AUG 1 2 2008

K081942

US Vygon (US), LLC, 2495 General Armistead Avenue, Norristown, PA 19403, USA
Office Phone: 610 539-9300 800462-2562 Office Fax: 610 539-9333

PREMARKET NOTIFICATION
510(k) SUMMARY
(As Required By 21 CFR 807.93)

Date of Preparation: June 20, 2008

Applicant:	Vygon Neuro 2495 General Armistead Ave. Norristown, PA 19403
Contact Individual:	Courtney Smith, Regulatory Affairs Manager 610-539-9300 Ext. 110
Trade Name:	Neurocath Ag
Common Name:	External Drainage Catheter
Regulation Number:	882.5550
Product Code:	JXG
Classification Name:	Shunt, Central Nervous System and Components
Classification:	Class II
Predicate Device Name:	Fifth Ventricle External Drainage Catheter (K800168/ K870660), Extracorporeal Ventricular Catheters (preamendment)
Device Description:	The Neurocath Ag is an external drainage catheter composed of polyurethane and impregnated with the silver ions for the purpose of radiopacity. The catheter is available with 3 holes off-set at 120°, or 16 holes, in lengths of 32, 23.5, and 15.5cm. Biocompatibility and performance testing demonstrates the safety and efficacy of these devices. The Neurocath Ag is supplied with a stainless steel stylet (for introducing it into the ventricle), a stainless steel subgaleal trochar (for tunneled catheter placement), a male luer connector, a slitted wing and a compression hub (for connecting the catheter to the tubing set). The Neurocath Ag catheter is available individually or packaged with the tubing set.

The Neurocath Ag catheters are as follows:

Description	Reference
Neurocath Ag Catheters	8335.xxx

Intended Use: The Neurocath Ag catheter is designed to be temporarily implanted (less than 30 days) for the drainage of cerebrospinal fluid (CSF) to reduce and control increased intracranial pressure (ICP).

Technology Characteristics: The fundamental scientific technology of the Neurocath Ag is substantially equivalent to the predicate devices.

Summary of Design Control Activities:
Biocompatibility testing of the material demonstrate that it is non-irritant and non-toxic. Performance testing demonstrates that the changes do not affect safety or efficacy. Risk Assessment was conducted in compliance with ISO 14971.

Conclusion: The only change between the predicate device (Fifth Ventricle Drainage Catheter K800168 and K853365) and the preamendment predicate device and the Neurocath Ag is the change in material from barium impregnated silicone and silver impregnated silicone, respectively, to polyurethane impregnated with silver ions. Biocompatibility testing, performance testing and risk assessment demonstrate that the Neurocath Ag is safe and effective to use, when used in accordance with the supplied instructions for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Vygon Neuro
% Courtney Smith
Regulatory Affairs Manager
2495 General Armistead Avenue
Norristown, Pennsylvania 19403

AUG 12 2008

Re: K081942
Trade/Device Name: Neurocath Ag
Regulation Number: 21 CFR 882.5550
Regulation Name: Central nervous system fluid shunt and components
Regulatory Class: II
Product Code: JXG
Dated: July 7, 2008
Received: July 16, 2008

Dear Courtney Smith:

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

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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 (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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

Indications for Use

510(k) Number (if known): K081942

Device Name: Neurocath Ag

Indications For Use:

The Neurocath Ag catheter is designed to be temporarily implanted (less than 30 days) for the drainage of cerebrospinal fluid (CSF) to reduce and control increased intracranial pressure (ICP).

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K081942

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Vygon Neuro
% Courtney Smith
Regulatory Affairs Manager
2495 General Armistead Avenue
Norristown, Pennsylvania 19403

AUG 12 2008

Re: K081942
Trade/Device Name: Neurocath Ag
Regulation Number: 21 CFR 882.5550
Regulation Name: Central nervous system fluid shunt and components
Regulatory Class: II
Product Code: JXG
Dated: July 7, 2008
Received: July 16, 2008

Dear Courtney Smith:

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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.

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If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

Indications for Use

510(k) Number (if known): K081942

Device Name: Neurocath Ag

Indications For Use:

The Neurocath Ag catheter is designed to be temporarily implanted (less than 30 days) for the drainage of cerebrospinal fluid (CSF) to reduce and control increased intracranial pressure (ICP).

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

Page 1 of 1

510(k) Number K081942

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-40
9200 Corporate Blvd.
Rockville, Maryland 20850

July 17, 2008

VYGON NEURO
2495 GENERAL ARMISTEAD AVE.
NORRISTOWN, PA 19403
ATTN: COURTNEY SMITH

510(k) Number: K081942
Received: 16-JUL-2008
Product: NEUROCATH AG

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

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC)(HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 510(k) submission.

On September 27, 2007, the President signed an act reauthorizing medica device user fees for fiscal years 2008 - 2012. The legislation - the Medical Device User Fee Amendments of 2007 is part of a larger bill, th Food and Drug Amendments Act of 2007. Please visit our website at http://www.fda.gov/cdrh/mdufma/index.html for more information regardin fees and FDA review goals. In addition, effective January 2, 2008, any firm that chooses to use a standard in the review of ANY new 510(k) nee to fill out the new standards form (Form 3654) and submit it with their 510(k). The form may be found at http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf.

We remind you that Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) amended the PHS Act by adding new sectio 402(j) (42 U.S.C. ' 282(j)), which expanded the current database known ClinicalTrials.gov to include mandatory registration and reporting of results for applicable clinical trials of human drugs (including biological products) and devices. Section 402(j) requires that a certification form (http://www.fda.gov/opacom/morechoices/fdaforms/ FDA-3674.pdf) accompany 510(k)/HDE/PMA submissions. The agency has issu

a draft guidance titled: "Certifications To Accompany Drug, Biological Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Foo and Drug Administration Amendments Act of 2007" (http://www.fda.gov/oc/initiatives/fdaaa/guidance_certifications.html). According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

Please note the following documents as they relate to 510(k) review: 1)Guidance for Industry and FDA Staff entitled, "Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements". This guidance can be found at http://www.fda.gov/cdrh/ode/guidance/1655.pdf. Please refer to this guidance for information on a formalized interactive review process. 2)Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at www.fda.gov/cdrh/ode/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditiona or Abbreviated 510(k).

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electron copy. For more information about the program, including the formatting requirements, please visit our web site at www.fda.gov/cdrh/elecsub.html.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice www.fda.gov/cdrh/devadvice/" If you have questions on the status of your submission, please contact DSMICA at (240) 276-3150 or the toll-free number (800) 638-2041, or at their Internet address http://www.fda.gov/cdrh/dsma/dsmastaf.html. If you have procedural questions, please contact the 510(k) Staff at (240)276-4040.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Office of Device Evaluation
Center for Devices and Radiological Heal

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DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

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

July 09, 2008

VYGON NEURO
2495 GENERAL ARMISTEAD AVE.
NORRISTOWN, PA 19403
ATTN: COURTNEY SMITH

510(k) Number: K081942
Received: 08-JUL-2008
User Fee ID Number: 6037107
Product: NEUROCATH AG

The Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH), 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 all future correspondence that relates to this submission. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

The Federal Food, Drug, and Cosmetic Act (the Act), as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) and the FDA Amendments Act of 2007 (FDAAA) (Public Law 110-85), authorizes FDA to collect user fees for certain types of 510(k) submissions. The submission cannot be accepted for review until the fee is paid in full ; therefore, the file has been placed on hold. When your user fee payment has been received , review of the 510(k) will resume as of that date. Alternatively, you may request withdrawal of your submission. Please send a check to one of the addresses listed below:

By Regular Mail	By Private Courier(e.g.,Fed Ex, UPS, etc.)
Food and Drug Administration P.O. Box 956733 St. Louis, MO 63195-6733.	U.S. Bank 956733 1005 Convention Plaza St. Louis, MO 63101 (314) 418-4983

The check should be made out to the Food and Drug Administration referencing the payment identification number, and a copy of the User Fee Cover sheet should be included with the check. A copy of the Medical Device User Fee Cover Sheet should be faxed to CDRH at (240)276-4025 referencing the 510(k) number if you have not already sent it in with your 510(k) submission. After the FDA has been notified of the receipt of your user fee payment, your 510(k) will be filed and the review will begin. If payment has not been received within 30 days, your 510(k) will be deleted from the system. Additional information on user fees and how to submit your user fee payment may be found at www.fda.gov/oc/mdufma.

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, or HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at www.fda.gov/cdrh/elecsub.html.

Please note that since your 510(k) has not been reviewed, additional information may be required during the review process and the file may be placed on hold once again. If you are unsure as to whether or not you need to file a 510k Submission with FDA or what type of submission to submit, you should first telephone the Division of Small Manufacturers, International and Consumer Assistance (DSMICA), for guidance at (240) 276-3150 or its toll-fee number (800)638-2041, or contact them at their Internet address www.fda.gov/cdrh/dsma/dsmastaf.html, or you may submit a 513(g) request for information regarding classification to the Document Mail Center at the address above. If you have any questions concerning receipt of your payment, please contact Christina Zeender at Christina.Zeender@fda.hhs.gov. If you have questions regarding the status of your 510(k) Submission, please contact DSMICA at the numbers or address above.

Sincerely yours,

Diane M. Garcia
Public Affairs Specialist
Office of Device Evaluation
Center for Devices and
Radiological Health

K081942

Vygon us, LLC, 2495 General Armistead Avenue, Norristown, PA 19403, USA
Office Phone: 610 539-9300 800462-2563 Office Fax: 610 539-9333

July 7, 2008

Food and Drug Administration
Center for Devices and Radiologic Health
Office of Device Evaluation
Document Mail Center (HFZ-410)
9200 Corporate Blvd.
Rockville, MD 20850
301-594-1307

JUL - 9 2008

Dear Sirs:

Enclosed you will find the pre market notification 510(k) submission for the Vygon Neurocath Expert.

Should you have any questions, please don't hesitate to contact me.

