sur son ordre. Voricht: Das Bundesgesetz der USA erlaubt den Verkauf dieses Produktes nur auf Anordnung oder im Auftrag eines Arztes. Attenzione: In legge federale (USA) limita la vendita di questo apparecchio a un medico o dietro prescrizione medica. Precaución: La ley federal (E.U.A.) permite que se venda de este producto sólo por el médico o bajo su prescripción recetativa.

Integra NeuroSciences Plainsboro, NJ 08536 USA

10019-702-04

A002

46

DRAFT LABELING

REF INS-8302

Quantity 1

 **INTEGRA
NEUROSCIENCES™**

Hermetic Plus™

External CSF Drainage System with
Needleless Injection Sites

STERILE EO

Contains: One Hermetic Plus External CSF Drainage System with Needleless Injection Sites: 700ml drainage bag, 50ml burette, 150cm green striped tubing line with needleless injection sites, pole mounted support panel.

Read entire product insert prior to use. **Sterile for single use only.**



Caution: Federal (USA) law restricts this device to sale by or on the order of a physician. Sterile and non-pyrogenic unless damaged or opened. Do not use if package has been opened or damaged. NOT RETURNABLE IF OPENED.

Integra NeuroSciences
Plainsboro, NJ 08536 USA

10018-702-03

A003

47

DRAFT LABELING

REF INS-8301

Quantity 1



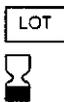
Hermetic Plus™

External CSF Drainage System with
Anti-Reflux Valve and Needleless Injection Sites

STERILE EO

Contains: One Hermetic Plus External CSF Drainage System with Anti-Reflux Valve and Needleless injection Sites: 700ml drainage bag, 50ml burette, 130cm green striped tubing line with anti-reflux valve, needleless injection sites, pole mounted support panel.

Read entire product insert prior to use. **Sterile for single use only.**



Caution: Federal (USA) law restricts this device to sale by or on the order of a physician. Sterile and non-pyrogenic unless damaged or opened. Do not use if package has been opened or damaged. NOT RETURNABLE IF OPENED.

Integra NeuroSciences
Plainsboro, NJ 08536 USA

10018-701-04

48



Hermetic Plus™ External CSF Drainage Systems

Sterile For Single Use Only



REF INS-8301
REF INS-8700

REF INS-8302
REF NL850-8305N

Description

The Hermetic Plus External CSF Drainage Systems provides a sterile fluid path resistant to microbial particles. The systems are used to drain cerebrospinal fluid (CSF) from the ventricles of the brain or the lumbar subarachnoid space to a drainage bag. System components facilitate CSF drainage, fluid injection, CSF sampling and Intracranial Pressure (ICP) monitoring.

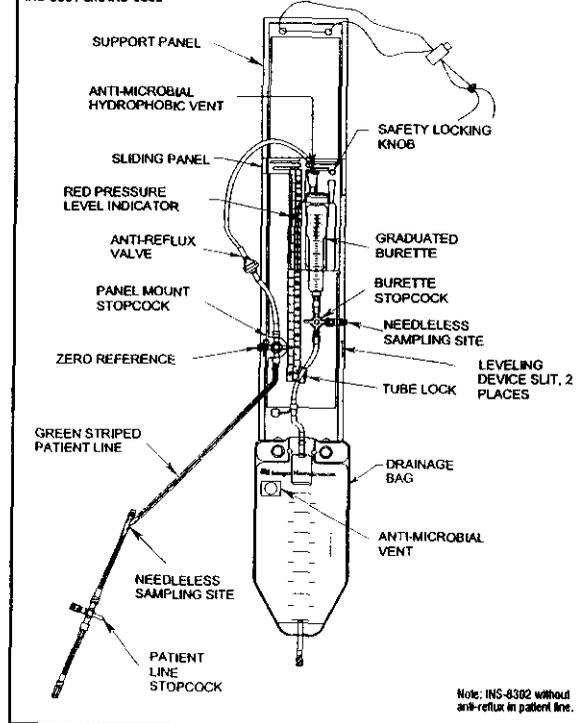
Common features to each system include a calibrated 50ml graduated burette, 700ml drainage bag, anti-microbial hydrophobic vent, two sampling aspiration sites, a patient stopcock, a four-way high flow burette stopcock, dual hole planar cord suspension, sight window for referencing the pressure scale and an integral pole mounting support panel.

The graduated burette enables visualization of the CSF flow, clarity and volumetric readings to be made prior to fluid entering the drainage bag.

The Hermetic Plus External CSF Drainage Systems can be used with all of the Integra NeuroSciences ventricular and lumbar catheters. A tubing connector with luer fitting is provided.

A fluid filled ICP monitoring transducer can be attached to the red end capped port of the patient stopcock or panel stopcock for catalogs INS-8301 and the INS-8302. If monitoring is not used, it is imperative to keep the red end capped port securely tightened.

Figure 1. Hermetic Plus System Components INS-8301 and INS-8302



10020-702-03

49

Use of this device in a MR environment has been demonstrated to present no additional risk to the patient or other users. Refer to Figure 2 for information on the MR environment to which the device was tested.

Features and Benefits

The following features and benefits are common to each system.

- Closed integral system
- Integrated pressure scale from -5 to +28 cmH₂O and -3 to +20mmHg
- 4-1/2" support panel width for easy single hand panel manipulations
- Large suspension cord locking mechanism for easy manipulation of system height
- Velcro® pole mount for more secure attachment
- The pole mount forms are compatible with standard IV poles with pole diameters ranging from 3/4" to 1-1/8"
- Sight window on sliding panel to reference pressure scales
- 50ml graduated burette with large bore full radius outlet designed to resist clogging
- Anti-microbial hydrophobic vent
- Line level device can be attached to Zero Reference on panel
- Removable 700ml drainage bag with anti-reflux valve and drain tube
- Luer connector in sterile pack included for catheter connection
- CSF access port labeled
- This device is MR safe* when used in the MR environment described in Figure 2.

* MRI safe is defined by the CDRH Magnetic Resonance Working Group (Feb 7, 1997) draft document A Primer on Medical Device Interactions with MRI Systems as "The device, when used in the MRI environment, has been demonstrated to present no additional risk to the patient or other individuals, but may affect the quality of the diagnostic information". Data on file at Integra NeuroSciences.

Hermetic Plus INS-8301

- Patient line is green striped pressure monitoring tubing

- Needleless sampling site at patient and burette stopcocks
- Red end capped panel mount stopcock at Zero Reference on panel for connection of fluid filled pressure transducer
- Low pressure anti-reflux valve distal to panel mount stopcock in patient line
- Red pressure level indicator

Hermetic Plus INS-8302

- Patient line is green striped pressure monitoring tubing
- Needleless sampling site at patient and burette stopcocks
- Red end capped panel mount stopcock at Zero Reference on panel for connection of fluid filled pressure transducer
- No anti-reflux valve in patient line
- Red pressure level indicator

Indications

Draining and monitoring of Cerebrospinal Fluid (CSF) flow from the lateral ventricles of the brain or lumbar subarachnoid space is indicated in selected patients to:

- Reduce Intracranial Pressure (ICP)
- Monitor Intracranial Pressure (ICP)
- Monitor Cerebrospinal Fluid (CSF)
- Provide temporary CSF drainage for patients with infected hydrocephalic shunts

Monitoring of Intracranial Pressure (ICP) is usually performed in selected patients with:

- Severe head injury
- Subarachnoid hemorrhage
- Reyes syndrome or similar encephalopathies
- Hydrocephalus
- Intracranial hemorrhage
- Under physician supervision and discretion when drainage is to be used as a therapeutic maneuver

Monitoring can also be used to evaluate the status pre- and postoperatively for space-occupying lesions.

Contraindications

This device is not designed, sold, or intended for use except as indicated.

Lumbar drainage and/or lumbar pressure monitoring should not be used in the presence of: non-communicating hydrocephalus; a large intracranial mass, tumor or hematoma; and in patients who have demonstrated a blockage of cerebrospinal fluid pathways due to trauma, tumor, hematoma or other large intracranial mass.

Lumbar catheters are contraindicated in cases of spinal abnormalities that would prevent free insertion of the lumbar catheter.

Lumbar catheters are contraindicated in infants where the lower end of the spinal cord has not yet migrated to its cephalad L1-2 position.

In view of the marked narrowing of the lumbosacral canal in achondroplastic patients, a lumbar catheter in the subarachnoid space is contraindicated.

Warnings

Patients with cerebrospinal fluid drainage systems must be kept under close observation for signs and symptoms of changing intracranial pressure due to shunt failure. These signs and symptoms may vary from patient to patient. Increasing intracranial pressure is characterized by headache, vomiting, irritability, listlessness, drowsiness, other signs of deterioration of consciousness and nuchal rigidity. In the infant, increased scalp tension at the anterior fontanelle and congestion of scalp veins will be noted.

Failure to appropriately adjust the rate of CSF outflow through the external drainage system may result in potentially serious injury to the patient. Improper drainage system setup can lead to overdrainage or underdrainage and potentially serious injury to the patient.

Proper placement of the drainage system is critical. The one-way valve is designed to prevent reflux; it is not a pressure-regulating device. Intracranial pressure is controlled only by the height of the drainage system. It is essential that neither the patient nor the drainage system be raised or lowered accidentally. Height changes should only be made by qualified personnel on the orders of the physician.

50

It is possible that the puncture of the ventricle or the opening of the dura will result in an intracranial hemorrhage. It is possible that if too much CSF is removed from the ventricles, either during a drainage procedure or when the ventricle is first punctured, the ventricle may collapse and occlude the catheter.

It is possible that the monitoring system may give a false pressure reading either due to a pressure line becoming clogged or kinked or from an air bubble lodged in the system. An incorrect pressure reading may lead to the wrong therapy being given to the patient.

In order to minimize the possibility of infection, meningitis or ventriculitis, the sampling site should be cleaned according to hospital protocol prior to use. Sterile technique should be observed in setting up the system and in the placement of the catheter.

This product has not been tested for drug compatibility and therefore is not intended for drug administration.

Precautions

Prior to surgery, prospective patients or their representatives should be informed of the possible complications associated with this product.

Do not insert a needle directly into the needleless sampling site.

Integra NeuroSciences makes no claim for or representation as to the performance characteristics of this product if it is used in conjunction with components of other manufacturers.

Complications

Complications which may result from the use of this product include the risks associated with the medications and methods utilized in the surgical procedure, as well as the patient's degree of intolerance to any foreign object implanted in the body.

The principal complications associated with cerebrospinal fluid drainage are infection, catheter obstruction, or intracranial hypotension/hypertension.

Ventricular catheters may migrate into the lateral ventricles. Lumbar catheters may migrate into the subarachnoid space.

The presence of a foreign body (i.e. the catheter system) may trigger ventriculitis or a dormant meningitis. Infection is a common and serious

complication of a drainage system and is most frequently caused by skin contaminants. The incidence of these infections can be reduced by care in inserting the ventricular catheter and stabilizing it by passing it through a subgaleal tunnel before it emerges. The lumbar catheter should be stabilized by suture collars. Wound infections may occur but usually subside when the catheter is removed. Septicemia, which occurs most frequently in debilitated infants, can result from infections anywhere in the body and may develop with few or no symptoms. It may occur as a result of a wound infection.

Lesions developing from the breakdown of skin or tissue over the drainage system may also serve as foci of serious infections. In the event of an infection, replacement of the drainage system is indicated in addition to the appropriate therapy.

Ventricular or lumbar catheters may be obstructed by particulate matter such as blood clots, fibrin, or brain fragments. If not properly located in the lateral ventricle, the ventricular catheter may become embedded in the ventricular wall or choroid plexus. Less commonly, the catheter may be obstructed by the excessive reduction of ventricular size to slit-like proportions.

Excessive lowering of intracranial pressure may result in complications, particularly in the infant. Complications for infants can include subdural hematomas, markedly sunken fontanelles, over-riding of cranial bones and conversion of a communicating to a noncommunicating hydrocephalus due to obstruction of the aqueducts of Sylvius.

Failure of the drainage system may be evidenced by continuing symptoms of increased ICP. Any failure of the system requires immediate replacement of the drainage system or the affected component.

Instructions for Use

Prior to system use, it is necessary for all responsible personnel to understand the use and function of the system components, system preparation, and system control.

Preparation and Alignment
Introduce and position the catheter. Placement of these catheters may be accomplished through a variety of

surgical techniques; therefore, the surgeon is best advised to use the method which his/her own practice and training dictate to be best for the patient. The system should be prepared under sterile conditions prior to the placement of ventricular or lumbar catheter.

The system should be filled with preservative free sterile normal saline prior to connecting to the patient. Caps may be temporarily loosened to allow air to escape. Check to ensure the absence of any residual air bubbles that may affect pressure transducer monitoring. Ensure that fluid flows from the burette to the drainage bag.

When the ICP monitoring port is not in use, the red end cap must be in place to help prevent contamination. Aseptically clean all injection sites according to hospital protocol before connecting a sterile syringe.

Suspend the support panel from the IV pole via the suspension cord and position the drainage system height via the cord lock. If connecting the panel directly to the IV pole, push the pole mount forms on the back of the support panel onto the IV pole then secure the velcro straps in place. The velcro straps should be securely tightened to prevent the support panel from slipping. Once the velcro straps are secured, tighten the suspension cord over the IV pole by moving the cord lock so that the suspension cord is taut. Ensure that the system has been properly mounted with the "0" point of the reference pressure scale leveled to the patient's Foramen of Monro. Attach line level to Zero Reference point.

System Calibration

Initial system calibration should be completed prior to connecting to the patient.

Instructions for transducer calibration should be followed from the transducer manufacturer.

To Set Pressure Head

Ensure that the Zero Reference is not placed below the patient's Foramen of Monro or below the level of exit of the lumbar catheter. Increase or decrease the height of the Pressure Level by moving the sliding panel relative to the patient to set the pressure head.

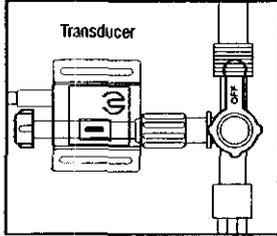
Align the top of the red pressure indicator with drainage level ordered

(mmHg or cmH₂O). Secure the burette sliding panel with the locking knob.

To Monitor Pressure

If accurate pressure monitoring is desired with pressure wave forms, the system should be temporarily closed to drainage to the graduated burette. Turn

To Monitor Pressure



off transducer stopcock with the OFF arm to stop flow to the burette.

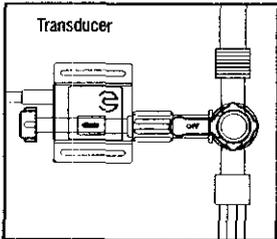
Note: CSF will not drain into the burette while the stopcock is in the monitoring only position.

To Drain CSF

Turn patient stopcock handle OFF to transducer to drain CSF. CSF will flow into the graduated burette.

The ICP is controlled by the height of the pressure level of the burette chamber above the tip of the catheters. It is critical that neither the patient nor the

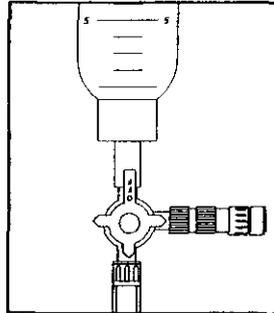
To Drain CSF



drainage system be raised or lowered accidentally. Height changes should only be made by qualified personnel on the orders of the physician.

To Collect and Measure CSF
Accurate determination of fluid accumulation may be accomplished

To Measure CSF Flow



with the graduated burette from 1 to 50 ml in 1 ml increments. The burette stopcock should be OFF to the burette.

To drain CSF from burette to the drainage bag, the stopcock should be OFF to the sample port.

To Sample CSF

Sampling of CSF may be accomplished at various injection sites that have been cleaned according to hospital protocol. The needleless site can be accessed with any standard luer fitting syringe. Access may be accomplished at the patient line stopcock or the Y-site immediately distal to the patient stopcock or beneath the burette. If CSF access is desired from the burette, use the injection site at the burette stopcock. Do not insert a needle directly into the needleless sampling site. In addition, CSF may be sampled from the drainage bag at the bottom injection site.

To Flush System

Injection sites that have been cleaned according to hospital protocol may be flushed. Orient the stopcocks to temporarily prevent flow back to the patient. Ensure and verify fluid flush into the drainage bag.

Once flushing has been accomplished, reorient stopcocks to allow flow from the patient to the burette and into the drainage bag.

To Replace Drainage Bag

Orient the burette stopcock to temporarily stop flow into the drainage

bag. Close clamp on drain tube. Using sterile handling technique, disconnect the drainage bag from the drain tube, attach tethered blue cap and detach bag from the system panel.

Using sterile handling technique, connect the sterile replacement drainage bag to drain tube. Attach bag to system panel.

Reorient burette stopcock to allow flow from the burette into the drainage bag. Open drain tube clamp. Verify flow into the drainage bag.

To Empty Drainage Bag

The drainage bag may be emptied with sterile handling technique by syringe access with a 25-gauge needle or luer syringe if SmartSite® needleless site on bag.

To Transport Patient

If it is necessary to transport a patient while system is in full use, the system should remain correctly aligned with the patient for desired pressure head and drainage.

If this is not possible, the graduated burette should be emptied into the drainage bag. The burette stopcock should then be temporarily closed to prevent retrograde flow of CSF from the drain tube into the burette. The panel mount stopcock on the INS-8301 and INS-8302 should be oriented to temporarily stop flow from the patient to the burette. The patient should then be transported as required.

After patient transport has been completed, system use should be re-established with correct reference relative to patient. All stopcocks should be reoriented to reestablish flow. Ensure and verify flow from the patient into the burette.

SD

Figure 2
MR environment to which the device was tested:

<u>Scan Parameters</u>	
Sequence	Fast Spin Echo
Plane	Sagittal
TR (sequence repetition rate)	9900
TE1 (echo delay time)	196 milliseconds (ms)
Echo Train Length	16
FLIP/TI (flip angle)	180°
TH/K, (slice thickness)	3 millimeters (mm)
Number of Slices	44
Distance between slices	0.2 millimeters (mm)
NEX (number of excitations)	4
FOV(Field of View)	24 x 24 centimeters (cm)
Static Magnetic Field Strength	1.5 Tesla (T)
Maximum Spatial Gradient	1 gauss/centimeter (G/cm)
Bandwidth	31.25 kilohertz (KHz)
Matrix	256
R1,R2	11,13
Transmit Gain	135
Coil Frequency	63.8 megahertz (MHz)
Coil RF Power Max	2 kilowatts (KW)
Max Estimated SAR (Specific Absorption Rate)	7.74 watt/kilogram (W/kg)

Determination of a product defect or mislabeling will be made by Integra NeuroSciences, which determination will be final.

Products will not be accepted for replacement if they have been in the possession of the customer for more than 90 days.

Product Order Information

All products can be ordered through your Integra NeuroSciences Neuro Specialist or customer service representative or by contacting:

Integra NeuroSciences
 311 Enterprise Drive
 Plainsboro, NJ 08536 USA
 Telephone: 1-800-654-2873
 Outside the US: 1-609-275-0500
 Fax: 609-275-5363

or

Integra NeuroSciences
 Newbury Road, Andover
 Hampshire SP10 4DR England
 Tel: +44(0) 1264-345-700
 Fax: +44 (0) 1264-332-113

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician. Do not use if the package has been opened or damaged.

Catalog Numbers

- INS-8301 Hermetic Plus External CSF Drainage System with Anti-Reflex Valve and Needleless Injection Sites
- INS-8302 Hermetic Plus External CSF Drainage System with Needleless Injection Sites
- INS-8700 Integra External CSF Drainage System Replacement Bags W/Drain Tube
- NL850-8305N Integra External CSF Drainage System Replacement Bags

Product Information Disclosure

Integra NeuroSciences has exercised reasonable care in the choice of materials and manufacture of this product. Integra NeuroSciences excludes all warranties, whether expressed or implied by operation of law or otherwise, including, but not limited to any implied warranties of merchantability or fitness for a particular purpose. Integra NeuroSciences shall not be liable for any incidental or consequential loss, damage, or expense, directly or indirectly arising from use of this product. Integra NeuroSciences neither assumes nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this device.

Special Order Products

If this product is a Special Order product as requested by a physician, there may be differences between the enclosed product and the product description in this brochure. These differences will not affect the safety or effectiveness of the special order product.

How Supplied

Integra NeuroSciences External CSF Drainage Systems are supplied sterile and non-pyrogenic in single wrap packaging.

Do Not Resterilize

All External CSF Drainage Systems are disposable devices. Integra NeuroSciences does not recommend resterilization of these products.

Returned Goods Policy

Products must be returned in unopened packages, with manufacturer's seals intact to be accepted for replacement or credit, unless returned due to a complaint of product defect or mislabeling.