Best Regards,

Courtney Smith

Courtney Smith
Manager, Regulatory / Quality

K48
NE
II

Vygon us, LLC, 2495 General Armistead Avenue, Norristown, PA 19403, USA
Office Phone: 610 539-9300 800462-2563 Office Fax: 610 539-9333

Original 510(K) Submission

Vygon Neuro

Neurocath Ag

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Table of Contents
Neurocath Ag
510(k) Submission

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Form Approved: OMB No. 0910-511 Expiration Date: January 31, 2010 See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
MEDICAL DEVICE USER FEE COVER SHEET

PAYMENT IDENTIFICATION NUMBER: (b)(4)
Write the Payment Identification number on your check.

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

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)

VYGON CORP
2495 GENERAL ARMISTEAD AVE
NORRISTOWN PA 19403
US

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
222505335

2. CONTACT NAME
Courtney Smith

2.1 E-MAIL ADDRESS
csmith@vygonus.com

2.2 TELEPHONE NUMBER (include Area code)
610-539-9300 110

2.3 FACSIMILE (FAX) NUMBER (Include Area code)
610-539-9333

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/dc/mdufma

Select an application type:
[X] Premarket notification(510(k)); except for third party
[ ] 513(g) Request for Information
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)
[ ] Annual Fee for Periodic Reporting (APR)
[ ] 30-Day Notice

3.1 Select one of the types below
[X] Original Application
Supplement Types:
[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] Real-Time (PMA, PMR, PDP)
[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)
[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
[X] NO, I am not a small business
4.1 If Yes, please enter your Small Business Decision Number:

5. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.
[ ] This application is the first PMA submitted by a qualified small business, including any affiliates, parents, and partner firms
[ ] The sole purpose of the application is to support conditions of use for a pediatric population
[ ] This biologics application is submitted under secion 351 of the Public Health Service Act for a product licensed for further manufacturing use only
[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

6. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).)
[ ] YES [X] NO

7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION
(b)(4)

23-Jun-2008

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 9010-0120
Expiration Date: May 31, 2007.
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number (if known)
9/7/08	(b)(4)	

SECTION A TYPE OF SUBMISSION

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

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

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

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name	Establishment Registration Number *(if known)*		
Vygon Neuro	2518608		
Division Name *(if applicable)*	**Phone Number** *(including area code)*		
NA	(610) 539-9300		
Street Address	**FAX Number** *(including area code)*		
2495 General Armistead Ave	(610) 539-9333		
City	**State / Province**	**ZIP/Postal Code**	**Country**
Norristown	PA	19403	USA
Contact Name			
Courtney Smith			
Contact Title	**Contact E-mail Address**		
Regulatory Affairs Manager	csmith@vygonus.com		

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SECTION C	APPLICATION CORRESPONDENT (e.g., consultant, if different from above)		
Company / Institution Name			
Division Name *(if applicable)*	Phone Number *(including area code)*		
Street Address	FAX Number *(including area code)*		
City	State / Province	ZIP/Postal Code	Country
Contact Name			
Contact Title	Contact E-mail Address		

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

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

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

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

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

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

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

- ☐ Response to FDA correspondence:

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

- ☐ Other Reason *(specify)*:

SECTION D2 REASON FOR APPLICATION - IDE

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

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

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

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

☐ Other Reason *(specify):*

SECTION D3 REASON FOR SUBMISSION - 510(k)

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

☒ Other Reason *(specify):*

Change in Material from Silicone to Polyurethane impregnated with AgION^{tm}

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	JXG			3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information
- ☒ 510 (k) summary attached
- ☐ 510 (k) statement

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

	510(k) Number	*Trade or Proprietary or Model Name*	*Manufacturer*
1	K853365	Fifth Ventricle External Drainage System and Components	Holter-Hausner
2	K800168	Fifth Ventricle External Drainage System and Components	Holter-Hausner
3	Preamendment	Silver Impregnated Ventricular Catheters	Holter Company
4			

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SECTION F — PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification

External Drainage Catheter

	Trade or Proprietary or Model Name for This Device		Model Number
1	Neurocath Ag	1	8335.xxx
2			
3		3	
4		4	
5		5	

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

1	2	3	4	5	6
K063292					
7	8	9	10	11	12

Data Included in Submission

☒ Laboratory Testing ☒ Animal Trials ☐ Human Trials

SECTION G — PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

duct Code G	C.F.R. Section *(if applicable)* 882.5550	Device Class ☐ Class I ☒ Class II ☐ Class III ☐ Unclassified
Classification Panel Neurology		

Indications *(from labeling)*

This device is intended for use as a means of temporary external diversion, pressure monitoring and collection of cerebrospinal fluid. The catheters incorporate silver ions for the purpose of radiopacity.

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

SECTION II MANUFACTURING, PACKAGING, STERILIZATION SITES RELATING TO A SUBMISSION

☒ Original ☐ Add ☐ Delete	FDA Establishment Registration Number 2518608	☒ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler	
Company / Institution Name Vygon Neuro		Establishment Registration Number 2518608		
Division Name *(if applicable)*		Phone Number *(including area code)* (610) 539-9300		
Street Address 2495 General Armistead Ave		FAX Number *(including area code)* (610) 539-9333		
City Norristown		State / Province PA	ZIP/Postal Code 19403	Country USA
Contact Name Courtney Smith	Contact Title Regulatory Affairs Manager	Contact E-mail Address csmith@vygonus.com		

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

☐ Original ☐ Add ☐ Delete	FDA Establishment Registration Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler	
Company / Institution Name		Establishment Registration Number		
Division Name *(if applicable)*		Phone Number *(including area code)* ( )		
Street Address		FAX Number *(including area code)* ( )		

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City	State / Province	ZIP/Postal Code	Country

Contact Name	Contact Title	Contact E-mail Address

SECTION I UTILIZATION OF STANDARDS

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

	Standards No.	Standards Organization	Standards Title	Version	Date
1	13485	CAN-CSA ISO	Medical devices – Quality management systems – Requirements for regulatory purposes	2003	2003
2	14971	BS EN ISO	Medical devices – Application of risk management to medical devices	2000	2001
	10993-1	BS EN ISO	Biological evaluation of medical devices. Part 1. Evaluation and testing	1997	1998
4	1617	EN	Sterile drainage catheters and accessory devices for single use	1997	1997
5	1618	EN	Catheters other than intravascular catheters – Test methods for common properties	1997	1997
6	13868	EN	Catheters – Test methods for kinking of single lumen catheters and medical tubing	2002	2002

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

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Food and Drug Administration
CDRH (HFZ-342)
9200 Corporate Blvd.
Rockville, MD 20850

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

Indications for Use

510(k) Number (if known):

Device Name: Neurocath Ag

Indications For Use:

This device is intended for use as a means of temporary external diversion, pressure monitoring and collection of cerebrospinal fluid. The catheters incorporate silver ions for the purpose of radiopacity.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Vygon us, LLC, 2495 General Armistead Avenue, Norristown, PA 19403, USA
Office Phone: 610 539-9300 800462-2563 Office Fax: 610 539-9333

PREMARKET NOTIFICATION
510(k) SUMMARY
(As Required By 21 CFR 807.93)

Date of Preparation: June 20, 2008

Applicant:	Vygon Neuro 2495 General Armistead Ave. Norristown, PA 19403
Contact Individual:	Courtney Smith, Regulatory Affairs Manager 610-539-9300 Ext. 110
Trade Name:	Neurocath Ag
Common Name:	External Drainage Catheter
Regulation Number:	882.5550
Product Code:	JXG
Classification Name:	Shunt, Central Nervous System and Components
Classification:	Class II
Predicate Device Name:	Fifth Ventricle External Drainage Catheter (K800168/ K870660), Extracorporeal Ventricular Catheters (preamendment)
Device Description:	The Neurocath Ag is an external drainage catheter composed of polyurethane and impregnated with the silver ions for the purpose of radiopacity. The catheter is available with 3 holes off-set at 120°, or 16 holes, in lengths of 32, 23.5, and 15.5cm. Biocompatibility and performance testing demonstrates the safety and efficacy of these devices.

The Neurocath Ag catheters are as follows:

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Description	Reference
Neurocath Ag Catheters	8335.xxx

Intended Use: This device is intended for use as a means of temporary external diversion, pressure monitoring and collection of cerebrospinal fluid. The catheters incorporate silver ions for the purpose of radiopacity.

Technology Characteristics: The fundamental scientific technology of the Neurocath Ag is substantially equivalent to the predicate devices.

Summary of Design Control Activities:

Biocompatibility testing of the material demonstrate that it is non-irritant and non-toxic. Performance testing demonstrates that the changes do not affect safety or efficacy. Risk Assessment was conducted in compliance with ISO 14971.

Conclusion: The only change between the predicate device (Fifth Ventricle Drainage Catheter K800168 and K853365) and the preamendment predicate device and the Neurocath Ag is the change in material from barium impregnated silicone and silver impregnated silicone, respectively, to polyurethane impregnated with silver ions. Biocompatibility testing, performance testing and risk assessment demonstrate that the Neurocath Ag is safe and effective to use, when used in accordance with the supplied instructions for use.

Courtney Smith 6/26/08

Courtney Smith Date
Regulatory Affairs Manager

Vygon us, LLC, 2495 General Armistead Avenue, Norristown, PA 19403, USA
Office Phone: 610 539-9300 800462-2563 Office Fax: 610 539-9333

PREMARKET NOTIFICATION

TRUTHFUL AND ACCURATE STATEMENT

[As Required by 21 CFR 807.87(k)]

I certify that, in my capacity as Regulatory Affairs Manager for Vygon Corporation, I believe to the best of my knowledge that all data and information submitted in the premarket notification are truthful and accurate and that no material has been omitted.

Courtney Smith 6/26/08

Courtney Smith Date
Regulatory Affairs Manager

Device Description/Specifications

Neurocath Ag

DESCRIPTION

The Neurocath Ag is an external drainage catheter composed of polyurethane and impregnated with the silver ions for the purpose of radiopacity.
The catheter is available with 3 holes off-set at 120°, or 16 holes, in lengths of 32, 23.5, and 15.5cm. Biocompatibility and performance testing demonstrates the safety and efficacy of these devices.