53

Symbols Used On Labeling

	See instructions for use
	Expiration date
	Do not reuse after opening
	Lot number
	Sterile unless package is opened or damaged. Method of sterilization-ethylene oxide.

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Integra NeuroSciences
311 Enterprise Drive, Plainsboro, NJ 08536 USA

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Integra NeuroSciences External Drainage Systems are covered by US Patent number 5,772,625. Velcro® is a registered trademark of Velcro Industries, LLC

54

Draft Labeling

**Hermetic Plus™ External CSF Drainage System
MRI Safety Panel Label**

This device, when used in a MR (Magnetic Resonance) environment, has been demonstrated to present no additional risk to the patient or other users. Tested in a Static Magnetic Field Strength: 1.5 Tesla, Maximum Spatial Gradient: 1G/cm (shielded magnet), and a Maximum RF Transmitter Power: 2KW @ 64 MHz.

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55

DOC. CONTROL ORIGINAL

DOC. CONTROL ORIGINAL



Hermetic Plus™ and Hermetic II™ External CSF Drainage Systems

Sterile For Single Use Only



REF INS-8300
REF INS-8302

REF INS-8301
REF INS-8700

STERILE EO

Description

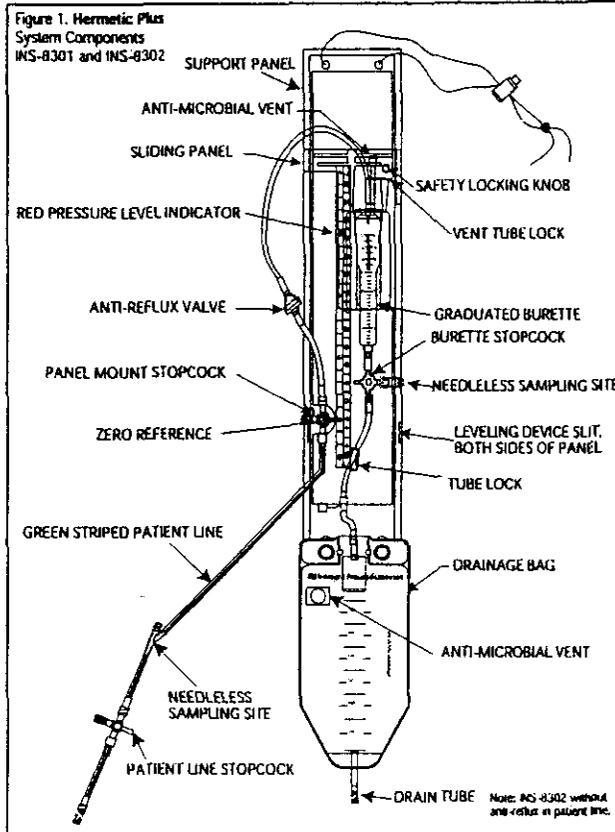
The Hermetic Plus and Hermetic II External CSF Drainage Systems provide a sterile fluid path resistant to microbial particles. The systems are used to drain cerebrospinal fluid (CSF) from the ventricles of the brain or the lumbar subarachnoid space to a drainage bag. System components facilitate CSF drainage, fluid injection, CSF sampling and Intracranial Pressure (ICP) monitoring.

Common features to each system include a calibrated 50ml graduated burette, 700ml drainage bag, two sampling aspiration sites, a patient stopcock, a four-way high flow burette stopcock, a dual hole planar cord suspension, sight window for referencing the pressure scale and an integral pole mounting support panel.

The graduated burette enables visualization of the CSF flow, clarity and volumetric readings to be made prior to fluid entering the drainage bag.

The Hermetic External CSF Drainage Systems can be used with all of the Integra NeuroSciences ventricular and lumbar catheters. A tubing connector with luer fitting is provided.

A fluid filled ICP monitoring transducer can be attached to the red end capped port of the patient stopcock for catalog INS-8300 or panel stopcock for catalogs INS-8301 and INS-8302. If monitoring is not used, it is imperative to keep the red end capped port securely tightened.



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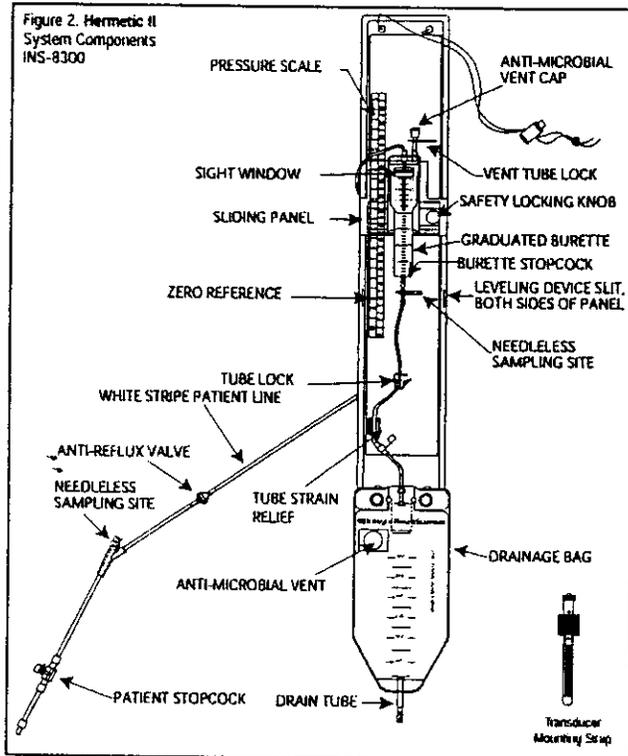
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DOC. CONTROL ORIGINAL

DOC. CONTROL ORIGINAL



Features and Benefits

The following features and benefits are common to each system.

- Closed integral system
- Integral pole mounting system
- Integrated pressure scale from -5 to +28 cmH₂O and -3 to +20mmHg
- 4-1/2" support panel width for easy single hand panel manipulations
- Large suspension cord locking mechanism for easy manipulation of system height
- Velcro® pole mount for more secure attachment
- The pole mount forms are compatible with standard IV poles with pole diameters ranging from 3/4" to 1-1/8"

- Sight window on sliding panel to reference pressure scales
- 50ml graduated burette with large bore full radius outlet designed to resist clogging
- Anti-microbial vent cap with slider clamp to protect vent during patient transport
- Line level device can be attached to Zero Reference on panel
- Removable 700ml drainage bag with anti-reflux valve and drain tube
- Luer connector in sterile pack included for catheter connection
- CSF access port labeled

Hermetic Plus INS-8301

- Patient line is green striped pressure monitoring tubing
- SmartSite® needleless sampling site at patient and burette stopcocks
- Red end capped panel mount stopcock at Zero Reference on panel for connection of fluid filled pressure transducer
- Low pressure anti-reflux valve distal to panel mount stopcock in patient line
- Red pressure level indicator

Hermetic Plus INS-8302

- Patient line is green striped pressure monitoring tubing
- SmartSite® needleless sampling site at patient and burette stopcocks
- Red end capped panel mount stopcock at Zero Reference on panel for connection of fluid filled pressure transducer
- No anti-reflux valve in patient line
- Red pressure level indicator

Hermetic II INS-8300

- Patient line is white striped, large bore tubing
- SmartSite® needleless sampling site at patient and burette stopcock
- Red end capped patient stopcock for connection of fluid filled pressure transducer
- Adhesive backed strap to attach pressure transducer near patient
- Low pressure anti-reflux valve distal to patient stopcock
- Pressure level indicator labeled mmHg/cmH₂O

Indications

Draining and monitoring of Cerebral Spinal Fluid (CSF) flow from the lateral ventricles of the brain or lumbar subarachnoid space is indicated in selected patients to:

- Reduce Intracranial Pressure (ICP)
- Monitor Intracranial Pressure (ICP)
- Monitor Cerebral Spinal Fluid (CSF)
- Provide temporary CSF drainage for patients with infected hydrocephalic shunts

57

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Monitoring of Intracranial Pressure (ICP) is usually performed in selected patients with:

- Severe head injury
- Subarachnoid hemorrhage
- Reyes syndrome or similar encephalopathies
- Hydrocephalus
- Intracranial hemorrhage
- Under physician supervision and discretion when drainage is to be used as a therapeutic maneuver

Monitoring can also be used to evaluate the status pre-and postoperatively for space-occupying lesions.

Contraindications

This device is not designed, sold, or intended for use except as indicated.

Lumbar drainage and/or lumbar pressure monitoring should not be used in the presence of: non-communicating hydrocephalus; a large intracranial mass, tumor or hematoma; and in patients who have demonstrated a blockage of cerebrospinal fluid pathways due to trauma, tumor, hematoma or other large intracranial mass.

Lumbar catheters are contraindicated in cases of spinal abnormalities that would prevent free insertion of the lumbar catheter.

Lumbar catheters are contraindicated in infants where the lower end of the spinal cord has not yet migrated to its cephalad L1-2 position.

In view of the marked narrowing of the lumbosacral canal in achondroplastic patients, a lumbar catheter in the subarachnoid space is contraindicated.

Warnings

Patients with cerebrospinal fluid drainage systems must be kept under close observation for signs and symptoms of changing intracranial pressure due to shunt failure. These signs and symptoms may vary from patient to patient. Increasing intracranial pressure is characterized by headache, vomiting, irritability, listlessness, drowsiness, other signs of deterioration of consciousness and nuchal rigidity. In the infant, increased scalp tension at the anterior fontanelle and congestion of scalp veins will be noted.

Failure to appropriately adjust the rate of CSF outflow through the external drainage system may result in potentially serious injury to the patient. Improper drainage system setup can lead to overdrainage or underdrainage and potentially serious injury to the patient.

Proper placement of the drainage system is critical. The one-way valve is designed to prevent reflux; it is not a pressure-regulating device. Intracranial pressure is controlled only by the height of the drainage system. It is essential that neither the patient nor the drainage system be raised or lowered accidentally. Height changes should only be made by qualified personnel on the orders of the physician.

It is possible that the puncture of the ventricle or the opening of the dura will result in an intracranial hemorrhage. It is possible that if too much CSF is removed from the ventricles, either during a drainage procedure or when the ventricle is first punctured, the ventricle may collapse and occlude the catheter.

It is possible that the monitoring system may give a false pressure reading either due to a pressure line becoming clogged or kinked or from an air bubble lodged in the system. An incorrect pressure reading may lead to the wrong therapy being given to the patient.

In order to minimize the possibility of infection, meningitis or ventriculitis, the sampling site should be cleaned according to hospital protocol prior to use. Sterile technique should be observed in setting up the system and in the placement of the catheter.

This product has not been tested for drug compatibility and therefore is not intended for drug administration.

Precautions

Prior to surgery, prospective patients or their representatives should be informed of the possible complications associated with this product.

Integra NeuroSciences makes no claim for or representation as to the performance characteristics of this product if it is used in conjunction with components of other manufacturers.

Complications

Complications which may result from the use of this product include the risks associated with the medications and methods utilized in the surgical

procedure, as well as the patient's degree of intolerance to any foreign object implanted in the body.

The principal complications associated with cerebrospinal fluid drainage are infection, catheter obstruction, or intracranial hypotension/hypertension.

Ventricular catheters may migrate into the lateral ventricles. Lumbar catheters may migrate into the subarachnoid space.

The presence of a foreign body (i.e. the catheter system) may trigger ventriculitis or a dormant meningitis. Infection is a common and serious complication of a drainage system and is most frequently caused by skin contaminants. The incidence of these infections can be reduced by care in inserting the ventricular catheter and stabilizing it by passing it through a subgaleal tunnel before it emerges. The lumbar catheter should be stabilized by suture collars. Wound infections may occur but usually subside when the catheter is removed. Septicemia, which occurs most frequently in debilitated infants, can result from infections anywhere in the body and may develop with few or no symptoms. It may occur as a result of a wound infection.

Lesions developing from the breakdown of skin or tissue over the drainage system may also serve as foci of serious infections. In the event of an infection, replacement of the drainage system is indicated in addition to the appropriate therapy.

Ventricular or lumbar catheters may be obstructed by particulate matter such as blood clots, fibrin, or brain fragments. If not properly located in the lateral ventricle, the ventricular catheter may become embedded in the ventricular wall or choroid plexus. Less commonly, the catheter may be obstructed by the excessive reduction of ventricular size to slit-like proportions.

Excessive lowering of intracranial pressure may result in complications, particularly in the infant. Complications for infants can include subdural hematomas, markedly sunken fontanelles, over-riding of cranial bones and conversion of a communicating to a noncommunicating hydrocephalus due to obstruction of the aqueducts of Sylvius.

Failure of the drainage system may be evidenced by continuing symptoms of

58

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increased ICP. Any failure of the system requires immediate replacement of the drainage system or the affected component.

Instructions for Use

Prior to system use, it is necessary for all responsible personnel to understand the use and function of the system components, system preparation, and system control.

Preparation and Allignment

Introduce and position the catheter. Placement of these catheters may be accomplished through a variety of surgical techniques; therefore, the surgeon is best advised to use the method which his/her own practice and training dictate to be best for the patient. The system should be prepared under sterile conditions prior to the placement of ventricular or lumbar catheter.

The system should be filled with preservative free sterile normal saline prior to connecting to the patient. Caps may be temporarily loosened to allow air to escape. Check to ensure the absence of any residual air bubbles that may affect pressure transducer monitoring. Ensure that fluid flows from the burette to the drainage bag.

When the ICP monitoring port is not in use, the red end cap must be in place to help prevent contamination. Aseptically clean all injection sites according to hospital protocol before connecting a sterile syringe.

Suspend the support panel from the IV pole via the suspension cord and position the drainage system height via the cord lock. If connecting the panel directly to the IV pole, push the pole mount forms on the back of the support panel onto the IV pole then secure the velcro straps in place. The velcro straps should be securely tightened to prevent the support panel from slipping. Once the velcro straps are secured, tighten the suspension cord over the IV pole by moving the cord lock so that the suspension cord is taut. Ensure that the system has been properly mounted with the "0" point of the reference pressure scale leveled to the patient's Foramen of Monro. Attach line level to Zero Reference point.

System Calibration

Initial system calibration should be completed prior to connecting to the patient.

Instructions for transducer calibration should be followed from the transducer manufacturer.

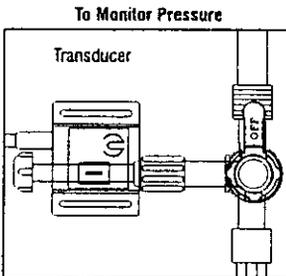
To Set Pressure Head

Ensure that the Zero Reference is not placed below the patient's Foramen of Monro or below the level of exit of the lumbar catheter. Increase or decrease the height of the Pressure Level by moving the sliding panel relative to the patient to set the pressure head.

Align the top of the red pressure indicator with drainage level ordered (mmHg or cmH₂O). Secure the burette sliding panel with the locking knob.

To Monitor Pressure

If accurate pressure monitoring is desired with pressure wave forms, the system should be temporarily closed to drainage to the graduated burette. Turn off transducer stopcock with the OFF arm to stop flow to the burette.

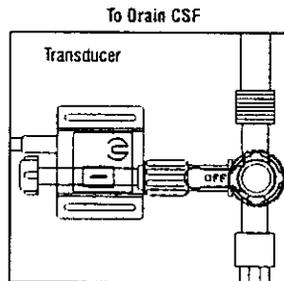


Note: CSF will not drain into the burette while the stopcock is in the monitoring only position.

To Drain CSF

Turn patient stopcock handle OFF to transducer to drain CSF. CSF will flow into the graduated burette.

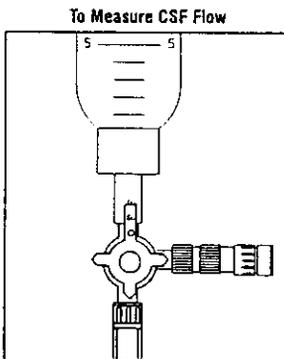
The ICP is controlled by the height of the pressure level of the burette chamber above the tip of the catheters. It is critical that neither the patient nor the drainage system be raised or lowered accidentally. Height changes should only be made by qualified personnel on the orders of the physician.



To Collect and Measure CSF

Accurate determination of fluid accumulation may be accomplished with the graduated burette from 1 to 50 ml in 1 ml increments. The burette stopcock should be OFF to the burette.

To drain CSF from burette to the drainage bag, the stopcock should be OFF to the sample port.



To Sample CSF

Sampling of CSF may be accomplished at various injection sites that have been cleaned according to hospital protocol. The SmartSite® needleless ports can be accessed with any standard luer fitting syringe. Access may be accomplished at the patient line stopcock or the Y-site immediately distal to the patient stopcock or beneath the burette. If CSF access is desired from the burette, use the injection site at the burette stopcock. In addition, CSF may be sampled from the drainage bag at the bottom injection site.

59

DOC. CONTROL ORIGINAL

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To Flush System

Injection sites that have been cleaned according to hospital protocol may be flushed. Orient the stopcocks to temporarily prevent flow back to the patient. Ensure and verify fluid flush into the drainage bag.

Once flushing has been accomplished, reorient stopcocks to allow flow from the patient to the burette and into the drainage bag.

To Replace Drainage Bag

Orient the burette stopcock to temporarily stop flow into the drainage bag. Close clamp on drain tube. Using sterile handling technique, disconnect the drainage bag from the drain tube, attach tethered blue cap and detach bag from the system panel.

Using sterile handling technique, connect the sterile replacement drainage bag to drain tube. Attach bag to system panel.

Reorient burette stopcock to allow flow from the burette into the drainage bag. Open drain tube clamp. Verify flow into the drainage bag.

To Empty Drainage Bag

The drainage bag may be emptied with sterile handling technique by syringe access with a 25-gauge needle or luer syringe if SmartSite[®] needleless site on bag.

To Transport Patient

If it is necessary to transport a patient while system is in full use, the system should remain correctly aligned with the patient for desired pressure head and drainage.

If this is not possible, the graduated burette should be emptied into the drainage bag. Close the slider clamp on the burette vent tube. The burette stopcock should then be temporarily closed to prevent retrograde flow of CSF from the drain tube into the burette. The panel mount stopcock on the INS-8301 and INS-8302 or the patient stopcock on the INS-8300 should be oriented to temporarily stop flow from the patient to the burette. The patient should then be transported as required.

After patient transport has been completed, system use should be re-established with correct reference relative to patient. All stopcocks should be reoriented to reestablish flow. All clamps should be opened. Ensure and verify flow from the patient into the

burette. Note: Burette vent tube slider clamp must be open to ensure drainage.

Product Information Disclosure

Integra NeuroSciences has exercised reasonable care in the choice of materials and manufacture of this product. Integra NeuroSciences excludes all warranties, whether expressed or implied by operation of law or otherwise, including, but not limited to any implied warranties of **merchantability or fitness**. Integra NeuroSciences shall not be liable for any **incidental or consequential loss, damage, or expense**, directly or indirectly arising from use of this product. Integra NeuroSciences neither assumes or authorizes any other person to assume for it, any other or **additional liability or responsibility** in connection with this device.

Special Order Products

If this product is a Special Order product as requested by a physician, there may be differences between the enclosed product and the product description in this brochure. These differences will not affect the safety or effectiveness of the special order product.

How Supplied

Integra NeuroSciences External CSF Drainage Systems are supplied sterile and non-pyrogenic in single wrap packaging.

Do Not Resterilize

All External CSF Drainage Systems are disposable devices. Integra NeuroSciences does not recommend resterilization of these products.

Returned Goods Policy

Products must be returned in unopened packages, with manufacturer's seals intact to be accepted for replacement or credit, unless returned due to a complaint of product defect or mislabeling.

Determination of a product defect or mislabeling will be made by Integra NeuroSciences, which determination will be final.

Products will not be accepted for replacement if they have been in the possession of the customer for more than 90 days.

Product Order Information

All products can be ordered through your Integra NeuroSciences NeuroSpecialist or customer service representative.

Integra NeuroSciences
105 Morgan Lane
Plainsboro, NJ 08536 USA
Telephone: 1-800-654-2873
Outside the US: 1-609-275-0500
Fax: 1-609-275-5363

OR
Integra NeuroSciences
Newbury Road Andover
Hampshire SP10 4DR England
Tel: +44(0) 1264-345-700
Fax: +44 (0) 1264-332-113

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

Catalog Numbers

- INS-8300 Hermetic II External CSF Drainage System
- INS-8301 Hermetic Plus External CSF Drainage System with Anti-Reflex Valve and Needleless Injection Sites
- INS-8302 Hermetic Plus External CSF Drainage System with Needleless Injection Sites
- INS-8700 Integra External CSF Drainage System Replacement Bags

Symbols Used On Labeling

- See instructions for use
- Expiration date
- Do not reuse after opening
- Lot number
- STERILE EO**

Sterile unless package is opened or damaged.
Method of sterilization-ethylene oxide.

60

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NEUROSCIENCES**

Integra NeuroSciences
105 Morgan Lane
Plainsboro, NJ 08536 USA

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Velcro® is a registered trademark of Velcro Industries, LLC

INDICATIONS FOR USE STATEMENT

510(k) Number:

Device Name: Hermetic Plus™ External CSF Drainage System

Indications for Use:

The Hermetic Plus™ External CSF Drainage System is indicated for draining and monitoring of Cerebrospinal Fluid (CSF) flow from the lateral ventricles of the brain or lumbar subarachnoid space in selected patients to reduce intracranial pressure (ICP), monitor intracranial pressure (ICP), monitor cerebrospinal fluid (CSF), and provide temporary CSF drainage for patients with infected hydrocephalic shunts.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

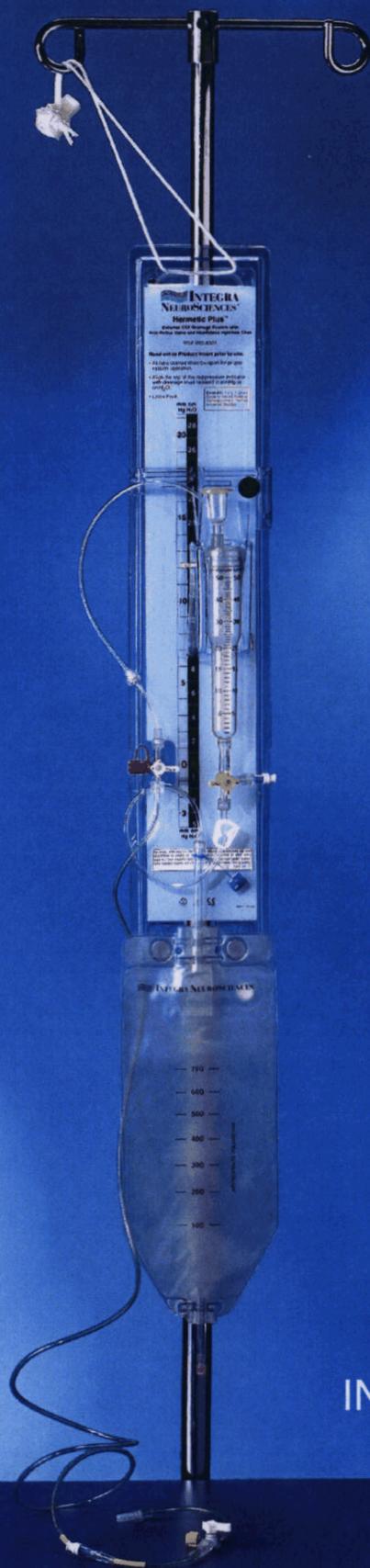
Prescription Use _____
(Per 21 CFR 801.109)

Or

Over-the-Counter Use _____

Optional Format 1-2-96)

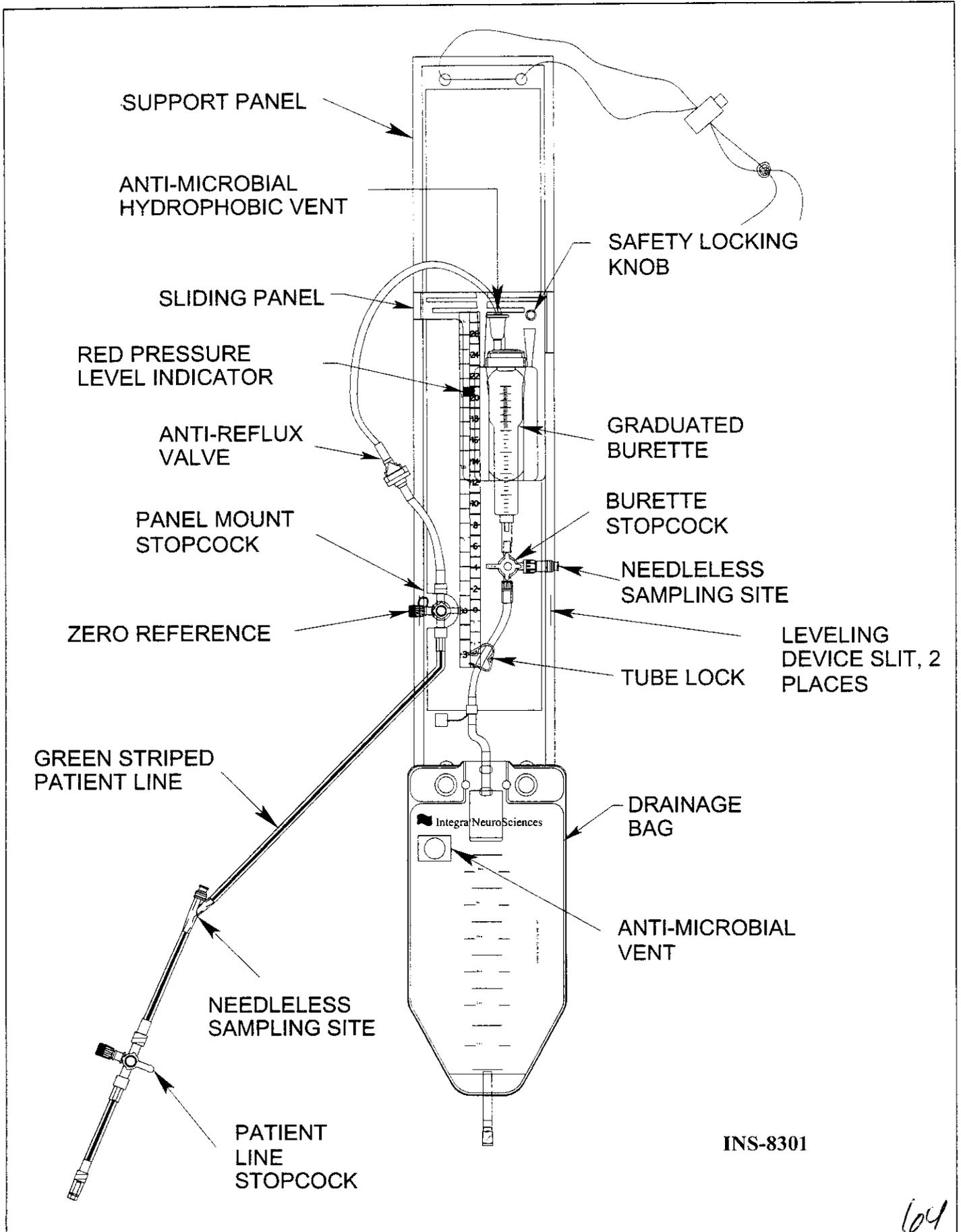
Modified Hermetic Plus™ External CSF Drainage System



INS-8301

103

Modified Hermetic Plus™
External CSF Drainage System



64

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Añasco, Puerto Rico

CONFIDENTIAL

Test Report:
Prepared By:

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Date: 1/9/03

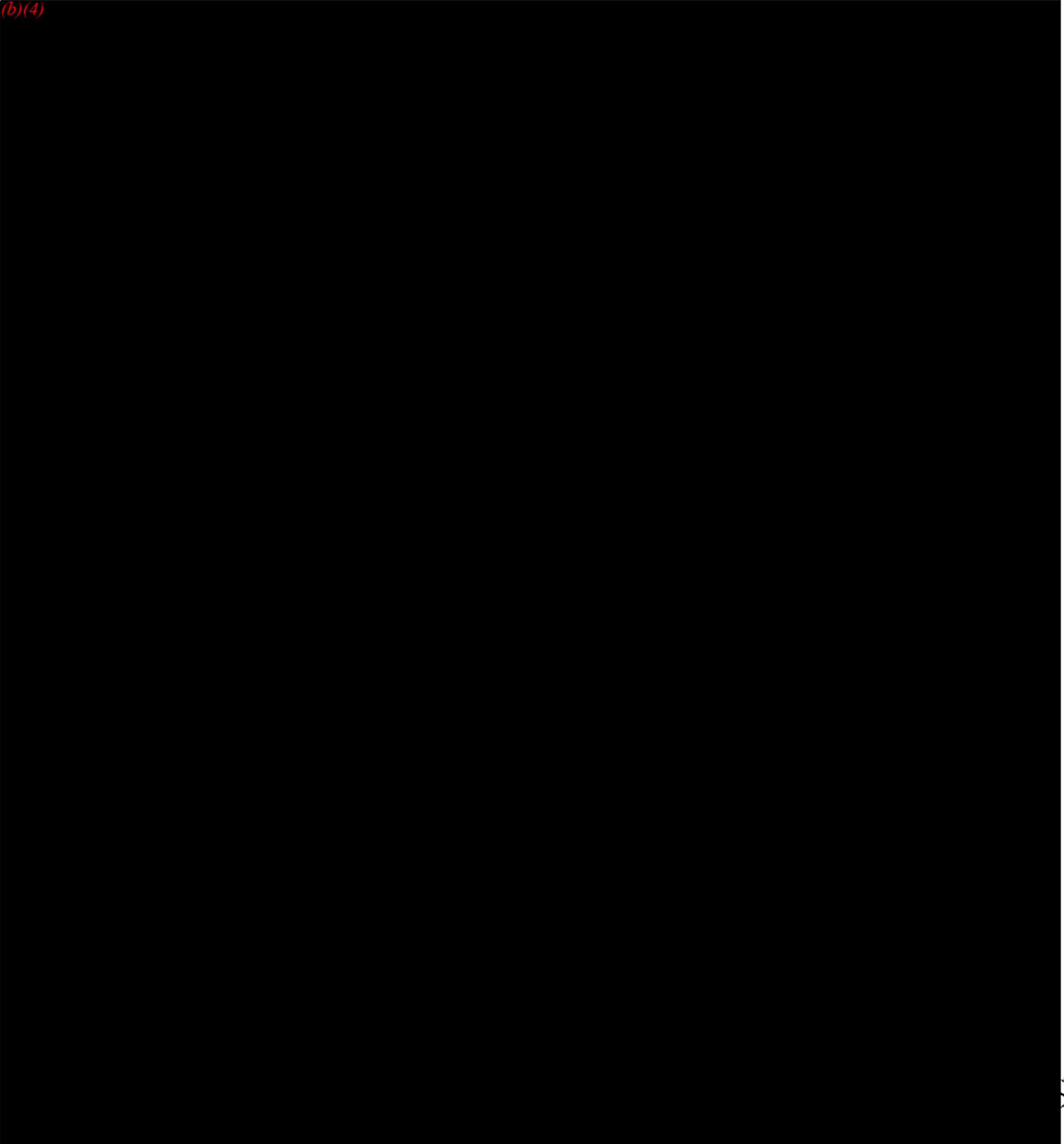
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TITLE: Test Report, (b) (4)

1 PURPOSE/SCOPE

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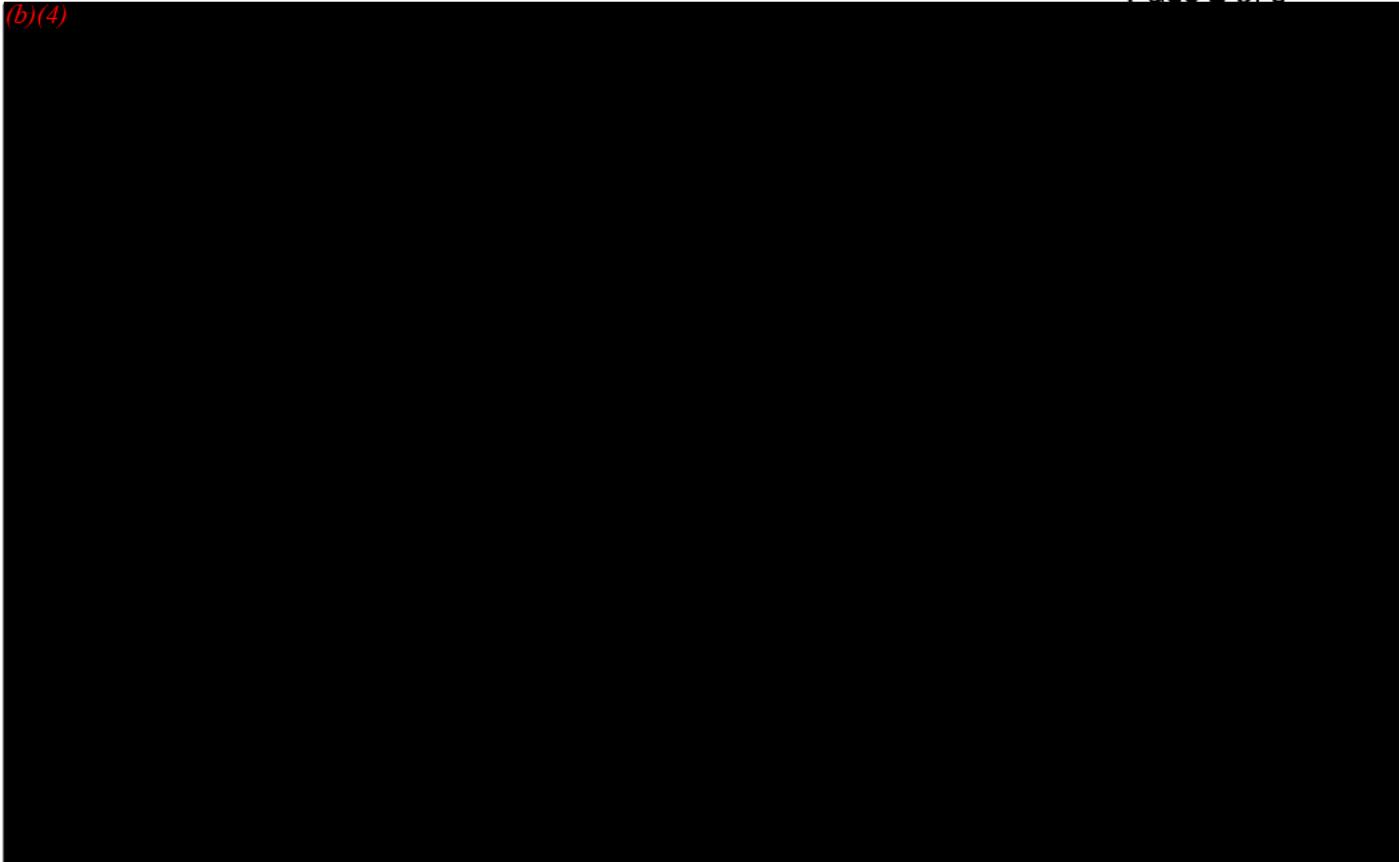
Integra NeuroSciences P.R., Inc.
Añasco, Puerto Rico

CONFIDENTIAL Test Report:
Prepared By

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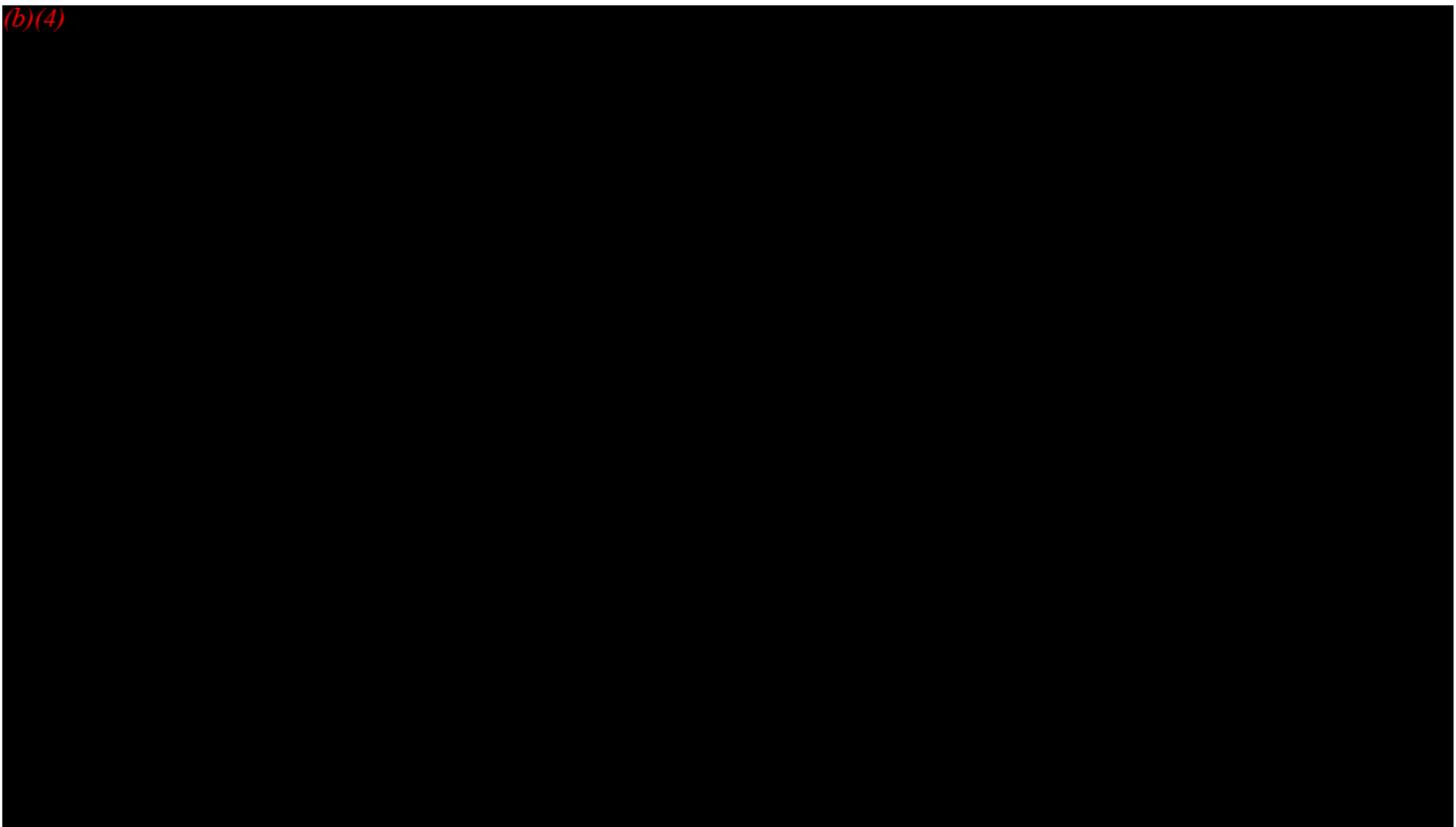
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2 MATERIALS AND METHODS