The Neurocath Ag is double-packaged, and is STERILE AND NON-PYROGENIC unless the inner pouch is opened or damaged.

PRODUCT HISTORY

The Neurocath Ag is a new device and as such does not yet have any market history. Similar external drainage catheters, such as the FVPC, FVPC1, FVPC2, have been manufactured and distributed world wide, by Vygon and it predecessor companies, since the early 1980s.

PERFORMANCE

Feature	**8335.139 8335.239**	**8335.129 8335.229**	**8335.119 8335.229**
Catheter Material	Polyurethane impregnated with AgION		
Catheter length (cm)	32	23.5	15.5
OD (mm)	2.9		
ID (mm)	1.8		
Force at Break (N)	61.29		
Kink Test (mm)	6.3		
Resistance to Deformation	Pass		

See Annex 5 for additional performance information.

Labeling

1. Instructions for Use

Refer to Annex 1 for a draft of the Instructions for Use.

2. Labeling

Sample labeling is attached in Annex 1

Sterilization Information

Neurocath Ag is sterilized by Ethylene Oxide. The Neurocath Ag is packaged in a (b)(4) pouch and a tray with a (b)(4) lid. The material specifications are as follows:

Pouch:
- (b)(4)
- (b)(4)

Lidstock:
- (b)(4)

Tray:
(b)(4)

The See Annex 2 for sterilization validation information.

Substantial Equivalence Tables

Device Name:	**Neurocath Ag**	**Fifth Ventricle Drainage Catheter (K800168/ K870660)**	**Holter Drainage Catheters (preamendment)**
Classification	II	II	NA
Classification Name	Shunt, Central Nervous System and Components	Shunt, Central Nervous System and Components	Shunt, Central Nervous System and Components
Indications for Use	This device is intended for use as a means of temporary external diversion, pressure monitoring and collection of cerebrospinal fluid. The catheters incorporate silver ions for the purpose of radiopacity.	This device is intended for use as a means of temporary external diversion, pressure monitoring and collection of cerebrospinal fluid.	This device is intended for use as a means of temporary external diversion, pressure monitoring and collection of cerebrospinal fluid. The catheters incorporate silver for the purpose of radiopacity.
Materials	Polyurethane impregnated with silver ions	Silicone	Silicone impregnated with silver
Usable Length (cm)	15.5, 23.5, 32	15, 23.5, 35	15, 23.5, 35
Target Population	Pediatric and Adults	Pediatric and Adults	Pediatric and Adults
Sterility	EO	EO	EO

Vygon has conducted chemical composition testing on the Neurocath Ag, as well as the preamendment predicate device. The results are as follows:

Device	**% Silver Composition**
Holter Ventricular Drainage Catheters (preamendment)	(b)(4)
Neurocath Ag	(b)(4)

The See Annex 3 for the following predicate information:

1. Copy of Holter Catalog indicating silver catheters
2. Chemical composition testing of Neurocath Ag and predicate catheter
3. Letter from (b)(6) former employee of Holter Company

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Materials and Biocompatibility Information

The Neurocath Ag was designed and conforms with the International biocompatibility standard ISO10993-1 (1997) Biological Evaluation of Medical Devices Part 1 Evaluation and Testing, and USP testing requirements. The Neurocath Ag consists of the following materials:

Component	Vendor	Material	Contact
Catheter Tube	Agion	Polyurethane impregnated with Agion [redacted]	Direct
Stylet	Vygon GmBh	[redacted] Stainless Steel	In Direct

AL85H-M Product Specifications:

Parameter	Analytical Method	Unit	AL85H-M Specification Values
Maximum Water Content	Gravimetric Analysis	Wt%	[redacted]
Silver Content	Atomic Absorption	Wt%	
Zinc Content	Atomic Absorption	Wt%	
Particle Size Distribution	Laser Particle Analysis	µm	

AL85H-M Typical Properties:

Appearance	Fine white to yellow powder
Crystal Structure	[redacted]
pH in water (1g/100ml)	
True Specific Gravity	
Bulk Density	

See Annex 4 for the following biocompatibility information:

1. Agion powder compounded into PUR Biocompatibility Testing
2. Multicath Expert Biocompatibility Testing
3. Stability testing on Expert catheters
4. Brain Implant Study

Performance Data and Testing

The Neurocath Ag was designed and conforms to International testing standards EN 1617:1997, EN 1618:1997, EN 13868:2002. See Annex 5 for the following documents:

1. Engineering Drawings
2. Risk Analysis
3. Validation Test Reports

Vygon us, LLC, 2485 General Armistead Avenue, Norristown, PA 19403, USA
Office Phone: 610 539-9300 800462-2563 Office Fax: 610 539-9333

DECLARATION OF CONFORMITY

Neurocath Ag Catheter

We hereby declare that the Neurocath Ag Catheter meets the predetermined performance criteria. The Catheter, as demonstrated by the submission, is substantially equivalent to predicate devices, the Fifth Ventricle External Drainage Catheter (K800168, K853365) and the preamendment, Holter ventricular drainage catheters. All verification and validation activities were performed by the designated individual(s) and the results demonstrate that the predetermined acceptance criteria were met.

All of the products at designed and manufactured at Vygon Neuro conform to the Quality System Requirements and Design Controls set forth in FDA 21 CFR Part 820 Medical Devices and 21 CFR 820.30 in particular and all appropriate records are available for review.

Courtney Smith 6/26/08

Courtney Smith Date
Regulatory Affairs Manager

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Vygon US, LLC, 2495 General Armistead Avenue, Norristown, PA 19403, USA
Office Phone: 610 539-9300 800 462-2563 Office Fax: 610 539-9333

Sterilization Specifications

Cycle: All Vygon products are sterilized by 100% ethylene oxide.

Validation: The cycle has been validated according to the requirements of ISO-11135, EN 550, "Medical Devices – Validation and Routine Control of Ethylene Oxide Sterilization."

Re-validation: Conducted annually according to ISO-11135. EN 550

Expiration: Five years from date of sterilization. Verified by membrane filtration analysis on real time product units.

Residuals: (b)(4) [redacted]

Sterility: Sterility assurance Level 10^{-6}(each lot of product).

Pyrogen: (b)(4) [redacted]

(b)(4) [redacted]

Sterilization

(b)(4)

[redacted]

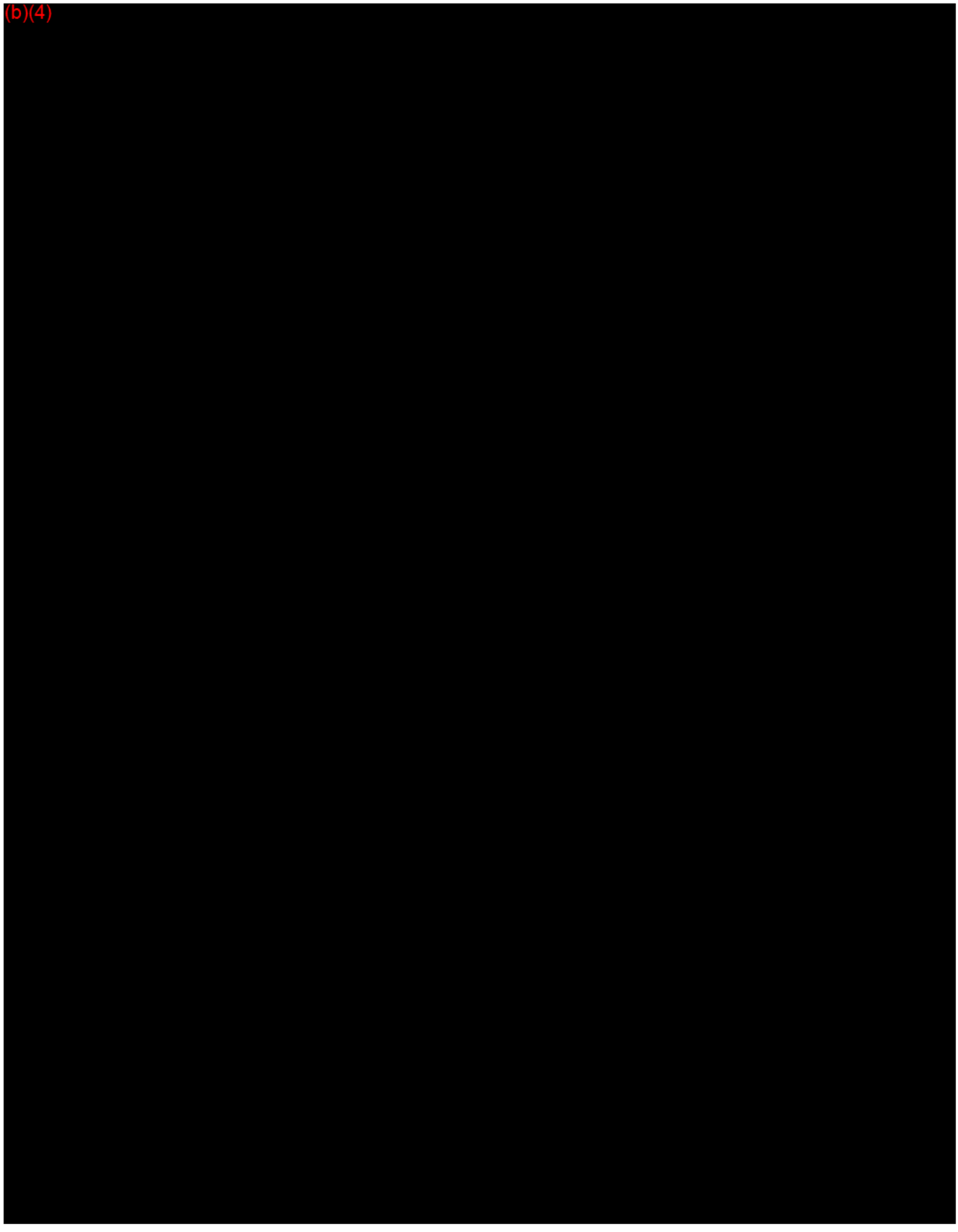
Sterilization Equivalency

(b)(4)

[redacted]

Sterilization Equivalency

(b)(4)



Sterilization Equivalency

(b)(4)

II. Risk Evaluation

(b)(4)

Sterilization Equivalency

III. Risk Reduction

(b)(4)

IV. Residual Risk/ Completeness of Risk Evaluation

All foreseeable risks have been identified and evaluated. No residual risks were identified after the control measures were applied.