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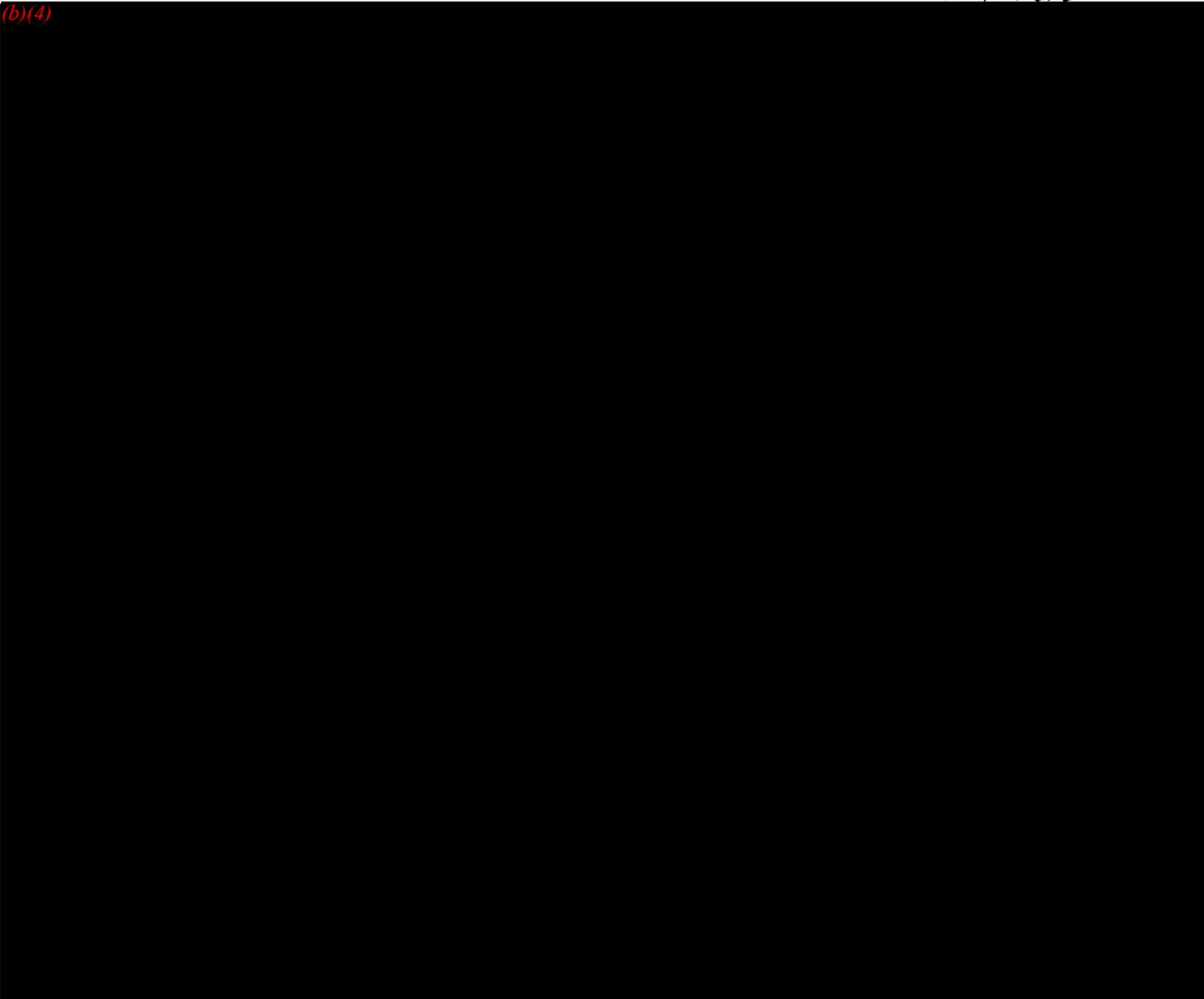
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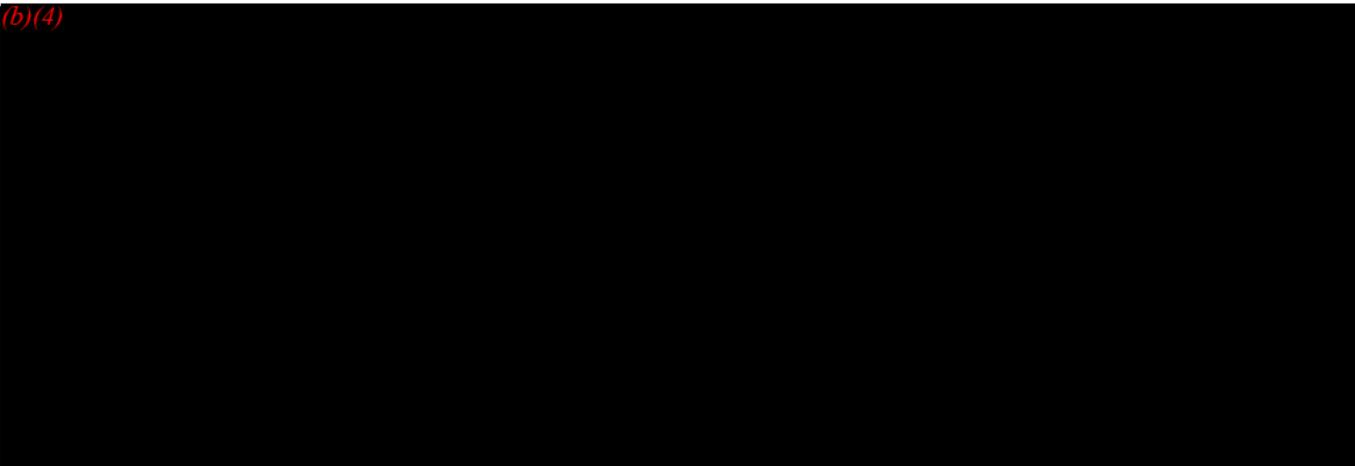
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Page 3 of 8

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3 ACCEPTANCE CRITERIA

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67

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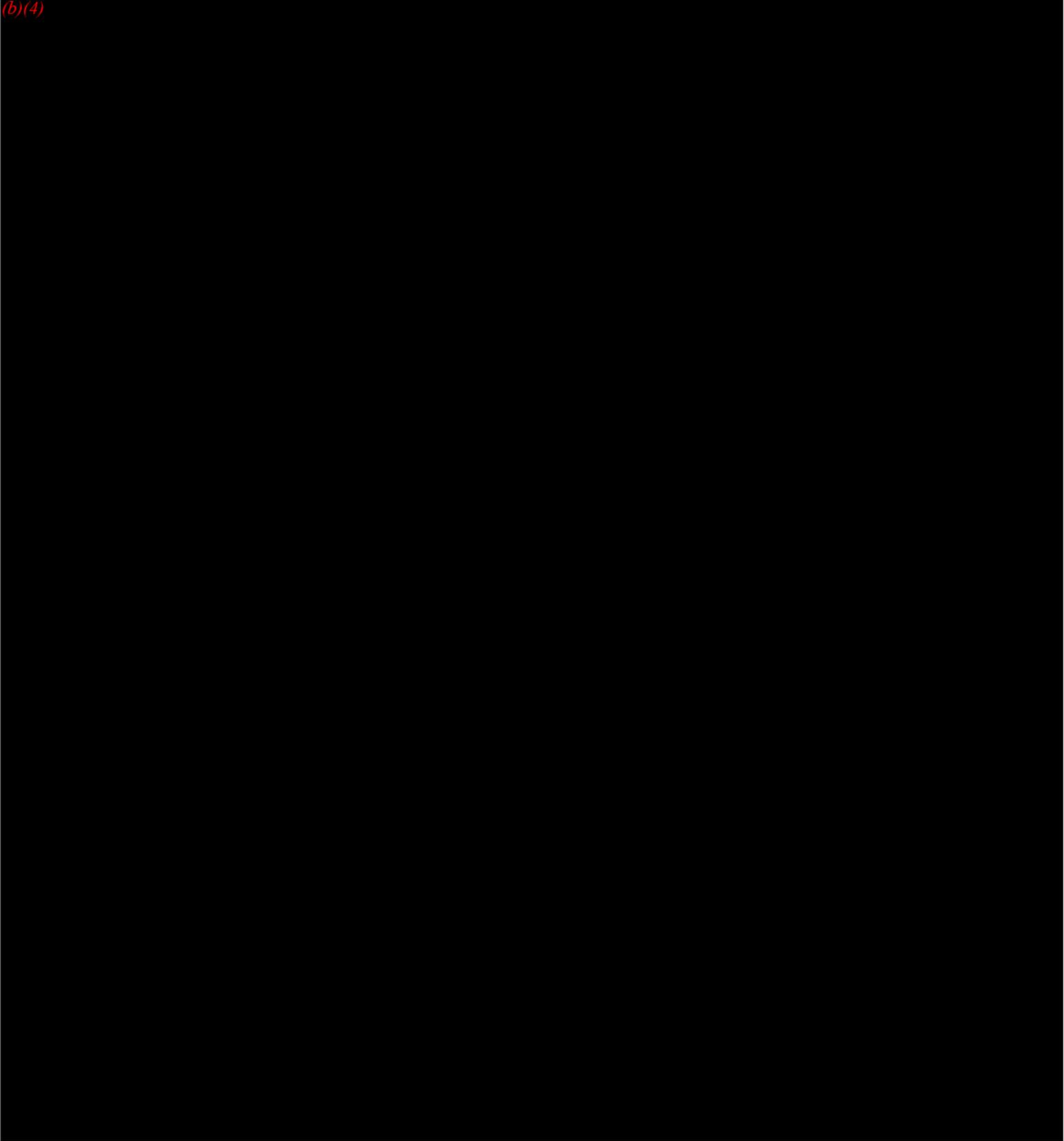
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Page 4 of 8

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4 TEST RESULTS



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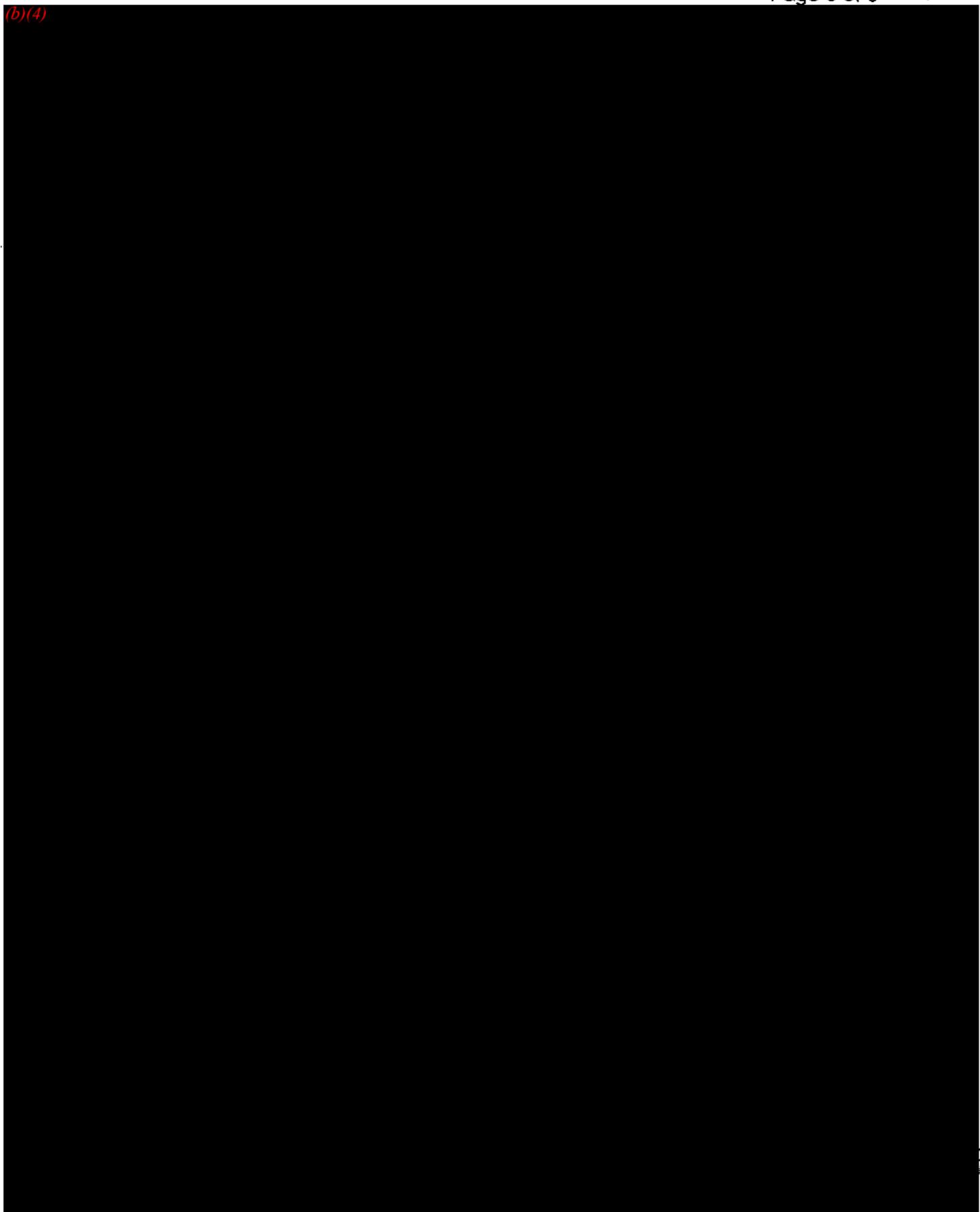
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Page 5 of 8

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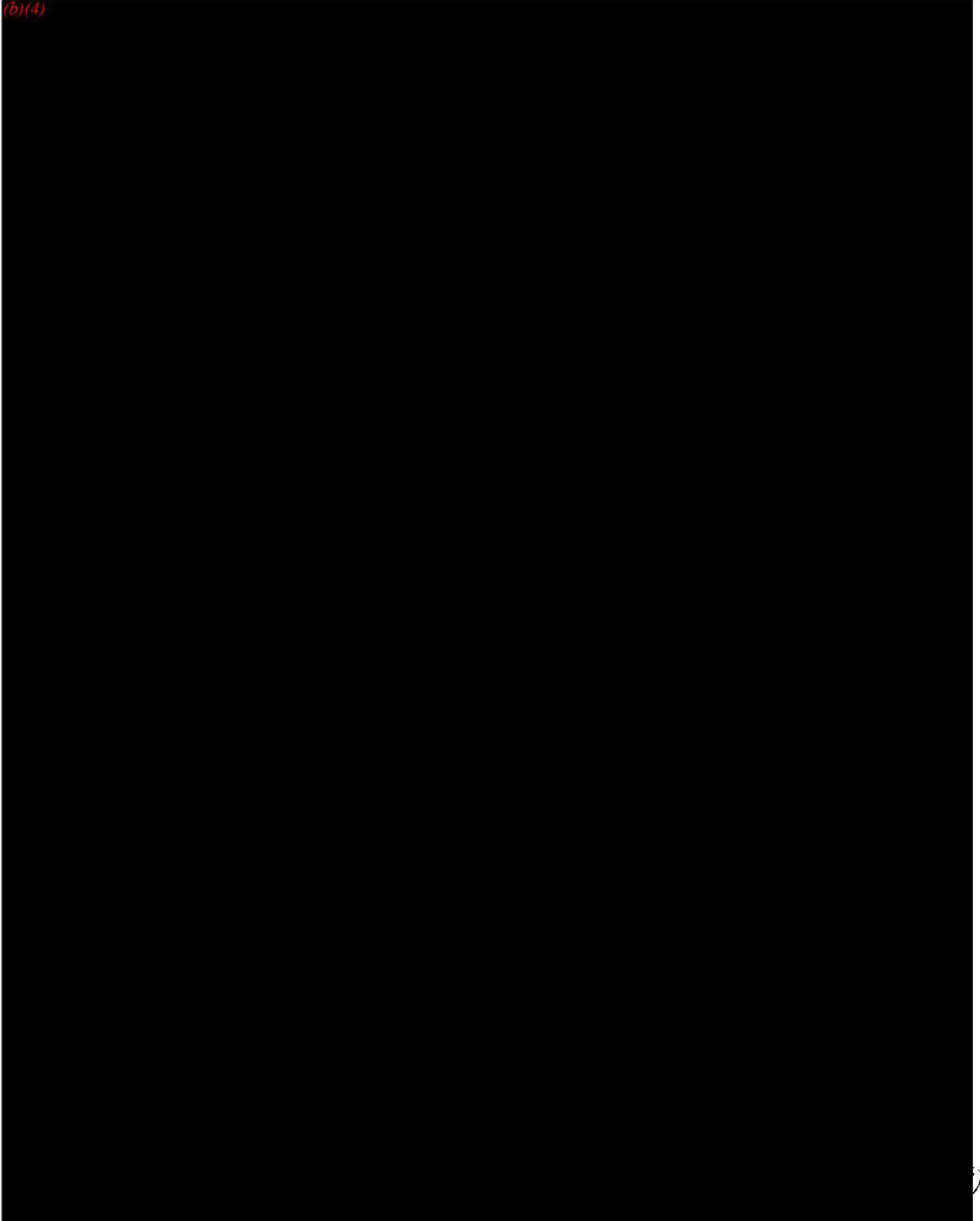
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Page 6 of 8

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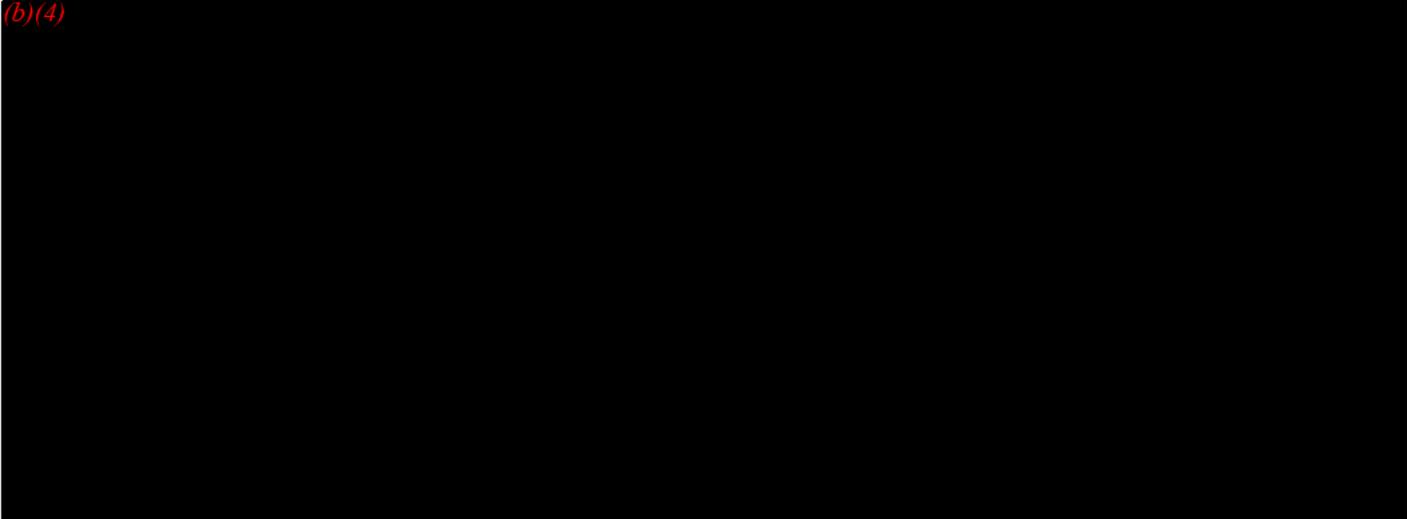
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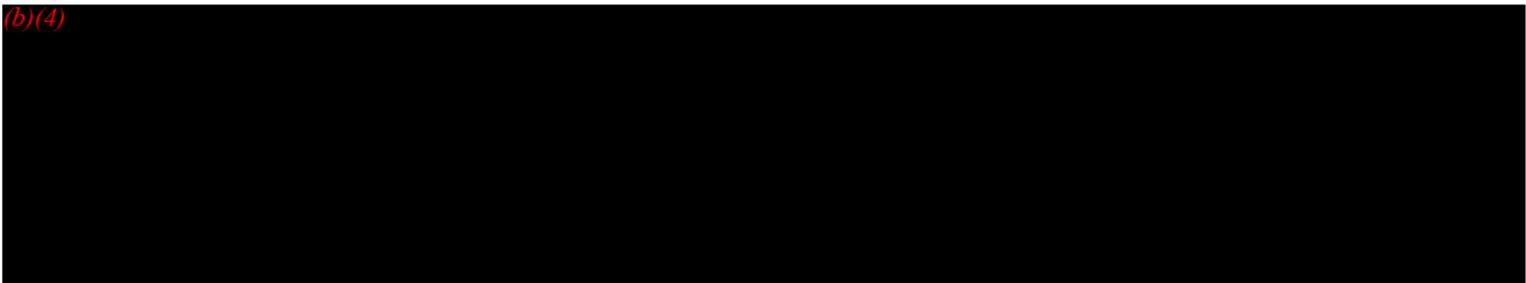
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Page 7 of 8

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5 CONCLUSIONS / RECOMMENDATIONS

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71

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Page 8 of 8

6 APPROVALS

(b) (6)

6.1 Engineering

1-10-03
Date

(b) (6)

6.2 Quality Assurance

1-10-03
Date

(b) (6)

6.3 Materials

1/9/03
Date

(b) (6)

6.4 Manufacturing

1-10-03
Date

(b) (6)

6.5 Research & Development

1/9/03
Date

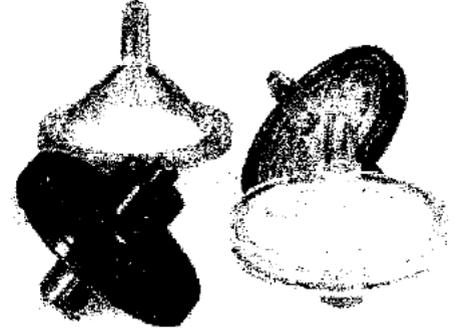


Intervene(TM) 25 mm Filter

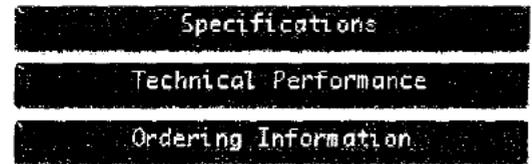
Description



Select from a full line of barrier devices used by some of the world's most respected medical equipment manufacturers.