V. Post-production Information

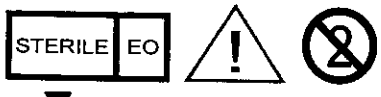
This is a new device. There is no post-production information available yet.

REF:OVA

8335.139

Neurocath Expert, 32cm long,
3 holes at 120°
9Fr Compression Hub
Trocar

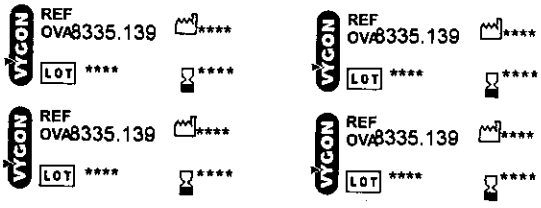
STERILIZATION LOT # VN-****



Pyrogen-Free
Made in the USA

VYGON NEURO

ISO 13485
P.O. Box 80390
Valley Forge, Pa. 19484
Ph 610/539-9300
800/462-2563 Fax 610/539-9333



Caution:	To be used by physicians only
Achtung:	Ausschliesslich von Ärzten zu verwenden
Attention:	À l'usage exclusif des médecins
Atenção:	Para ser usado somente por medicos
Atención:	Para ser usado solamente por médicos
Avvertenza:	Usato Solomente da dottori

EO 685-04/05

REF:OVA

8335.139

Neurocath Expert, 32 cm
3 Holes at 120°
9 Fr Compression Hub
Trocar

STERILIZATION LOT # VN-****

ISO 13485

FOLLOW INSTRUCTIONS FOR USE FOR PROPER DEVICE FUNCTION

VYGON NEURO

P.O. Box 80390
Valley Forge, Pa. 19484
610/539-9300
Fax 610/539-9333

EO 695-03/05

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REF:OVA

8335.239

Neurocath Expert, 32cm long, 16 holes
9Fr Compression Hub
Trocar

STERILIZATION LOT # VN-****

STERILE EO

Pyrogen-Free

Made in the USA

VYGON NEURO

ISO 13485

P.O. Box 80390
Valley Forge, Pa. 19484
Ph 610/539-9300
800/462-2563 Fax 610/539-9333

REF OVA 8335.239 **** LOT **** ****

REF OVA 8335.239 **** LOT **** ****

REF OVA 8335.239 **** LOT **** ****

REF OVA 8335.239 **** LOT **** ****

Caution: To be used by physicians only
Achtung: Ausschliesslich von Ärzten zu verwenden
Attention: À l'usage exclusif des médecins
Atenção: Para ser usado somente por medicos
Atención: Para ser usado solamente por médicos
Avvertenza: Usato Solomente da dottori

EO 685-04/05

REF:OVA **8335.239**

Neurocath Expert, 32cm long, 16 holes
9 Fr Compression Hub
Trocar

STERILIZATION LOT # VN-****

ISO 13485

LOT ****
**** ****

30°C 15°C

Made in the USA

FOLLOW INSTRUCTIONS FOR USE FOR PROPER DEVICE FUNCTION

VYGON NEURO

P.O. Box 80390
Valley Forge, Pa. 19484
610/539-9300
Fax 610/539-9333

EO 695-03/05

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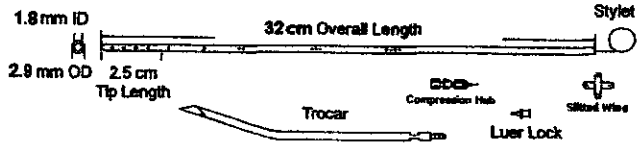
NEUROCATH® Ag™ CATHETER

Code Number 8335

READ ALL INSTRUCTIONS, PRECAUTIONS AND WARNINGS PRIOR TO USE



DEVICE DESCRIPTION

The Neurocath Ag™ catheter is a polyurethane catheter impregnated with silver ions for the purpose of radiopacity

The Neurocath Ag™ catheter is supplied with a stainless steel stylet (for introducing it into the ventricle), a stainless steel subgaleal trocar (for tunneled catheter placement),a male luer connector, a slitted wing and a compression hub (for connecting the catheter to the tubing set). The Neurocath Ag™ catheter is available individually or packaged with the tubing set.

INDICATIONS FOR USE

The Neurocath Ag™ catheter is designed to be temporarily implanted (less than 30 days) for the drainage of cerebrospinal fluid (CSF) to reduce and control increased intracranial pressure (ICP).

TECHNICAL INFORMATIONS

Code	ID/OD	Hole Size	Holes Number	Length
8335.239	1.8 mm/2.9 mm	Ø 1.3 mm	16	320 mm
8335.139	1.8 mm/2.9 mm	2.5 mm x 1.4 mm*	3	320 mm
8335.229	1.8 mm/2.9 mm	Ø 1.3 mm	16	235 mm
8335.129	1.8 mm/2.9 mm	2.5 mm x 1.4 mm*	3	235 mm
8335.219	1.8 mm/2.9 mm	Ø 1.3 mm	16	155 mm
8335.119	1.8 mm/2.9 mm	2.5 mm x 1.4 mm*	3	155 mm

* elliptical configuration

The Neurocath Ag™ catheter has markings to reference placement from the tip (cm) : 3, 4, 5, 6, 7, 8, 9, 10, 15 and 20. A specific marking is added at 7.5 cm from the tip.

The Neurocath Ag™ catheter is latex-free, DEHP free and contains no medication.

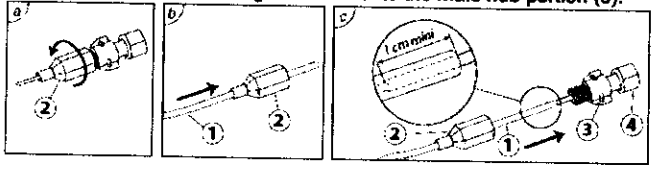
CATHETER PLACEMENT

Before placing the Neurocath Ag™ catheter, pull the catheter along the stylet so that the catheter tube is stretched and the stylet tip safely seated in the tip of the catheter to avoid the stylet from emerging through one of the side holes. Once properly placed, the Neurocath Ag™ catheter is connected to the compression hub.

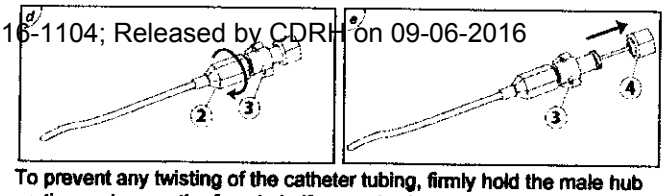
ASSEMBLY OF THE COMPRESSION HUB

Care should be taken to allow only a minimal amount of CSF to escape. The Neurocath Ag™ catheter may be occluded at the scalp level by pinching off with an appropriate clamp to minimize fluid loss during the assembly of the compression hub.

The female half of the compression hub (2) must be passed over the catheter (1) prior to attaching the catheter to the male hub portion (3).



The catheter should be attached and advanced first over the mandrel (4) and then over the stainless steel shaft a minimum distance of 1 cm. The catheter should not be twisted or damaged at this time.



To prevent any twisting of the catheter tubing, firmly hold the male hub portion and screw the female half securely, then test catheter attachment by pulling the catheter gently. Attach the compression hub to the patient line of the tubing set after discarding the mandrel (4).

If a suture may be required at the initial skin incision site, take care not to damage the catheter at this point.

CONTRAINDICATIONS

This device is not intended for any use other than that indicated.

Do not use this product in patients with hypersensitivity to silver or silver compounds, in case of recognized scalp infection and with treatment of systemic infections.

Intracranial pressure monitoring with a ventricular catheter is contraindicated in patients receiving anticoagulants or who are known to have a bleeding diathesis.

WARNINGS AND PRECAUTIONS

In order to minimize the possibilities of infection, meningitis or ventriculitis, several steps should be observed. First, the injection sites should always be cleaned with alcohol and the alcohol allowed to dry before a needle is inserted into them. Second, sterile technique should be observed in setting up the system and in the placement of the catheter. Third, subgaleal tunneling of the ventricular catheter should be approximately one to two inches. In addition, when the ventricle is first punctured during the insertion of the catheter, care should be taken so as little CSF as possible is lost. Check to ensure that the connection is tight prior to use. A patient undergoing external drainage and monitoring must be kept under continuous, close supervision.

WARRANTY

Vygon warrants that, during manufacture, packaging and sterilization of Vygon products, care was taken to make the devices suitable for use as indicated. Seller warrants that at the time of sale the goods shall be free from defects in workmanship and material. The foregoing warranty is in lieu of all other warranties, expressed or implied, and no other warranties exist including, without limitation, any warranty of merchantability or fitness for any other purpose other than that designated on the product insert sheet. Whether or not the device is appropriate for use in a particular patient depends on the nature of the patient's signs and symptoms, and such determination is the sole responsibility of the physician. If the goods do not conform to the warranty set forth herein, seller's sole liability and obligation shall be to replace the goods or refund the purchase price. In no event shall seller be liable for property damage, personal injury, or any consequential damages.

STERILIZATION

The product has been sterilized with ethylene oxide.

Do not use the product if package has been previously opened or damaged.

Resterilization can damage the product, potentially leading to patient injury.

Vygon is not responsible for the performance of any product which has been resterilized.

RE-STERILIZATION

Do not resterilize. Discard after use.

This device is intended for single use only.

VYGON NEURO

P.O. Box 80390,
Valley Forge PA 19484
phone 610 539-9300
800 462-2563
fax 610 539-9333

EU-Representative:
Vygon S.A.
5 Rue Adeline
95440 Ecouen
France
Tel: 31 39 92 65 72
Fax: 31 39 92 64 44

Made in USA

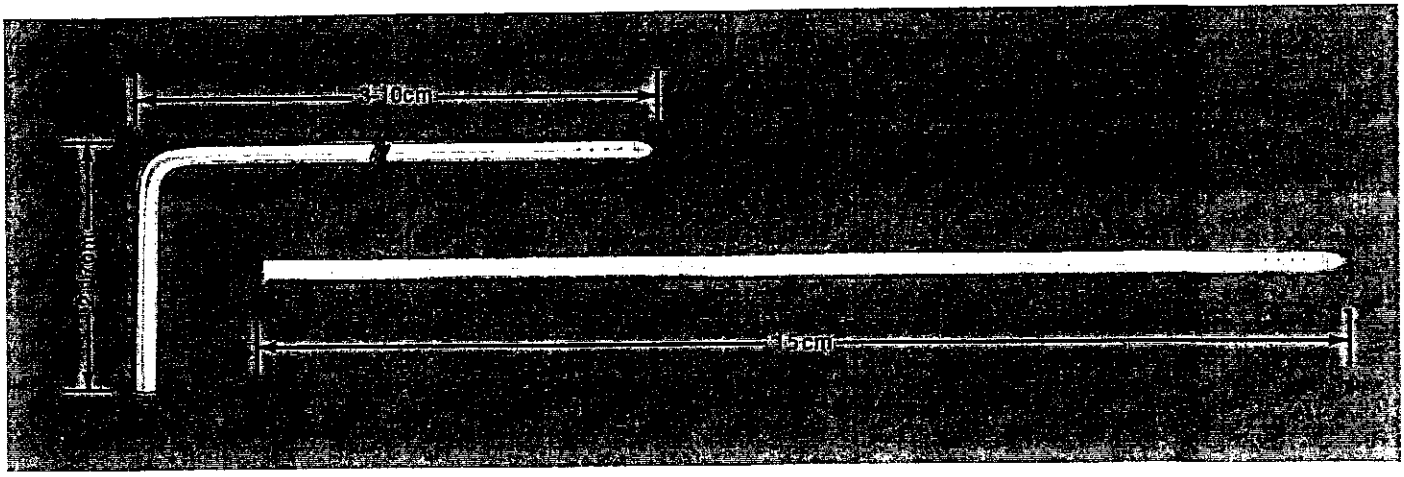
Item No. I8335-03-062308

The Holter® System

for control of intracranial pressure

50

H .er® Ventricular Catheters (packaged sterile)

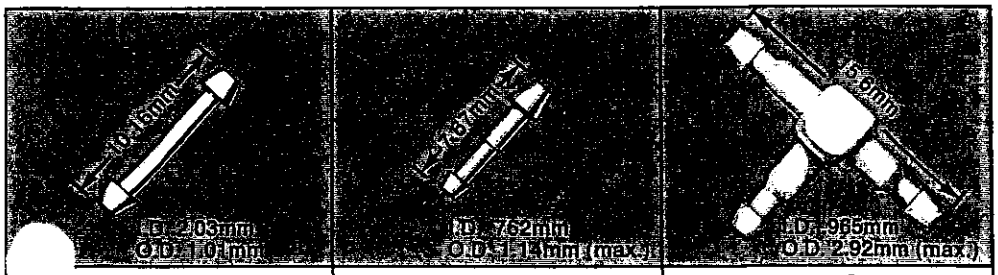


- Barium or silver impregnated
- Radiopaque
- Straight and right angle design
- Right angle designed for use when a reservoir is not used
- All catheters have a 3.0mm O.D. and 1.5mm I.D.
- M tiple perforations of the tip

Type	Nominal Length	Silver	Barium
Straight	**15cm.**	**A-015**	**B-015**
Right angle	3.0cm.	A-030	B-030
Right angle	4.0cm.	A-040	B-040
Right angle	5.0cm.	A-050	B-050
Right angle	6.0cm.	A-060	B-060
Right angle	7.0cm.	A-070	B-070
Right angle	8.0cm.	A-080	B-080
Right angle	9.0cm.	A-090	B-090
Right angle	10.0cm.	A-010	B-010

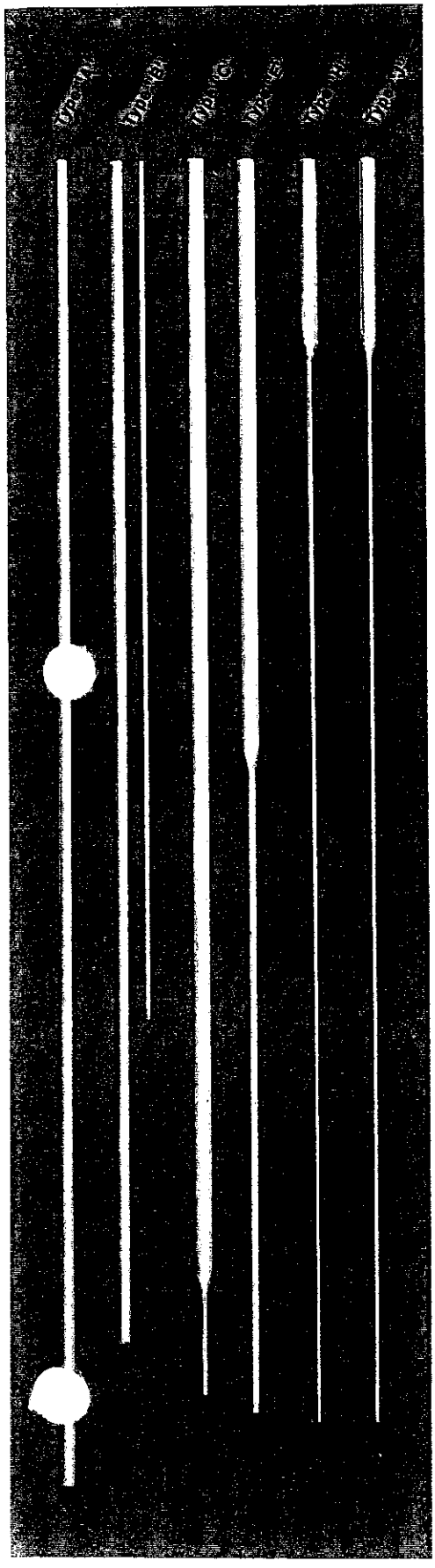
Holter Fixation and Joining Connectors (packaged non-sterile)

For easy joining and affixing of Holter Catheters



(stainless steel) Type A	(stainless steel) Type B	(Teflon®) Type "T"
for connecting type A or Holter peritoneal catheters	for connecting type B, E, H and J catheters	for bilateral drainage with one valve or other multiple connections using ventricular catheters
NA-1	NA-2	NA-3

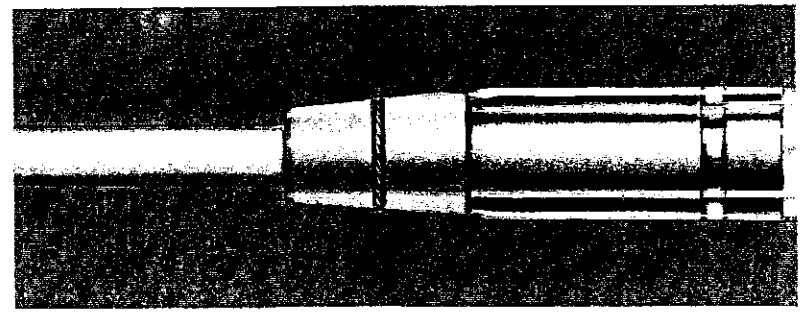
H(;r® Atrial Catheters (packaged sterile)



- Barium or silver impregnated
- Radiopaque
- Wide variety of catheters to meet specific shunting needs

Type	Material		Connectors			Small		Large	
	Silver	Barium	Included A	B	C	Diameter inside/outside (mm)	Length (cm)	Diameter inside/outside (mm)	Length (cm)
A	A-100	B-100	2	—	—	—	—	1.2 x 2.5	45.0
B	A-110	B-110	1	1	—	0.8 x 1.3	15.0	1.2 x 2.5	22.0
C	A-120	B-120	1	—	1	0.8 x 1.3	3.0	1.2 x 2.5	38.0
E	A-140	B-140	1	—	—	0.8 x 1.3	22.0	1.2 x 2.5	22.0
H	A-170	B-170	—	—	—	0.8 x 1.3	38.0	1.2 x 2.5	3.0
J	A-190	B-190	—	—	—	0.9 x 1.4	38.0	1.2 x 2.5	3.0

- Holter atrial catheters come in several designs which are based on the requests of neurosurgeons. The variations reflect the differences in surgical techniques employed in the treatment of hydrocephalus.



Hemmer Sleeve
Model Number NC-5
The silicone reinforcing sleeve is used to secure the catheters to the proximal or distal ends of the Holter valve and to round or "soften" the contour of the valve at this connection point. It helps prevent the disconnecting or shearing of catheters.

52

Ordering the Components of the H ter® Valve System

Which Holter Valve?

Holter Valves are available in two sutureless models with either straight or elliptical connector tubes both of which provide more sensitive and effective patency checking.

Each Holter Valve comes in four pressure ranges—high (normal), medium, low and extra low for virtually any CSF control situation. The valve you order is packaged sterile in a tray containing a syringe prefilled with saline for valve irrigation and plastic tubing for flow and reflux testing.

Please order by model number from page 3 of this brochure.

Example: NV-131 is the model number for a valve tray containing a medium-pressure, elliptical Holter Valve.

Which Holter reservoir?