- Protective hydrophobic barrier allows only sterile air to pass through, protecting patients and equipment from cross contamination
- Choice of media to accommodate sterilization methods
- Selection of 510(k) cleared products for transducer protection reduces your time to market
- Colored housings available for identification
- Mix and match over a dozen standard and custom connector styles
- Custom printed blister packaging available
- Housings designed to withstand pneumatic pulsing



Applications

- Transducer protection
- Moisture barriers
- Small volume venting
- Sterile air/gas delivery
- Pump protection
- Hydrophobic barrier

Specifications ▲

Biological Safety

Materials of construction pass USP Class VI-121 °C Plastic and Cytotoxicity tests

Effective Filtration Area

2.8 cm²

Inlet/Outlet Connections

- SO FLL/MLL
- SO FLS/MLS
- SO MLS/MLS
- SO MLS/MF
- SO FLL/MLL (DLL)

Materials of Construction

Filter Media: Versapor[®] R, Versapor H or PTFE
Housing: Modified acrylic

Maximum Operating Temperature

G001

7-3

<http://domino.pall.com/www/oem%20healthcare%20catalog.nsf/86ef06d3a6692aa9852566ff005dd96e/c56f3!...> 8/15/

55 °C (131 °F)

Minimum Water Breakthrough

Versapor: 0.8 bar (12 psi)/30 seconds

PTFE: 1.1 bar (16 psi)/30 seconds

Pore Size

0.2 µm

Pyrogenicity

< 0.25 EU/mL using the LAL test method

Sterilization Compatibility

Versapor H and Versapor R: EtO, gamma irradiation

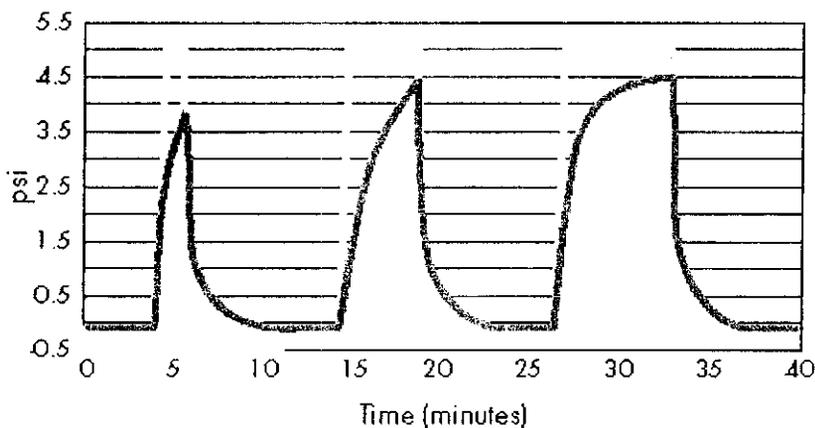
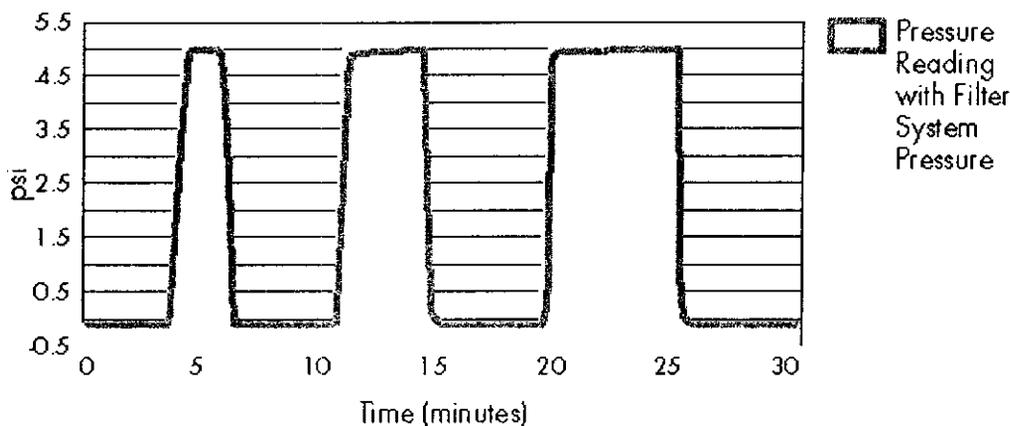
PTFE: EtO

Technical Performance ▲

Intervene 25 mm Filters, ΔP

Intervene 25 mm does not interfere with accurate and reliable system monitoring

Competitive Devices ΔP



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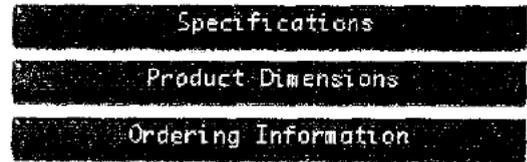
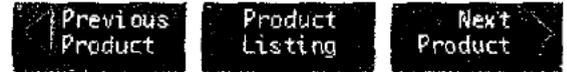


Intervene(TM) 4 and 13 mm Filters

Description

Effective and durable barrier devices for your small volume requirements.

- Different housing diameters to accommodate your filtration/venting needs
- Custom color printing options for product and/or company identification on 13 mm devices
- Rugged polypropylene housing withstands high temperature, high pressure and aggressive solvents
- Autoclavable



Applications

- Sterile air/gas delivery
- Venting
- Hydrophobic barrier
- Pump protection

Specifications ▲

Biological Safety

Materials of construction pass USP Class VI-121 °C Plastic and Cytotoxicity tests

Effective Filtration Area

4 mm: 0.1 cm²
 13 mm: 0.8 cm²

Inlet/Outlet Connections

FLL/MLS

Materials of Construction

Filter Media: PTFE, Versapor[®] R, Versapor H
 Housing: Polypropylene and modified acrylic

Maximum Operating Pressure

1 bar (15 psi) at ambient temperature

Maximum Operating Temperature

100 °C (212 °F)

Pore Size

.2, 0.45, 1, 5 µm

Sterilization Compatibility

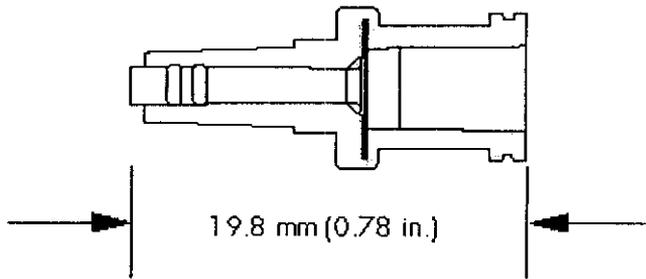
G003

75

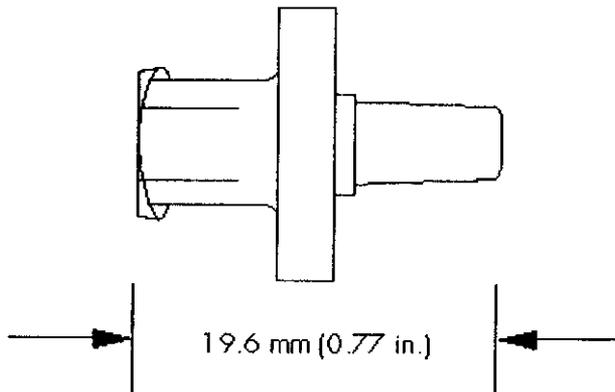
PTFE: Autoclave, EtO
 Versapor: Gamma irradiation

Product Dimensions ▲

4 mm Filter



13 mm Filter



Ordering Information ▲

Product No.	Pore Size	Description
6024423	0.2 μm	13 mm, PTFE, FLL/MLS
6804473	0.45 μm	4 mm, Versapor H, FLL/MLS
6004135	5 μm	13 mm, PTFE, FLL-MLS
6004137	1 μm	13 mm, PTFE, FLL-MLS

G004

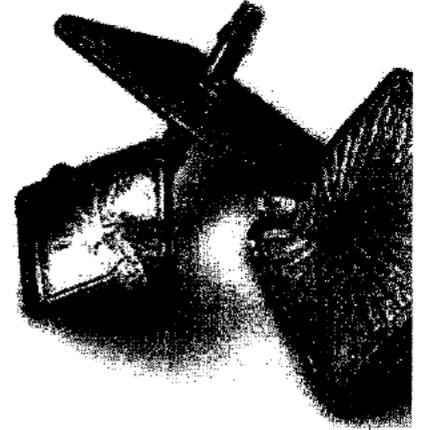
76



- GAS LINE FILTERS
- 25MM FILTERS
- FILTER GASKETS
- SUCTION FILTERS
- FILTER CUTTING
- CUSTOM FILTERS
- FAQS

Medical Filters

In medical procedures, it is critical to maintain a sterile field that is free of contaminants and bacteria. It is also crucial that air sources introduced into surgical applications or sterile lab environments are free of contaminants. PSI manufactures hydrophobic filters for use in insufflation, laparoscopy, open-heart surgery, kidney dialysis, blood administration and other medical procedures. Our membrane filters are rated to filter air down to 0.1 micron.



You can select a filter media based on your application. Microporous membrane and depth filters are available as well as custom design capabilities for specific applications.

You may also want to look at our [Analysis Filters](#).

- [Gas Line Filters](#) • [25mm Filters](#) • [Filter Gaskets](#) • [Suction Fil](#)
- [Cutting](#) • [Custom Filters](#) • [FAQs](#)
- [About PSI](#) • [Medical Filters](#) • [Container Venting](#) • [Laboratory](#)
- [Contact Us](#)

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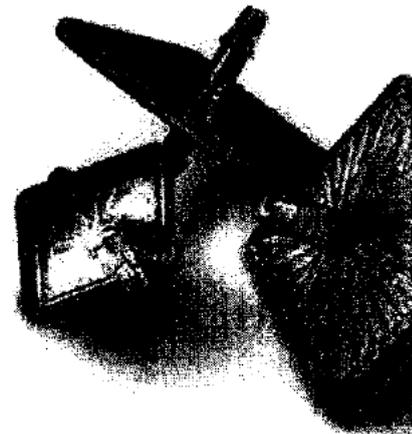
- GAS LINE FILTERS
- 25MM FILTERS
- FILTER GASKETS
- SUCTION FILTERS
- FILTER CUTTING
- CUSTOM FILTERS
- FAQs

Gas Line Filters

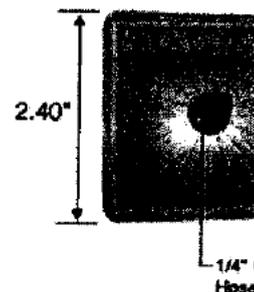
HydroCheck & MicroCheck

For applications requiring a clean, sterile air source and prevention of fluid contamination and overflow. Also used for particulate removal.

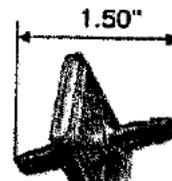
- Primarily used for insufflation; used in suction canisters and vacuum lines
- Bacteria retentive (down to 0.1 µm)
- Utilizes hydrophobic PTFE media
- Can utilize custom media such as hydrophobic microglass
- Clear acrylic housing provides instant visual inspection for contaminants



HydroCheck Gas Line Filter	
Housing Material	High Clarity Acrylic
Filter Media	Hydrophobic PTFE or Hydrophobic Microglass
Air Flow	10 to 35 LPM @ 1 psi (dependent on filter media)
Water Intrusion Rating	1.3 psi to 30 psi (dependent on filter media)
Filter Efficiency	Down to 0.1µm in Air (dependent on type of media)



MicroCheck Gas Line Filter	
Housing Material	High Clarity Acrylic
Filter Media	Hydrophobic PTFE or Hydrophobic Microglass
Air Flow	10 to 16LPM @ 1 psi (dependent on filter media)



78

	media)
Water Intrusion Rating	1.3 psi to 30 psi (dependent on filter media)
Filter Efficiency	Down to 0.1µm in Air (dependent on type of media)

[Gas Line Filters](#) • [25mm Filters](#) • [Filter Gaskets](#) • [Suction Fil Cutting](#) • [Custom Filters](#) • [FAQs](#)

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G007

79

 **INTEGRA NEUROSCIENCES**

CONFIDENTIAL

Date: January 13, 2003

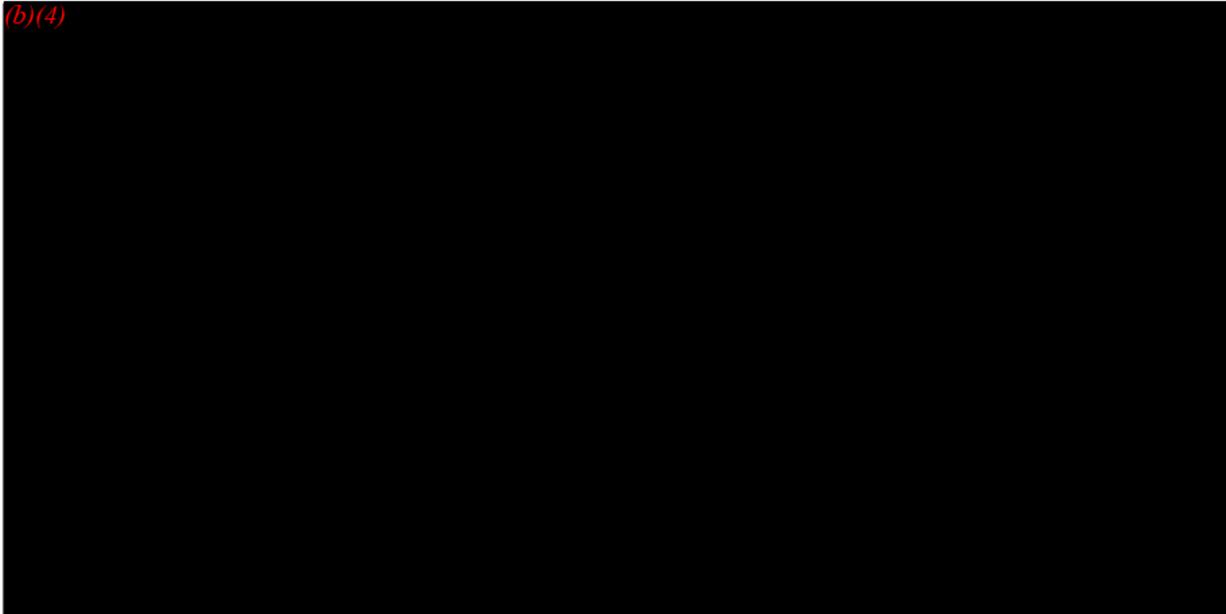
To: Hermetic Plus DHF

From: RA Baez – Product Development Engineer

R. Baez 1/17/03

Subject: **Verification Report for Anti-microbial Vent Filter – Hermetic Plus**

(b)(4)



H001

80

CONFIDENTIAL

Heyer-Schulte External Ventricular Drainage Vent Verification Testing Report

Prepared for:

 **INTEGRA NEUROSCIENCES**
Plainsboro, New Jersey

Prepared by:

(b) (6)
Research Associate Engineer

Contributions by:

(b) (6)
Scientist

(b) (6)
Product Development Manger

Study Supervisor:
Ronald Ingram, Ph.D.
Sr. Director, Research & Development

Integra NeuroSciences
Corporate Research Center
11045 Roselle Street, Suite A
San Diego, CA
92121-1299

Report Number:
Revision:
Issue Date:

(b)(4)
5/2/02

81

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I hereby assert that all information contained in this document is true and correct to the best extent of my knowledge:

Preparer:

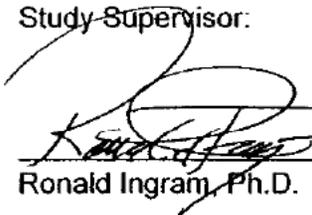
(b) (6)



5/31/02

Date

Study Supervisor:



Ronald Ingram, Ph.D.

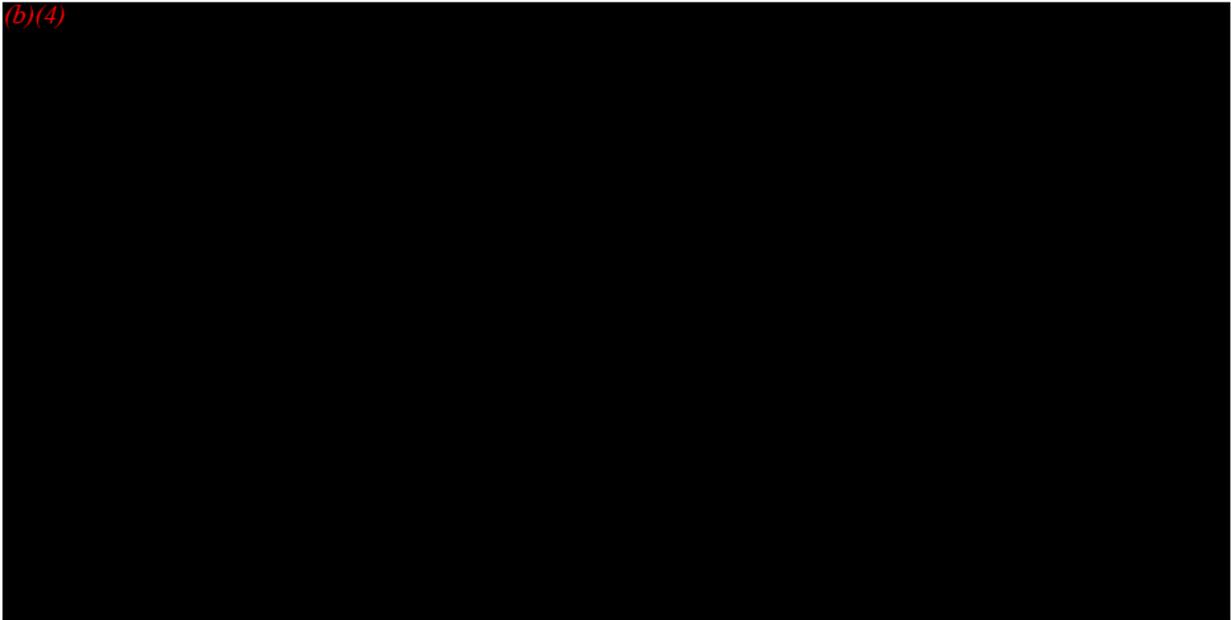
5/31/02

Date

CONFIDENTIAL

1.0 INTRODUCTION & BACKGROUND

(b)(4)



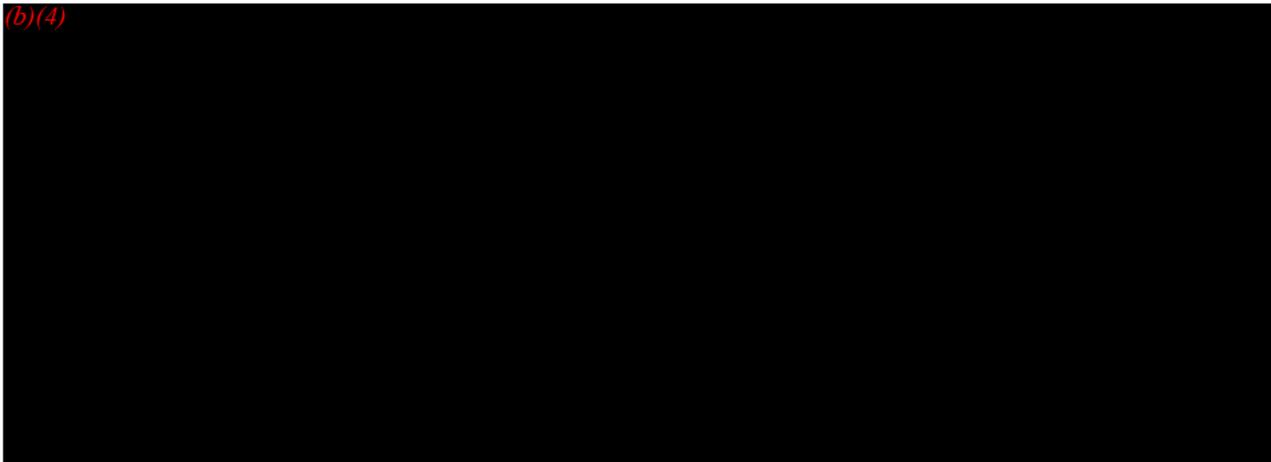
2.0 MATERIALS

(b)(4)