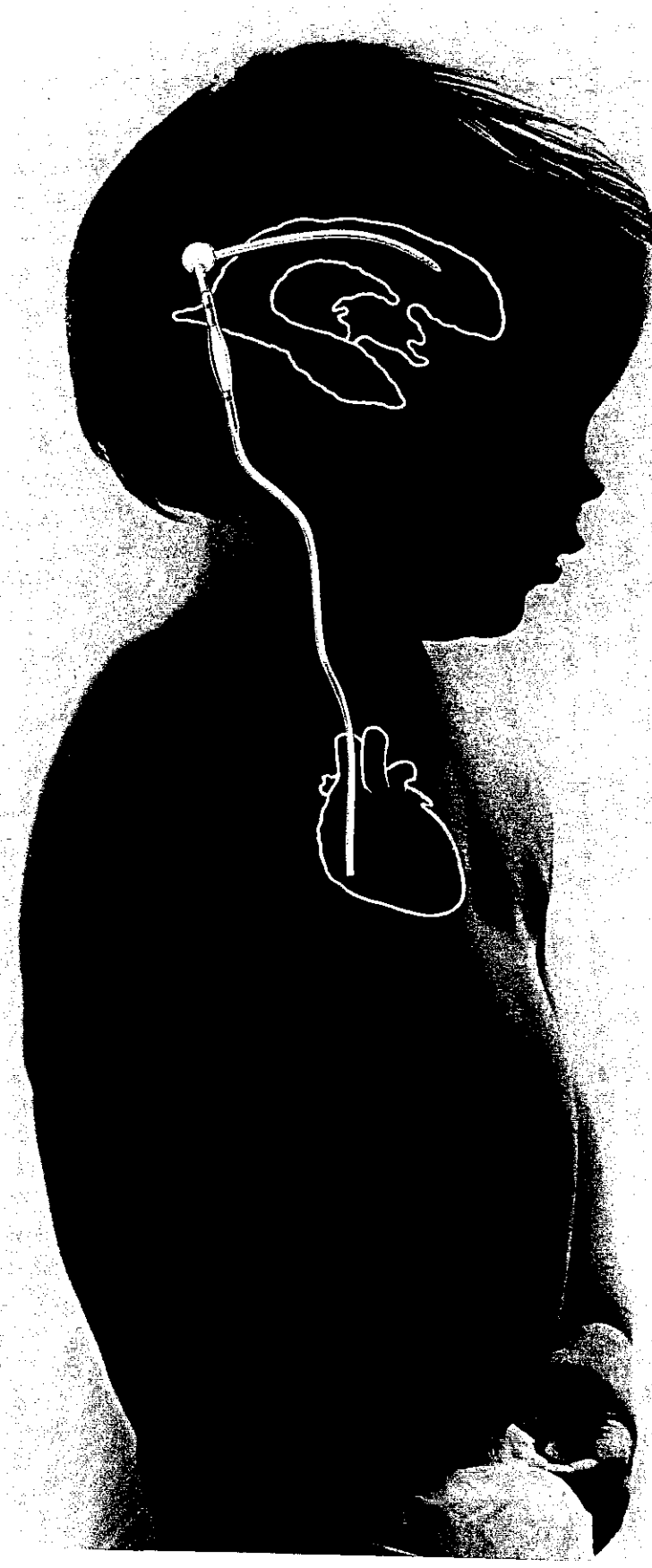
If Holter ventriculostomy reservoirs are used there are 5 models to choose from:

- dard Rickham reservoir
- Rickham reservoir (large)
- Salmon-Rickham low-profile reservoir
- Selker reservoirs (available with diameters of either 14mm or 18.5mm)

Two types of silicone caps are provided with each reservoir: (1) a cap with a side-arm for use with the Holter Valve and a straight ventricular catheter and (2) a cap without side-arm for use when the reservoir is used for ventriculostomy prior to valve implantation.

The reservoir should be ordered as a sterile, Holter Ventriculostomy Reservoir Tray containing: a stainless-steel reservoir base in one of five models, two radiopaque, silicone caps, with and without side-arm, and one straight ventricular catheter. All Holter Straight Ventricular Catheters are barium or silver impregnated for radiopacity and are 15cm long. Please order Holter Reservoir Trays by model number from page 5 of this brochure.

Ex : R-270 is the model number for a ...servoir tray containing a Selker (14mm) reservoir with silver-impregnated, silicone components.



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If a reservoir is not used

If you do not use a reservoir you will need a straight or right-angle catheter which will connect directly to the Holter Valve. The right-angle catheters are available in lengths of from 3-10cm and the straight catheter is 15cm long. All ventricular catheters have a 3.0mm O.D. and a 1.5mm I.D.

Holter Ventricular Catheters are individually packaged sterile in peel-packs. Please order by model number from page 6 of this brochure.

Example: A-070 is a 7.0cm long, silver-impregnated, right-angle catheter.

For Atrial Shunting

If you decide on atrial shunting you will need a Holter Atrial Catheter. There are 6 types of atrial catheters available. All are packaged sterile. Please order by model number from page 7 of this brochure.

Example: A-100 is the model number for a silver-impregnated, atrial catheter (type "A").

For Peritoneal Shunting

If Peritoneal Shunting is planned you will need a Holter Peritoneal Catheter, either the Salmon design or the Type "A". Both peritoneal catheters are 90cm long (2.5mm O.D., 1.2mm I.D.) and may be trimmed to desired length at the operating table. Please order atrial or peritoneal catheters by model number from page 8 of this brochure.

Example: A-910 is the model number for a silver-impregnated, peritoneal catheter (Salmon design).

A minimum order for a single shunt would consist of the following components and insertion instruments:

- Holter Valve—in one of four pressure ranges (either straight or elliptical)
- Holter Reservoir— a right-angle or straight ventricular catheter if a reservoir is not used
- Holter Catheters—atrial or peritoneal
- Introducer and Cone Set
- Salmon Tube Passer (optional)
- Stylet (16cm)
- Huber Type Needle
- Hemmer Sleeve

We recommend a reserve set be available in the event of accidental contamination.

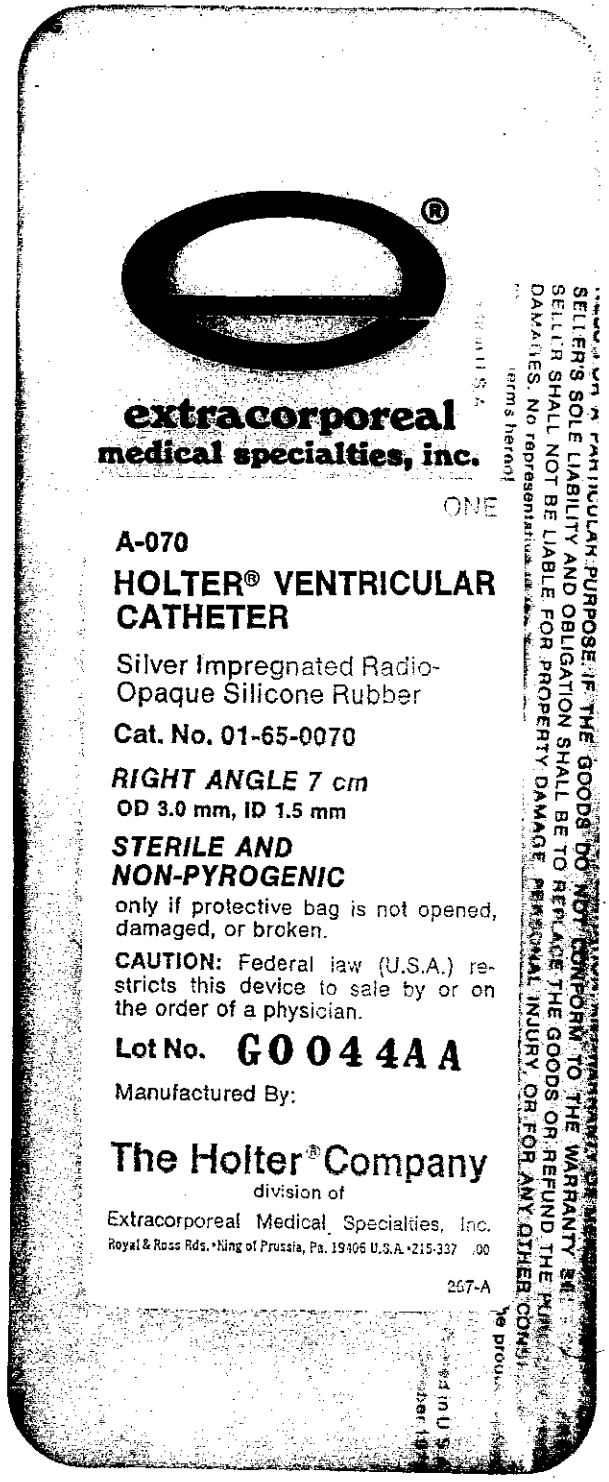
The Holter® Company

A Division of Extracorporeal Medical Specialties, Inc.
Royal & Ross Roads, King of Prussia, Pa. 19406 U.S.A. / 215-337-2400
Telex: 510-660-3975

HV 39/775

In Europe, write: Extracorporeal S.A., 256 Avenue Winston Churchill, 1180 Brussels, Belgium

Printed in U.S.A.



extracorporeal
medical specialties, inc.

ONE

A-070

HOLTER® VENTRICULAR CATHETER

Silver Impregnated Radio-Opaque Silicone Rubber

Cat. No. 01-65-0070

RIGHT ANGLE 7 cm
OD 3.0 mm, ID 1.5 mm

STERILE AND NON-PYROGENIC
only if protective bag is not opened, damaged, or broken.

CAUTION: Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.

Lot No. G0044AA

Manufactured By:

The Holter® Company
division of
Extracorporeal Medical Specialties, Inc.
Royal & Ross Rds. • King of Prussia, Pa. 19406 U.S.A. • 215-337 .00

267-A

HOLTER® VENTRICULAR CATHETER

READ ALL INSTRUCTIONS, CAUTIONS AND WARNINGS CAREFULLY PRIOR TO USE.

DESCRIPTION.

Refer to the package label for catheter type, size, and radio-opague media impregnated in the silicone rubber.

INDICATIONS.

Use of the Holter Ventricular Catheter is indicated in the treatment of hydrocephalus where a means of access to the lateral ventricles is required.

CONTRAINDICATIONS.