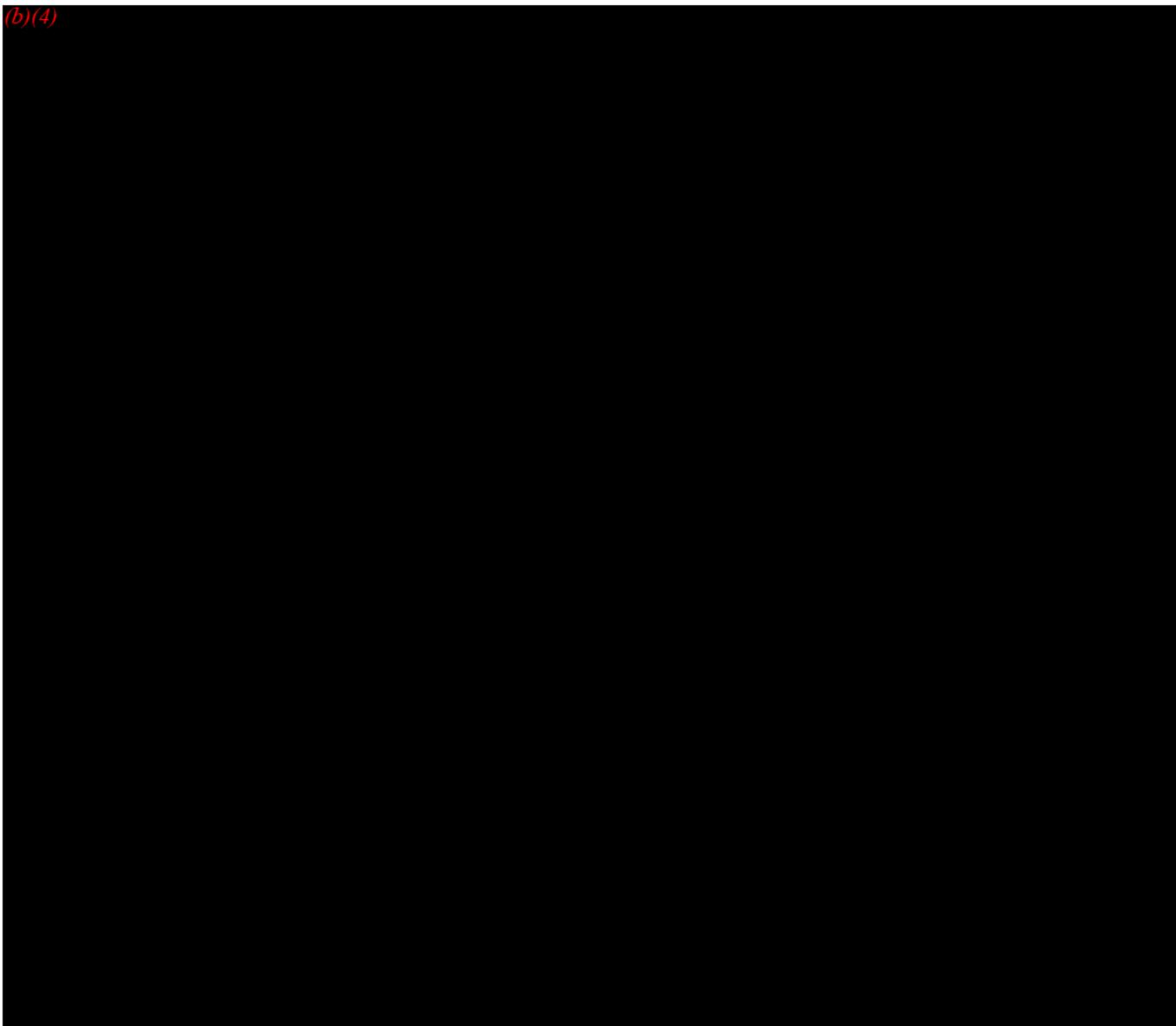
CONFIDENTIAL

(b)(4)



3.0 TESTING PROTOCOL

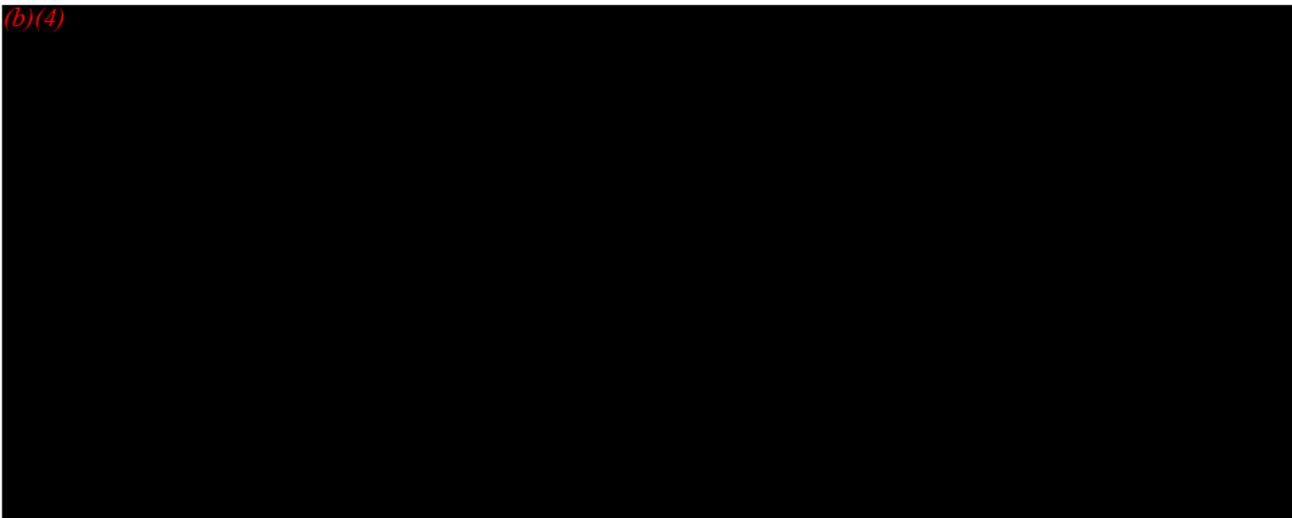
(b)(4)



84

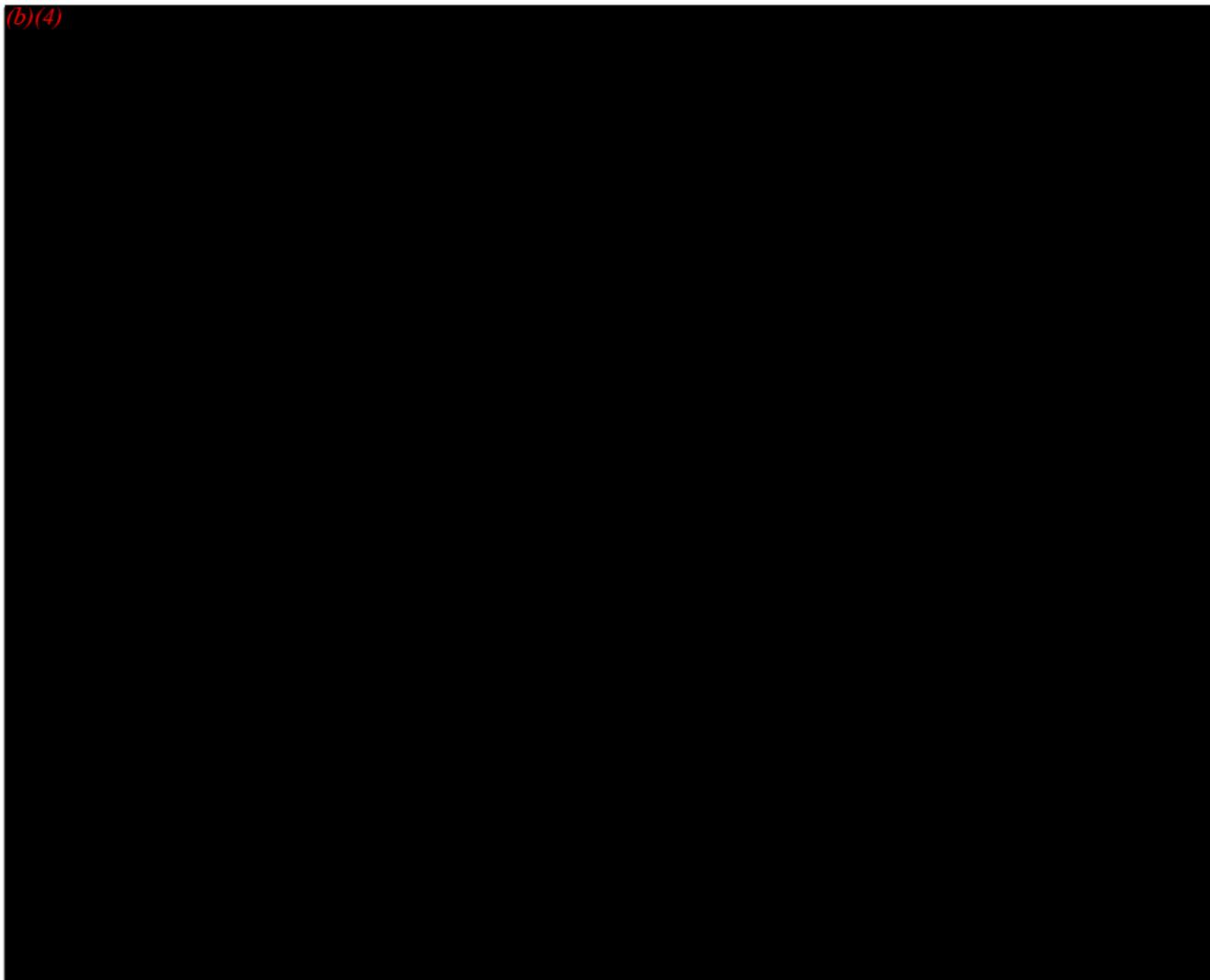
CONFIDENTIAL

(b)(4)



4.0 RESULTS

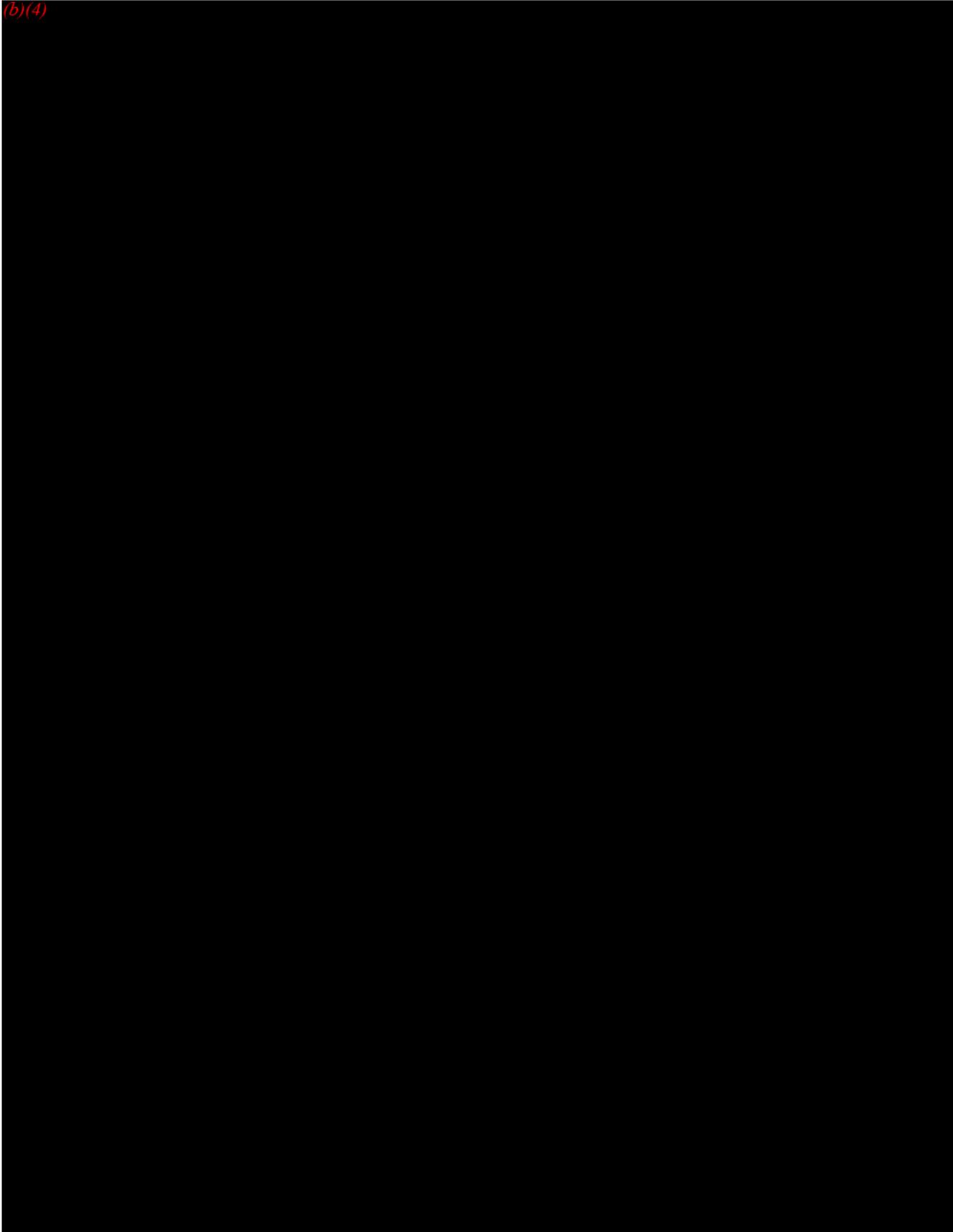
(b)(4)



85

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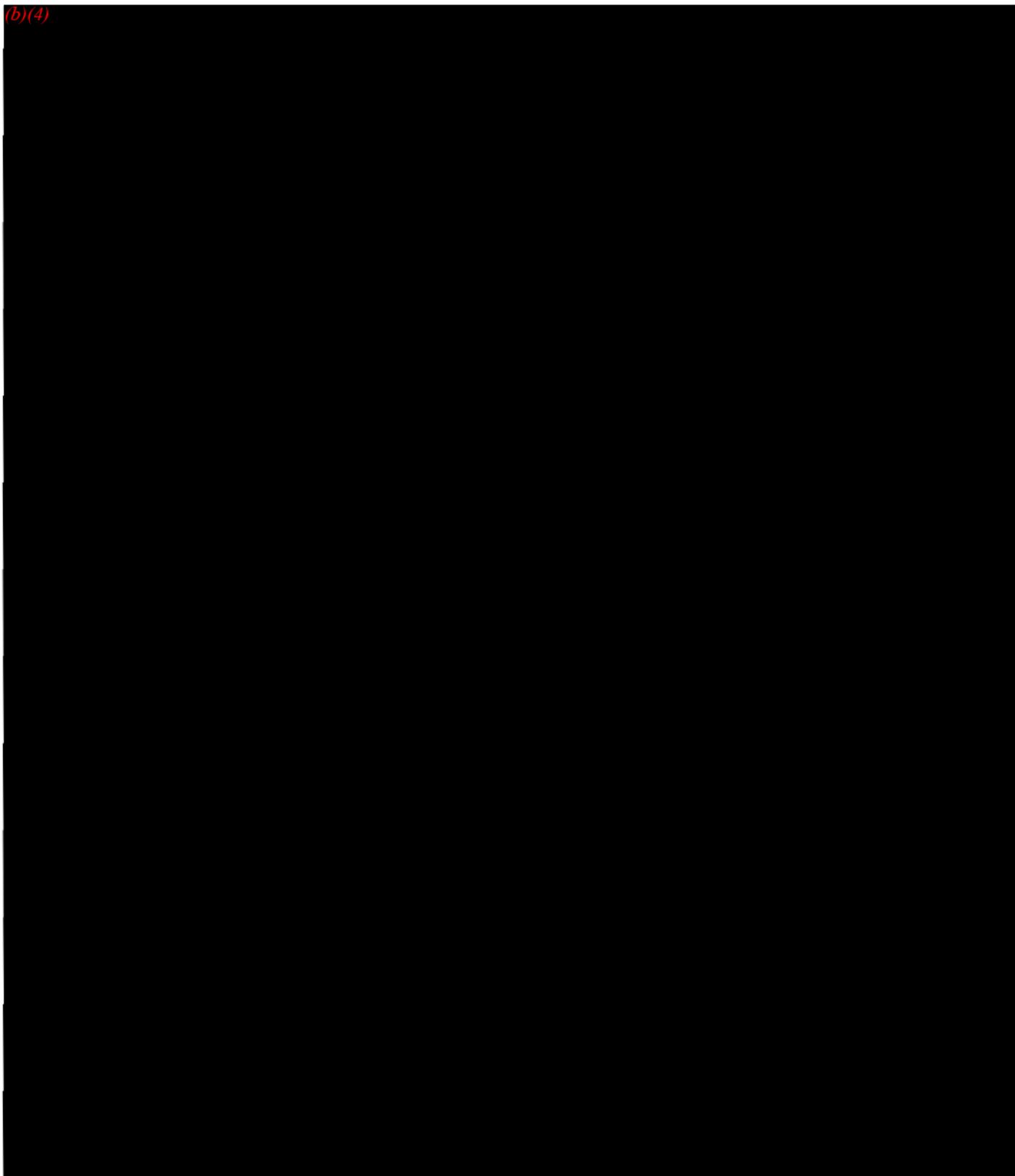
(b)(4)



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CONFIDENTIAL

(b)(4)

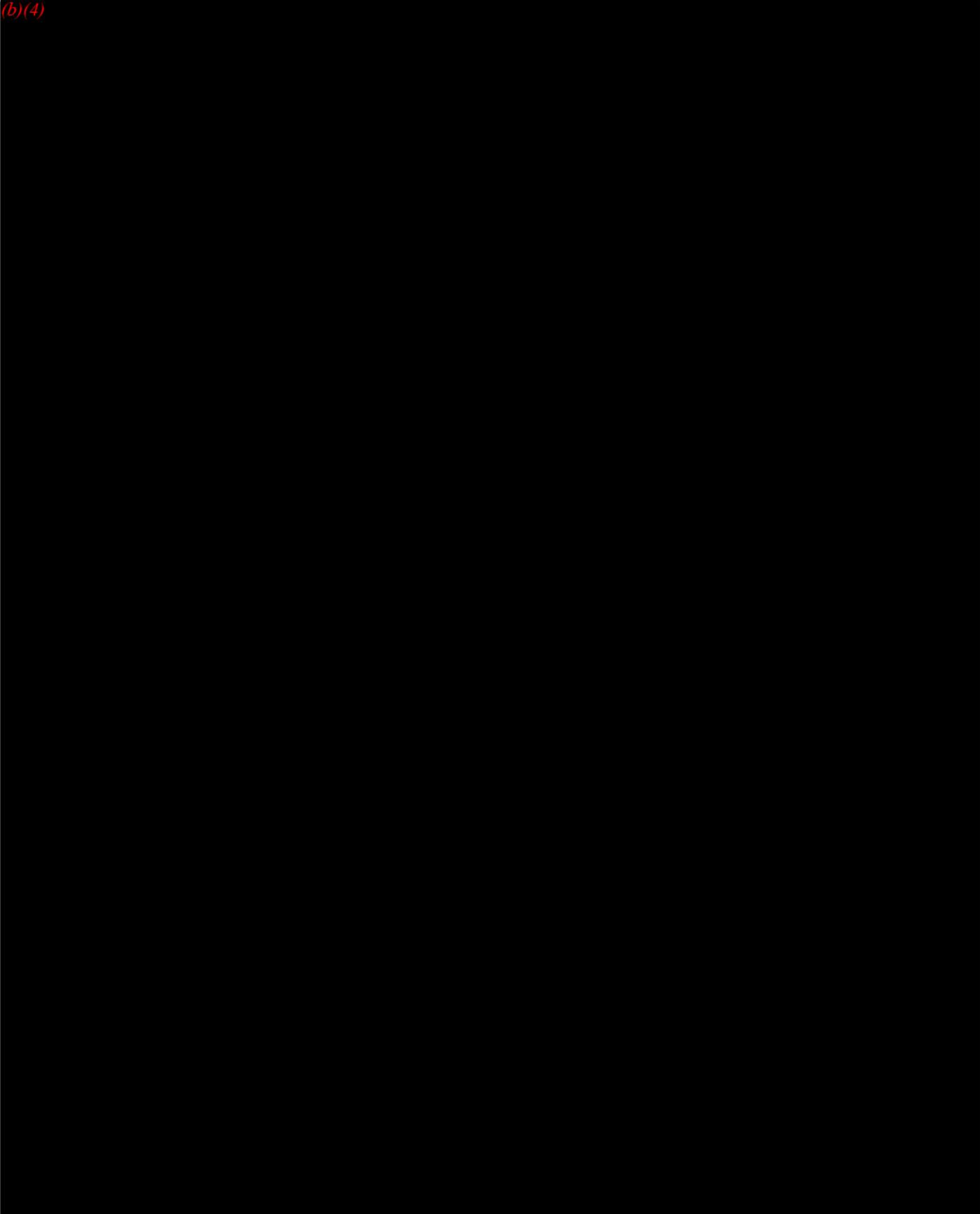


87

CONFIDENTIAL

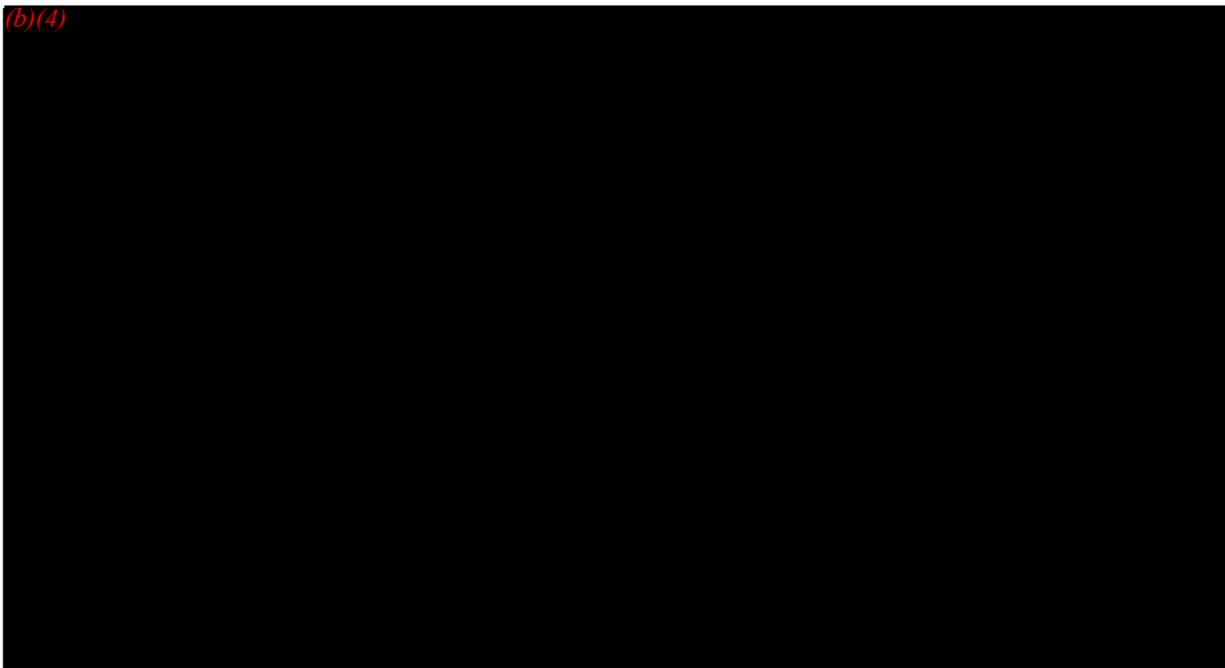
5.0 DISCUSSION & CONCLUSIONS

(b)(4)



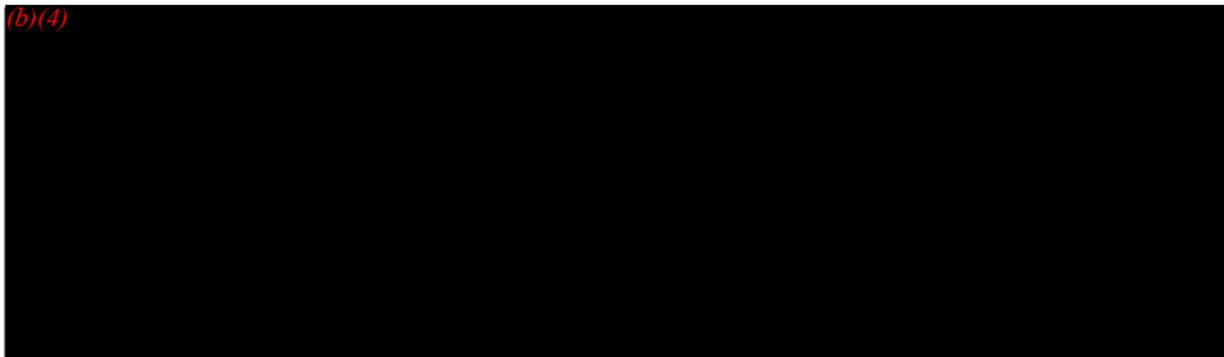
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(b)(4)



6.0 REFERENCES

(b)(4)



89

Integra NeuroSciences
Special 510(k): Device Modification
Hermetic Plus™ External CSF Drainage Systems

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**Hermetic Plus™
External CSF Drainage System**

510(k) SUMMARY

Submitter's name and address:

Integra LifeSciences Corporation
Integra NeuroSciences
311 Enterprise Drive
Plainsboro, NJ 08536

Contact person and telephone number:

Donna R. Wallace
Director, Regulatory Affairs
(609) 275-0500

Date summary was prepared:

January 24, 2003

Name of the device:

Proprietary Name: Hermetic Plus™ External CSF Drainage System
Common Name: External CSF Drainage System
Classification Name: Central Nervous System Shunt and Components JXG

Substantial Equivalence:

The Hermetic Plus™ External CSF Drainage System is substantially equivalent in function and intended use to the unmodified External CSF Drainage and Management Systems which has been cleared to market under Premarket Notification 510(k) K972994.

Intended use:

The Hermetic Plus™ External CSF Drainage System is indicated for draining and monitoring of cerebrospinal fluid (CSF) from the lateral ventricles of the brain or lumbar subarachnoid space in selected patients to reduce intracranial pressure (ICP), monitor intracranial pressure, to monitor cerebrospinal fluid, and provide temporary CSF drainage for patients with infected hydrocephalic shunts.

Device Description:

The Hermetic Plus™ External Drainage Systems are designed to externally drain cerebrospinal fluid (CSF) from the lateral ventricles of the brain or the lumbar subarachnoid space to a drainage bag in selected patients. The systems connect to a ventricular or lumbar catheter via a luer connection to a patient line and ultimately to a drainage bag. The patient line is connected to a graduated burette that is then connected to the drainage bag. CSF can be collected and measured in the burette and subsequently emptied into the drainage bag by opening the stopcock placed in line between the burette and the drainage bag. An antimicrobial vent is included in the burette cap. This antimicrobial vent allows air to enter the burette to facilitate drainage from the burette to the drainage bag while protecting the system from microbial contamination. The

antimicrobial vent used on the Hermetic Plus™ systems will allow better drainage of the CSF to the drainage bag and will resist occlusion after contact with CSF without the need for clamping the burette vent tube.

The Safety Locking Knob of the Hermetic Plus™ system will now contain a titanium screw component and the cord lock of the suspension cord has been changed to an all plastic component.

Safety

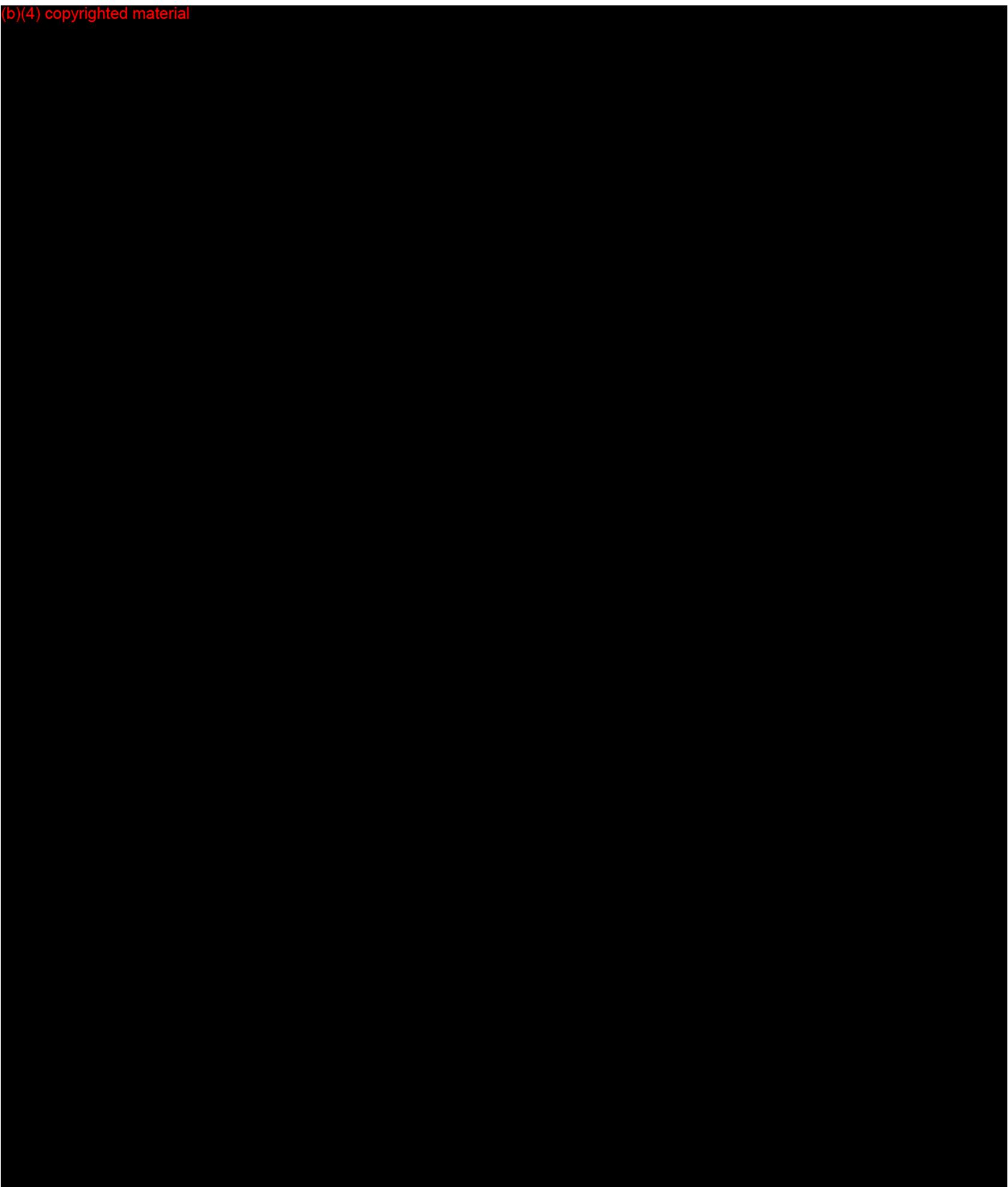
The Hermetic Plus™ External CSF Drainage Systems have been demonstrated to be MR safe* when used in the Magnetic Resonance (MR) environment.

*MRI safe is defined by the CDRH Magnetic Resonance Working Group (Feb. 7, 1997) draft document A Primer on Medical Device Interactions with MRI Systems as “The device, when used in the MRI environment, has been demonstrated to present no additional risk to the patient or other individuals, but may affect the quality of the diagnostic information.”

Testing has shown that the antimicrobial vent is resistant to occlusion after 30 minutes of exposure to fluids with high protein levels. The systems have been tested for strength of bonded components, leakage, drainage, and package integrity. Additionally, the needleless sampling sites were designed to reduce needlestick injuries and subsequent exposure to infected fluids.

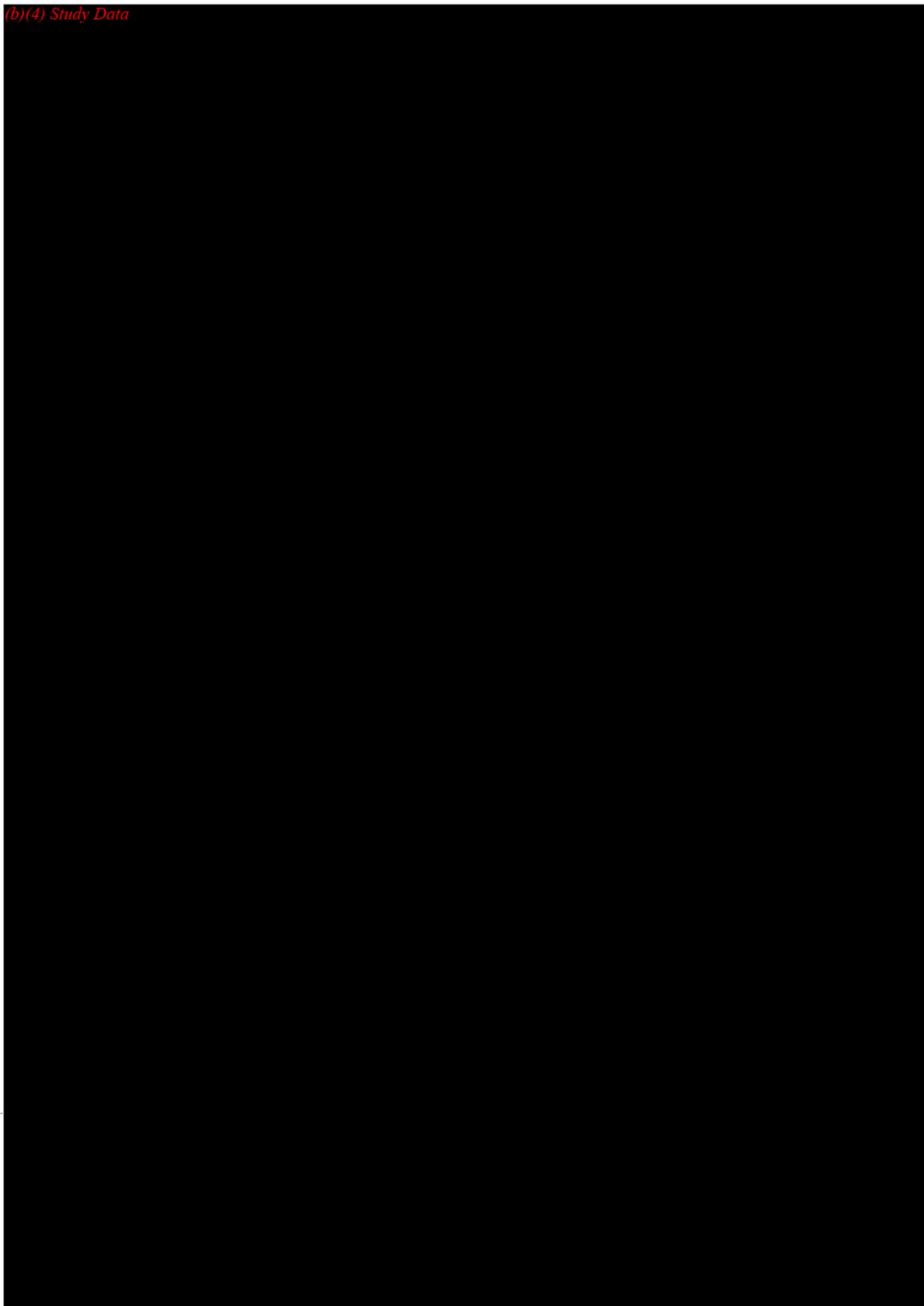
Conclusion

The Hermetic Plus™ External CSF Drainage System is substantially equivalent to the unmodified External CSF Drainage Management Systems. The modifications do not affect the intended use, the fundamental scientific technology of the device, and do not raise new issues of safety and effectiveness.

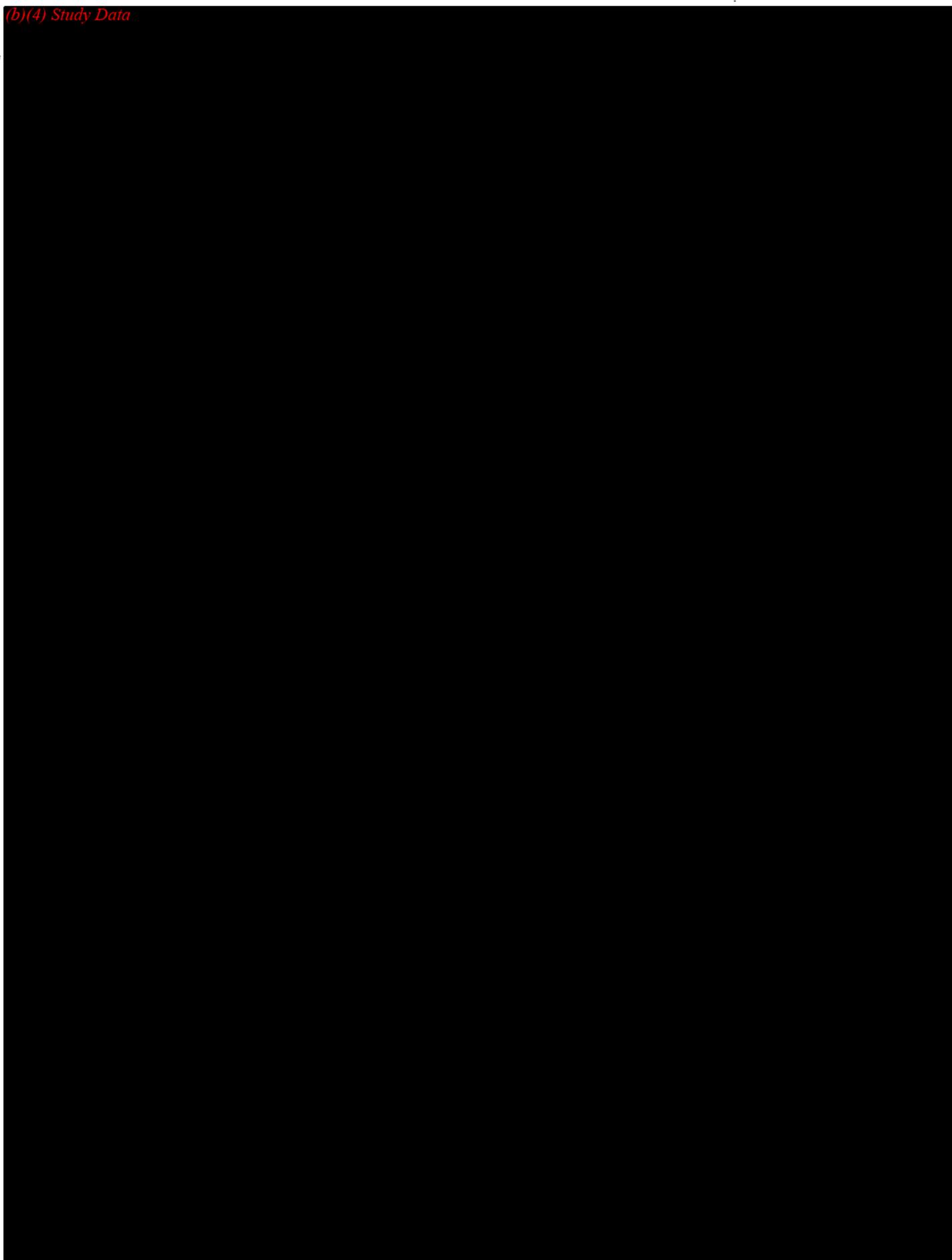


J001

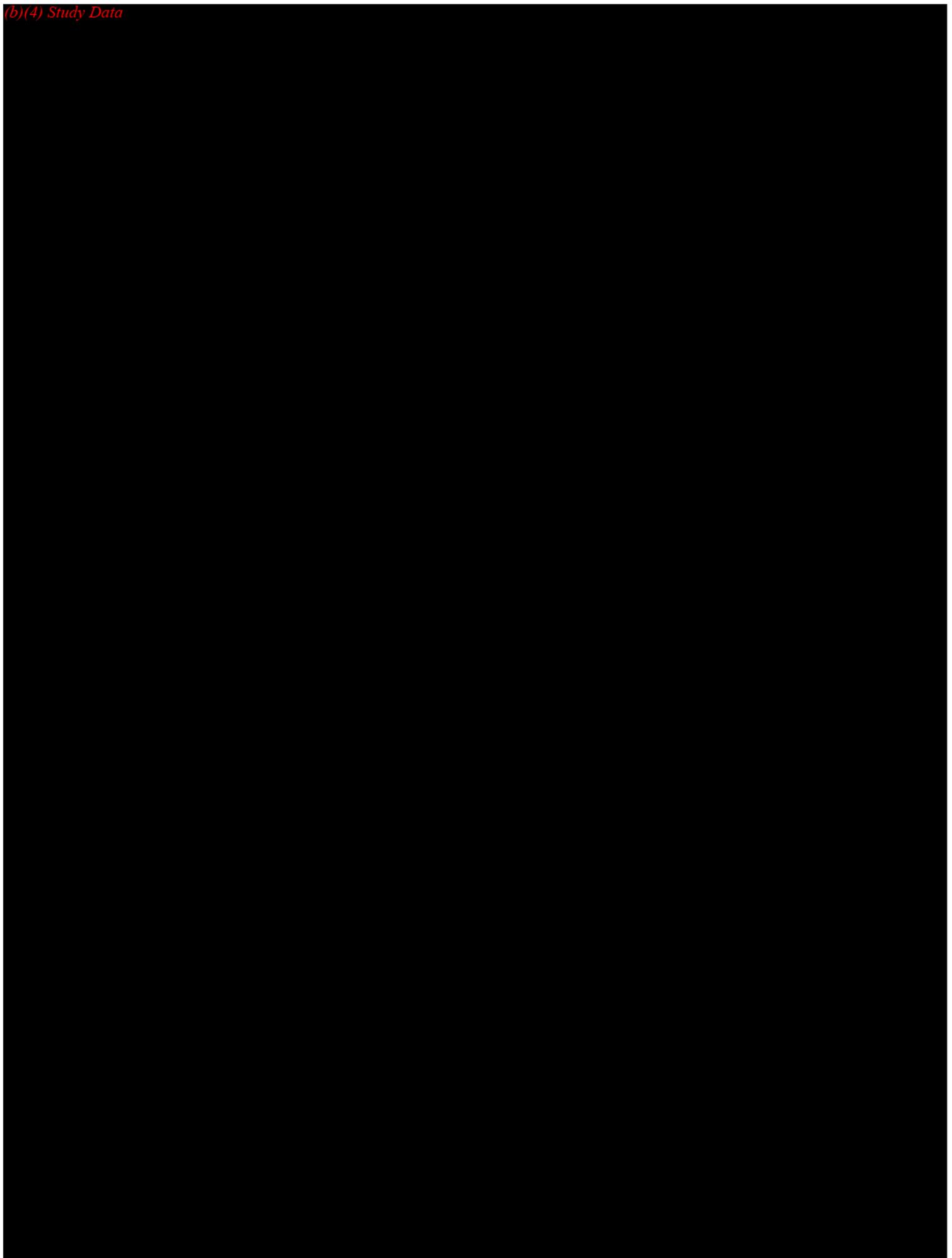
(b)(4) Study Data



(b)(4) Study Data



(b)(4) Study Data



Integra NeuroSciences
Special 510(k): Device Modification
Hermetic Plus™ External CSF Drainage System

Confidential

DECLARATION OF CONFORMITY with DESIGN CONTROLS

Verification Activities

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

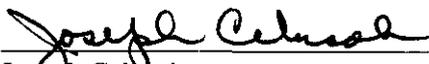


Zeev Hadass, PhD
Vice President Product Development
Integra LifeSciences Corporation

1/23/03
Date

Manufacturing Facility

The manufacturing facility, Integra NeuroSciences PR, Inc. is in conformance with the design control requirements as specified in 21 CFR 820.30 and the records are available for review.