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

CAUTIONS AND WARNINGS

- Extreme care should be exercised to prevent the silicone rubber catheter from coming in contact with bare fingers, towels, drapes, talc, or other fibrous or linty surfaces. Silicone rubber is highly electrostatic and attracts airborne particles and surface contaminants that could produce tissue reaction. Refer to the STERILIZATION PROCEDURES below should the catheter become contaminated.
- Silicone rubber has a low cut and tear resistance and care should be exercised when placing ligatures not to tie them too tightly. Furthermore, the use of stainless-steel ligatures on silicone rubber is not recommended.
- The surgical procedures described below are intended only as a general guide. Prior to surgery, the physician should consult and be familiar with the reference material in the BIBLIOGRAPHY which provides detailed surgical procedures. Reprints of the reference material are available upon request.

SURGICAL PROCEDURES

1. The scalp and pericranium are incised and reflected, and the skull opening made in the usual manner. Refer to the packaged Instruction Sheet for the Holter Valve and Ventriculostomy Reservoirs for additional information.
2. The dura and arachnoid may be electrocoagulated and then penetrated using a ventricular needle. The usual precautions should be observed when penetrating the cerebral cortex. The dura opening should be somewhat smaller than the ventricular catheter to affect a snug fit and prevent subsequent leakage of cerebrospinal fluid (CSF).
3. Using a V-420 Stainless Steel Stylet (Cat. No. 01-61-0036), introduce the ventricular catheter through the dura and advance it into the lateral ventricle. It is recommended that the catheter tip be placed in the frontal horn of the ventricle at the level of the coronal suture.[1] With removal of the stylet, free flow of CSF should occur. Flush the catheter repeatedly with 1-cc amounts of sterile saline solution to ensure that the distal openings will allow free flow of CSF. Clamp the ventricular catheter. Strict sterile precautions should be exercised during this phase.
4. Connect the ventricular catheter to the ventriculostomy reservoir[2] if used, or to the Holter Valve using 2-0 or 3-0 silk ligatures.
5. The pericranium is then pulled over the device and sutured in place. The scalp is then closed using No. 35 stainless steel sutures or suture material of surgeon's choice.

STERILIZATION PROCEDURES

If contamination of the silicone rubber catheter occurs, follow these steps carefully.

1. Wash the catheter in a hot water soap solution to remove possible surface contaminants. Use a non-oily mild soap, such as Ivory Flakes or green soap. Do not use synthetic detergents or oil-based soaps as they may be absorbed by the silicone rubber and may subsequently leach out and cause a tissue reaction.
2. Rinse the catheter copiously in hot water, with final rinses in distilled water.
3. Place the catheter in a clean, lint-free tray which is heat resistant and has a cover. Select a tray which will allow the catheter to assume its natural shape.
4. Steam sterilize the catheter for 30 minutes at 250° F. If gas sterilization is used, allow sufficient time after sterilization to permit the ethylene oxide to diffuse from the silicone rubber before use. Refer to the sterilizer manufacturer's instructions for aeration time.

BIBLIOGRAPHY

1. Nulsen, F. E. and Becker, D. P., "Control of Hydrocephalus by Valve-Regulated Shunt," *Journal of Neurosurgery*, XXVI, No. 3 (1967), 361-374.
2. Rickham, P. P. and Penn, I. A., "The Place of the Ventriculostomy Reservoir in the Treatment of Myelomeningocles and Hydrocephalus," *Developmental Medicine and Child Neurology*, 7 (1965), 296-301.

IMPORTANT NOTICE—WARRANTIES AND LIMITATIONS

Seller warrants only that during manufacture, packaging and sterilization due care was exercised to make this ventricular catheter suitable for use as indicated. Seller makes no representation regarding the suitability for any particular use or success in any particular treatment in which this ventricular catheter is used. Suitability for any particular use or treatment is the sole responsibility of the physician-buyer. THE FOREGOING WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, AND NO OTHER WARRANTIES EXIST INCLUDING, WITHOUT LIMITATION, ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. IF THE GOODS DO NOT CONFORM TO THE WARRANTY SET FORTH HEREIN, SELLER'S SOLE LIABILITY AND OBLIGATION SHALL BE TO REPLACE THE GOODS OR REFUND THE PURCHASE PRICE. SELLER SHALL NOT BE LIABLE FOR PROPERTY DAMAGE, PERSONAL INJURY, OR FOR ANY OTHER CONSEQUENTIAL DAMAGES. No representative of the Seller may change any of the foregoing and the Buyer hereby accepts the product subject to the terms hereof.

Made in U.S.A.

P1000-877-999-A

Printed in U S.A.
October 1972

Manufactured By:

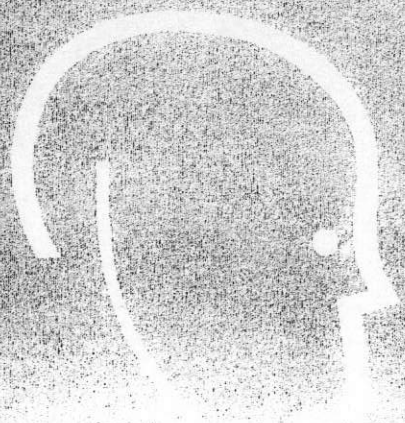
The Holter® Company
division of

57

NON-STERILE

SAMPLE

Holter™ Ventriculoatrial Shunt System



V-100 HIGH
KIT NO. 01-61-0100
VALVE CAT. NO. 01-61-0011
LOT NO.

Sterility guaranteed only if outer polyethylene bag is intact and unopened.
Federal law (U.S.A.) prohibits dispensing without prescription.

Contents

One Holter ventriculoatrial shunt valve
One V-300 15.0 cm straight ventricular catheter (Cat. No. 01-61-0024)
One R-142 Rickham cap with side-arm (Cat. No. 01-61-0005)
One V-250 type "C" Argenta-Flex™ atrial catheter (silver impregnated) with interlumenal stainless steel connector (Cat. No. 01-61-0022)
One T-100 type "A" stainless steel connector (Cat. No. 01-61-0052)
One 45 cm PVC tube **for testing only. Not to be implanted.**
One 5 cm PVC tube **for testing only. Not to be implanted.**
One 10 ml. bottle pyrogen-free sterile water **for testing only. Not to be injected.**

* Syringe for flushing valve is not supplied.

Refer to Holter system brochure "Control of Hydrocephalus Using the Holter Ventriculoatrial Shunt System" for detailed information.

EXTRACORPOREAL MEDICAL SPECIALTIES, INC.
Church Road, Mount Laurel Township
New Jersey 08057 U.S.A.
(609) 235-7530 Cable: EMSCO

Made in U.S.A. P-1000-096-099 Aug. 68 Printed in U.S.A.

(b)(4) Third Party Manufacturering Information

(b)(4) Third Party Manufacturering Information

Affidavit of Employment

I, (b)(6), [redacted] am currently employed as Production Manager of Vygon US LLC, and in this capacity, among my many management responsibilities, am responsible for the compounding of silicone and molding and extrusion of silicone catheters and tubing. I do hereby attest and affirm that I was employed by the Holter Company from 1966 to 1967, at which time the company was sold to the Extracorporeal. I continued to work at Extracorporeal until 1983. While employed by Holter, and later with Extracorporeal, I was employed in various capacities in packaging, in assembly, for the batch compounding of silicone and molding and extrusion of silicone catheters and tubing. I was personally involved in the compounding of silver power and silicone during my employment, as well as the packaging and labeling of such products. I attest to the fact that these catheters and reservoirs were manufactured, marketed and sold for implantation into the brain, for the treatment of hydrocephalus, prior to May 28, 1976. These were not research products, but products available for sale to physicians and surgeons. The invoices and shipping records of the Holter Company and Extracorporeal are no longer available, as these companies no longer exist. However I retained packaged sterile product with the silver catheters, which I have turned over to Vygon for testing and retention in their records. In addition a copy of the product catalog, illustrating the silver catheter is attached. I am currently employed by Vygon US LLC, however I have no financial interest in the company.

Signed and witnessed this 26th day of October, 2007, in Norristown, PA.

(b)(6)
[redacted]
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COMMONWEALTH OF PENNSYLVANIA
NOTARIAL SEAL
Barbara J Gulick, Notary Public
Lower Providence Twp, Montgomery County
My commission expires Jun 17, 2011

61

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Biocompatibility testing according to ISO 10993-1

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Test performed at (b)(4)

February 2001

(b)(4) Third Party Testing

RH on 09-06-2016

STUDY N° (b)(4)
January 31th, 2001

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Confidential

TEST REPORT

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This risk analysis was conducted in accordance with the requirements of EN ISO 14971:2000 to estimate and evaluate the risks associated with the Neurocath Ag.