Joseph Celusak
Director of Operations
Integra NeuroSciences PR, Inc.

1-17-03
Date

K001

97

510K Memo Record

Date: 25 February 2003

To: The record K030289

From: Dwight Yen, Electronics Engineer (HFZ 410)

Subject: Premarket notification from Integra LifeSciences Corporation for the Hermetic Plus External CSF Drainage System

Contact: Donna R. Wallace, RAC Director Regulator Affairs (609) 936-2397

Description: This is a special 510(k). The sponsor states that this is a modification of the Integra NeuroCare's External CSF Drainage System (K972994), which Integra LifeSciences has acquired (see statement dated February 24, 2003). Modifications include changes in materials, changes to the material and design of the antimicrobial vent, and changes to the labeling information for use in a Magnetic Resonance (MR) environment. Material changes include replacing the existing zinc coated steel screw with a titanium screw and using a totally plastic cord lock to make the device safe for use in an MR environment. The antimicrobial vent has been re-designed and replaced with a new hydrophobic antimicrobial vent using 1.0 um polytetrafluoroethylene (PTFE) with a polyester laminate filter. The sponsor described other changes made to the system under design control that did not require a new 510(k). These included changing the type of needleless sampling sites, mounting transducer port on support panel, and adding a leveling accessory as a convenience to the user.

The Hermetic Plus External CSF Drainage System, like the predicate, is designed to externally drain cerebrospinal fluid (CSF) from the lateral ventricles of the brain or the lumbar subarachnoid space to a drainage bag. The device connects to a ventricular or lumbar catheter via a luer connection to a patient line. The patient line connects to a graduated burette and ultimately to a drainage bag. The ventricular and lumbar catheters are provided separately and are not the subject of this 510(k).

The sponsor has satisfied the requirement for a special 510(k). The sponsor has provided statements that the intended use and indications of the modified device are the same as the predicate, and that the modification has not altered the fundamental scientific technology of the predicate device. A risk analysis using the Failure Modes and Effects Analysis (FMEA) method was performed. Design verification tests were performed based on the risk assessment, including the test method used

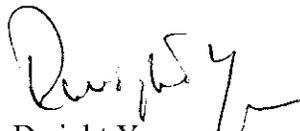
6

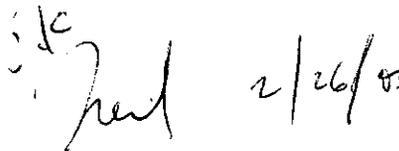
and the acceptance criteria to be applied. Finally, the sponsor has provided a declaration of conformity with design controls.

- Intended Use: The system is indicated for draining and monitoring of CSF flow from the lateral ventricles of the brain or lumbar subarachnoid space in selected patients to reduce ICP, monitor ICP, monitor CSF, and provide temporary CSF drainage for patients with infected hydrocephalic shunts. Although this intended use statement does not match the predicate (K972994) (see attached), the statement itself is accurate and is consistent with other external CSF drainage systems currently on the market. I spoke with the sponsor to verify that the changes in wording of the indication statement were to clarify the meaning of the intended use of the device. Therefore, this intended use is acceptable and is SE to predicate.
- Predicates: The device is a modification of the Integra NeuroCare's External CSF Drainage System (K972994). Changes to the device did not raise new issues of safety and effectiveness. The device is SE to predicate.
- Labeling: Draft package labels and instructions for use are provided. Information is adequate.
- Sterility: No change to the sterilization and packaging of the device.
- Manufacture: Risk assessment was performed. Validation and verification activities were performed in accordance to design control.
- Materials: Changes do not alter the biocompatibility of patient contact materials.
- Technical: Drawings of the device are provided.

An Indication for use, a 510K Summary, a Truthful and Accurate Statement are provided.

RECOMMENDATION: SE to predicate, 84 JXG Class II (882.5550).


Dwight Yen


JLC
JLC 2/26/03

SECTION 8 - DEVICE INDICATIONS FOR USE

510(k) Number (if known): K972994

Device Name: External CSF Drainage Management Systems

Indications for Use:

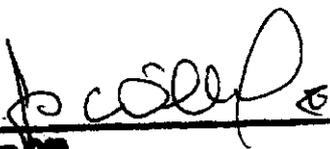
The major indication for use of the External CSF Drainage Management Systems is the management of hydrocephalic shunt infections.

If an internal shunt is not indicated, treatment of other cerebral conditions such as pre-operative drainage, intraventricular hemorrhage and post-operative pressure monitoring may also require external drainage to control increased intracranial pressure.

This device should only be used by a physician or qualified personnel under the direction of a physician.

Care must be taken to ensure compliance with the manufacturer's instructions for use.

Prescription Use Only X
(Per 21 CFR 801.109)



(Division Sign-off)
Division of General Restorative Devices
510(k) Number K972994

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

510(k) Number: K.030289

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

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

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

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

* - May not be applicable for Special 510(k)s.
 ** - Required for Class III devices, only.
 *** - See pages 3-12 and 3-13 in the Premarket Notification [510]] Manual and the Convenience Kits Interim Regulatory Guidance.

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

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

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

	Present	Inadequate or Missing
For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type. (If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.)		
For a submission, which relies on a recognized standard, a declaration of conformity [or a listing of the required elements of a declaration of conformity, SEE Required Elements for a Declaration of Conformity to a Recognized Standard, which		

is posted with the 510(k) boilers on the H drive.]		
For a submission, which relies on a recognized standard without a declaration of conformity, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has <u>not</u> been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device <u>and</u> any additional information requested by the reviewer in order to determine substantial equivalence.		
Any additional information, which is not covered by the guidance document, special control, recognized standard and/or non-recognized standard, in order to determine substantial equivalence.		

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

Section 4: Additional Requirements for ABBREVIATED and TRADITIONAL 510(k) submissions (If Applicable):

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

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

Passed Screening Yes No
 Reviewer: D. Chen
 Concurrence by Review Branch: _____

11

Date: _____

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

REVISED:3/14/95

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

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K 030299

Reviewer: DWIGHT YEN

Division/Branch: DGRND / B50A

Device Name: Hermetic Plus External CSF Drainage Sys

Product To Which Compared (510(K) Number If Known): K972994

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

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

13

1. **Intended Use:**
2. **Device Description:** Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device over-the-counter or prescription use? Does the device contain drug or biological product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

1. Explain why not a device:
2. Explain why not subject to 510(k):
3. How does the new indication differ from the predicate device's indication:
4. Explain why there is or is not a new effect or safety or effectiveness issue:
5. Describe the new technological characteristics:
6. Explain how new characteristics could or could not affect safety or effectiveness:
7. Explain how descriptive characteristics are not precise enough:
8. Explain new types of safety or effectiveness questions raised or why the questions are not new:
9. Explain why existing scientific methods can not be used:
10. Explain what performance data is needed:
11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

ATTACH ADDITIONAL SUPPORTING INFORMATION

Internal Administrative Form

	YES	NO
1. Did the firm request expedited review?	✓	
2. Did we grant expedited review?	✓	
3. Have you verified that the Document is labeled Class III for GMP purposes?	NA	
4. If, not, has POS been notified?		
5. Is the product a device?	✓	
6. Is the device exempt from 510(k) by regulation or policy?	✓	✓
7. Is the device subject to review by CDRH?	✓	
8. Are you aware that this device has been the subject of a previous NSE decision?		
9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?		✓
10. Are you aware of the submitter being the subject of an integrity investigation?		✓
11. If, yes, consult the ODE Integrity Officer.		
12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N0332, September 10, 1991.		

15



311C Enterprise Drive • Plainshoro, NJ 08536 • (609) 275-0500 • Fax: (609) 275-3684 • <http://www.Integra-LS.com>

Sent via facsimile
301-827-4350

February 24, 2003

Mr. Dwight Yen
Food and Drug Administration
Center for Devices and Radiological Health
9200 Corporate Blvd
Rockville, MD 20850

Re: Special 510(k) K030289
Hermetic Plus™ External CSF Drainage Systems

Dear Mr. Yen,

In response to our telephone conversation regarding the Special 510(k) for the Hermetic Plus™ External CSF Drainage System, please find below the responses to your questions.

1. Attached is a letter from Integra LifeSciences' General Counsel providing proof of ownership of the original (unmodified) 510(k), number K972994 for the External CSF Drainage Management Systems.
2. A report titled *Medical Device Risk Analysis Report – INS-8301 and INS-8302 Hermetic Plus Improvements* is attached. This report summarizes the medical device risk assessment for the family of external drainage systems which includes the Hemetic Plus™ External CSF Drainage Systems and is based upon the modifications made to the Hermetic Plus™ systems.

If you have any further questions, please do not hesitate to contact me at 609-936-2397 or by facsimile at 609-275-9445.

Sincerely,

Donna R. Wallace
Director, Regulatory Affairs

Attachments 3 pages

Hermetic Plus™ External CSF Drainage Systems

16



311C Enterprise Drive • Plainsboro, NJ 08536 • (609) 936-2238 • Fax: (609) 275-9006 • www.Integra-LS.com

February 24, 2003

By Fax 301-827-4350

Mr. Dwight Yen
Center for Devices and Radiological Health
United States Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

Re: Response to questions regarding review of Special 510K K030289

Dear Mr. Yen:

I write in response to the question raised during the review of the Special 510K-K030289 regarding ownership by Integra LifeSciences Corporation of the original (unmodified) 510(K) K 972994, External CSF Drainage Management System, cleared on November 3, 1997.

Integra LifeSciences Corporation currently is the owner of the above-referenced 510(k) file. Pursuant to an Asset Purchase Agreement dated March 29, 1999, two subsidiaries of Integra LifeSciences Corporation acquired substantially all of the assets of the Neurocare Group of companies from Heyer-Schulte NeuroCare, L.P. and Neuro Navigational L.L.C. Included among those assets were all regulatory filings made with any governmental agency, including, but not limited to, FDA, as well as all approvals and clearances from any governmental agency (again, including, but not limited to, those from FDA). As a result, the original (unmodified) 510(k) file was part of the assets sold to the Integra companies. The closing on the transactions that were the subject of the Asset Purchase Agreement took place in April 1999. In 2001, Integra merged the subsidiaries that were parties to the Asset Purchase Agreement with and into Integra LifeSciences Corporation. As a result of that merger, Integra LifeSciences Corporation became the owner of the original (unmodified) 510(k) file. FDA was notified in writing of the change in ownership of these companies.

If you have any questions about the ownership of this 510(k) file, please call me.

Sincerely,

Richard D. Gorelick
Vice President and General Counsel

cc D. Wallace

17

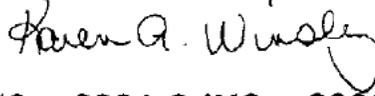


INTEGRA NEUROSCIENCES

Date: February 21, 2003

To: Donna Wallace – Director of Regulatory Affairs

From: KA Winsley – Senior Product Development Manager

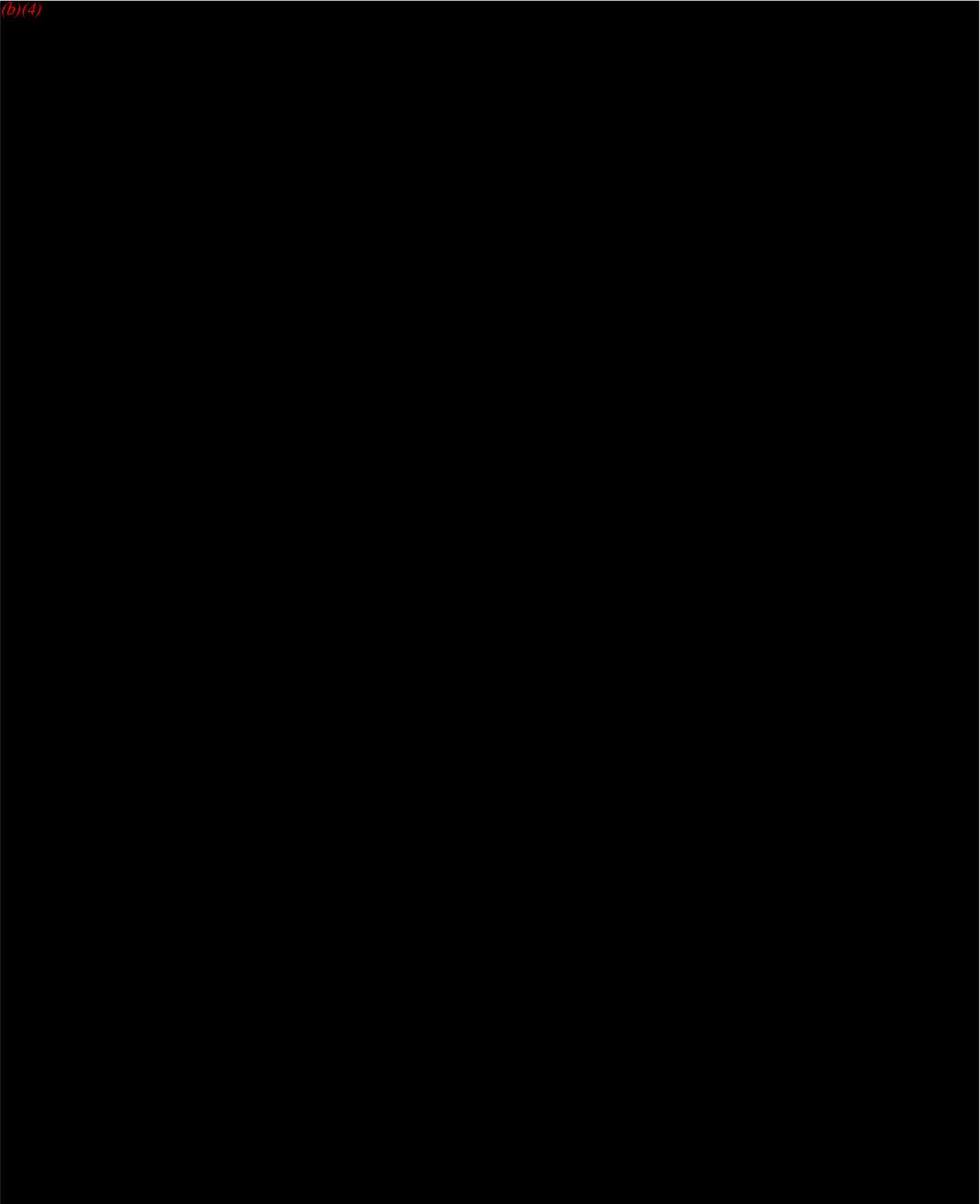


Medical Device Risk Analysis Report – INS – 8301 & INS – 8302 Hermetic Plus Improvements

(b)(4)



(b)(4)



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

From: Reviewer(s) - Name(s)

DWIGHT YEN

Subject: 510(k) Number

K030289

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

- Refused to accept.
- Requires additional information (other than refuse to accept).
- Is substantially equivalent to marketed devices.
- NOT substantially equivalent to marketed devices.

De Novo Classification Candidate? YES NO

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

Is this device subject to Postmarket Surveillance? YES NO

Is this device subject to the Tracking Regulation? YES NO

Was clinical data necessary to support the review of this 510(k)? YES NO

Is this a prescription device? YES NO

Was this 510(k) reviewed by a Third Party? YES NO

Special 510(k)? YES NO

Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers YES NO

This 510(k) contains:

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

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

The required certification and summary for class III devices

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

Animal Tissue Source YES NO

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

No Confidentiality Confidentiality for 90 days Continued Confidentiality exceeding 90 d

Predicate Product Code with class:

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

84 JxG Class II

882.5550

Review: *[Signature]*
(Branch Chief)

GSDB
(Branch Code)

2/26/03
(Date)

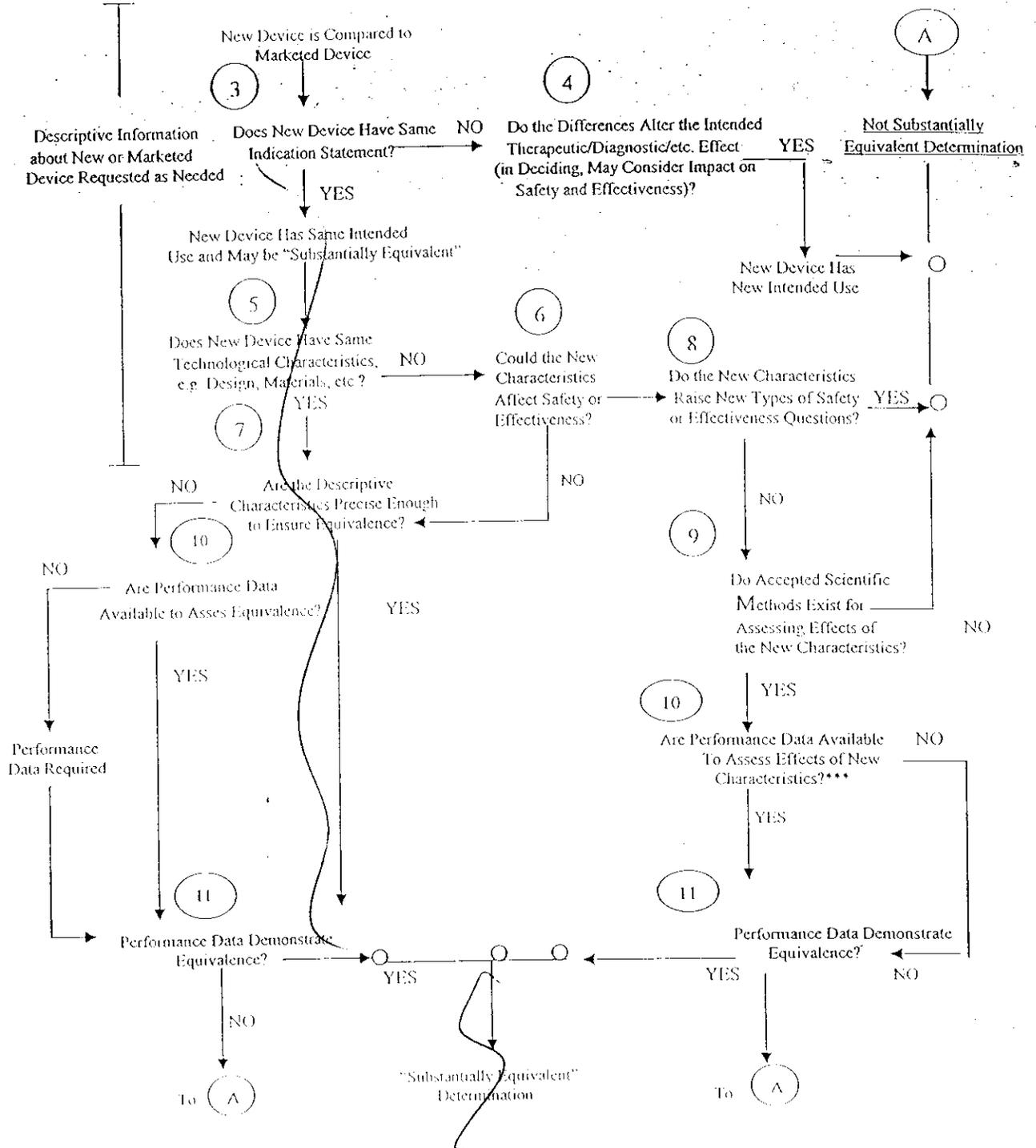
Final Review: *Miriam C. Provost*
for (Division Director)

2/26/03
(Date)

Revised 8/17/99

4

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



- ❖ 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear
- ❖❖ This decision is normally based on descriptive information alone, but limited testing information is sometimes required
- ❖❖❖ Data may be in the 510(f), other 510(k)s, the Center's classification files, or the literature