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Risk Analysis

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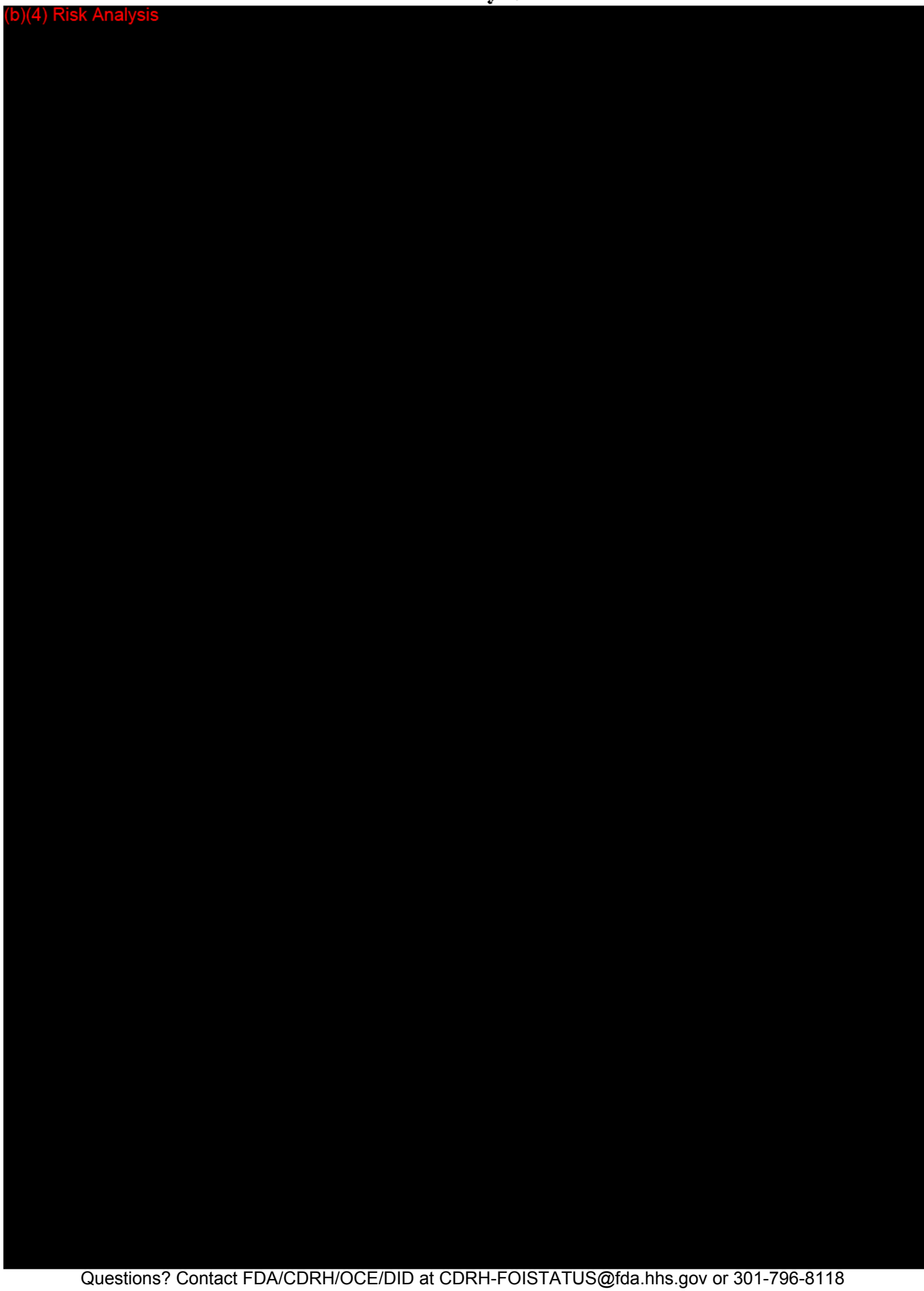

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II. Risk Evaluation

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Foreseeable Risks	Severity	Probability of Occurrence	Mode of Detection	Risk	Acceptability	Risk Control	Risk/Benefit
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Neurocath Expert
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By (b)(6)
Validation Protocol # (rev (

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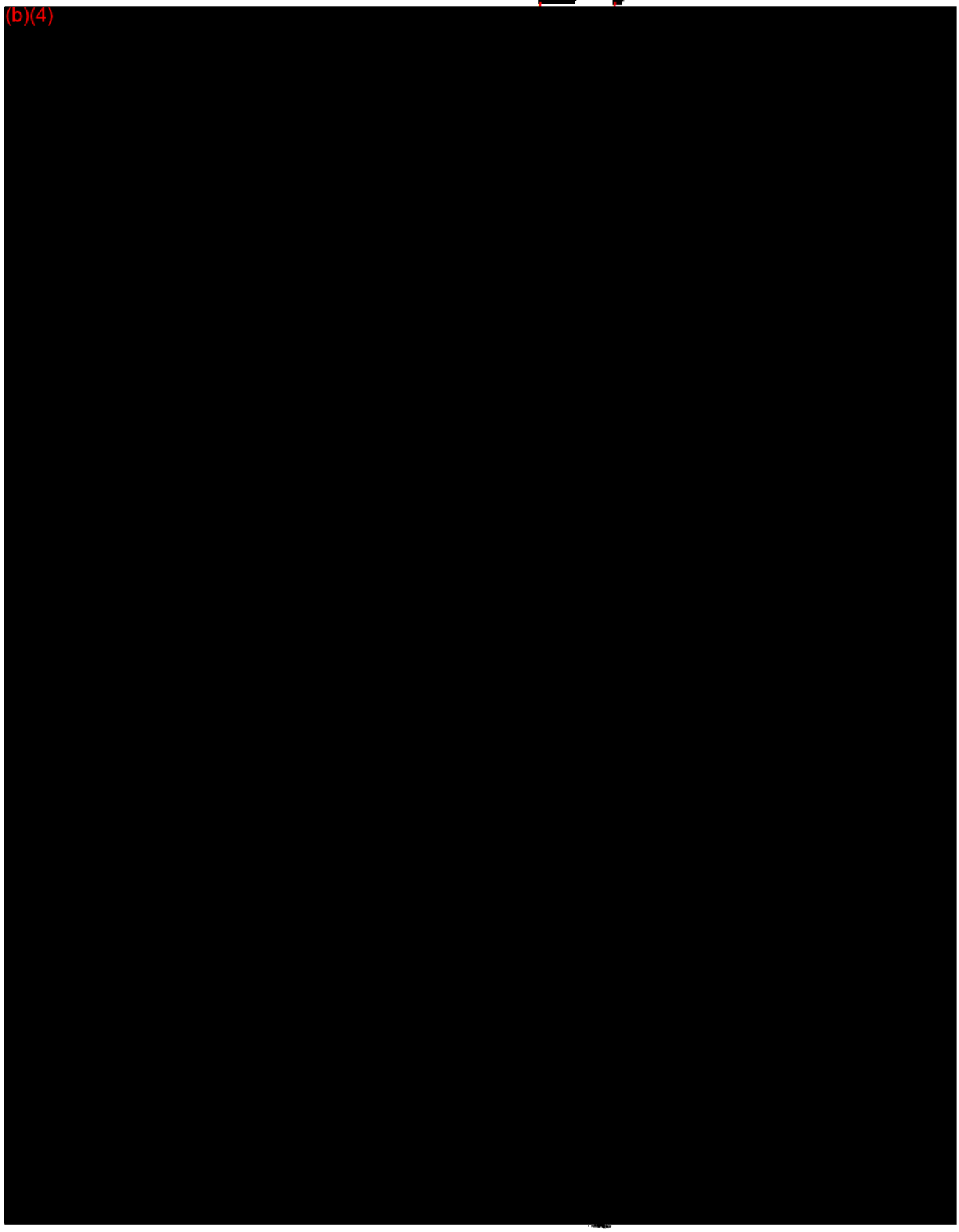

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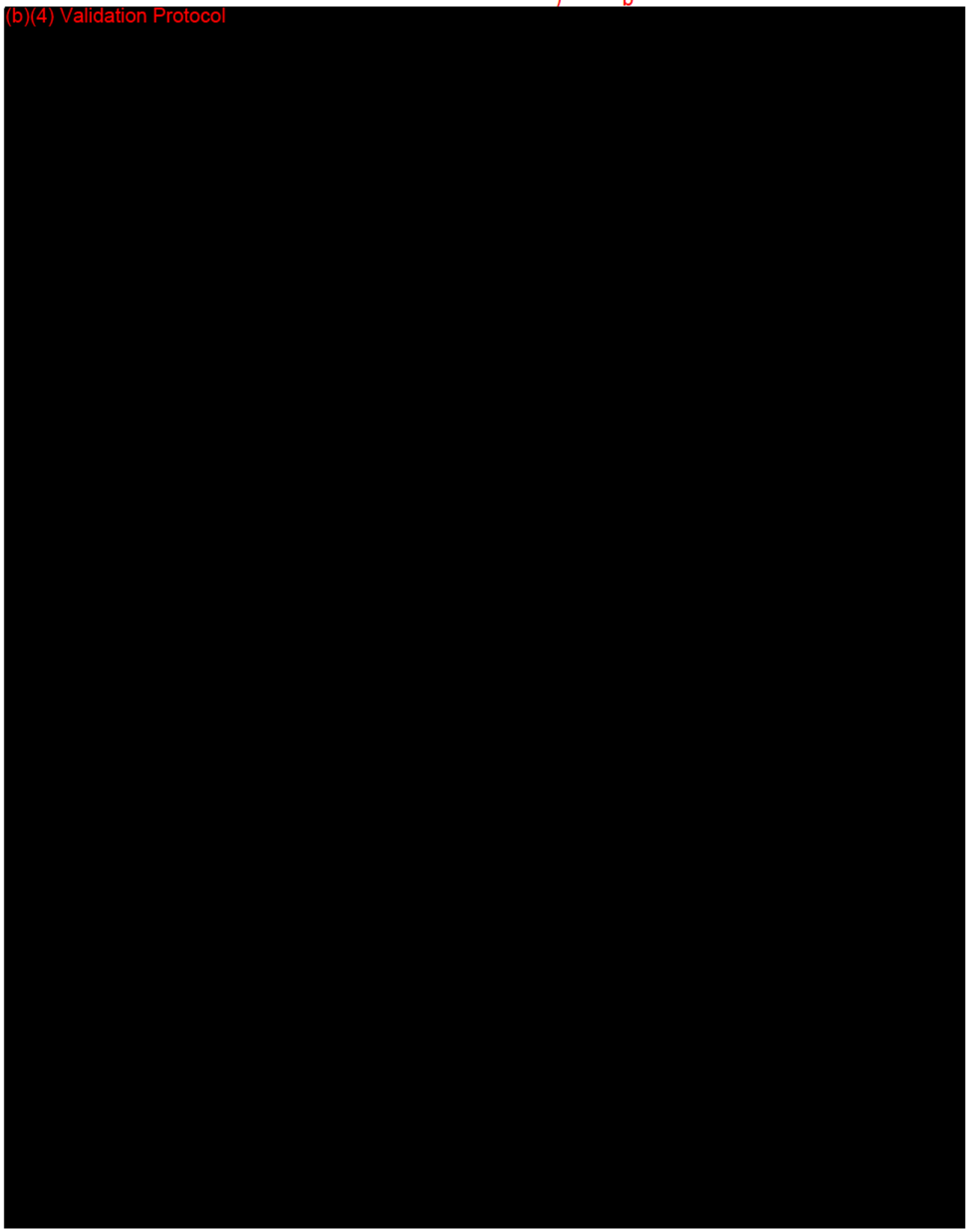

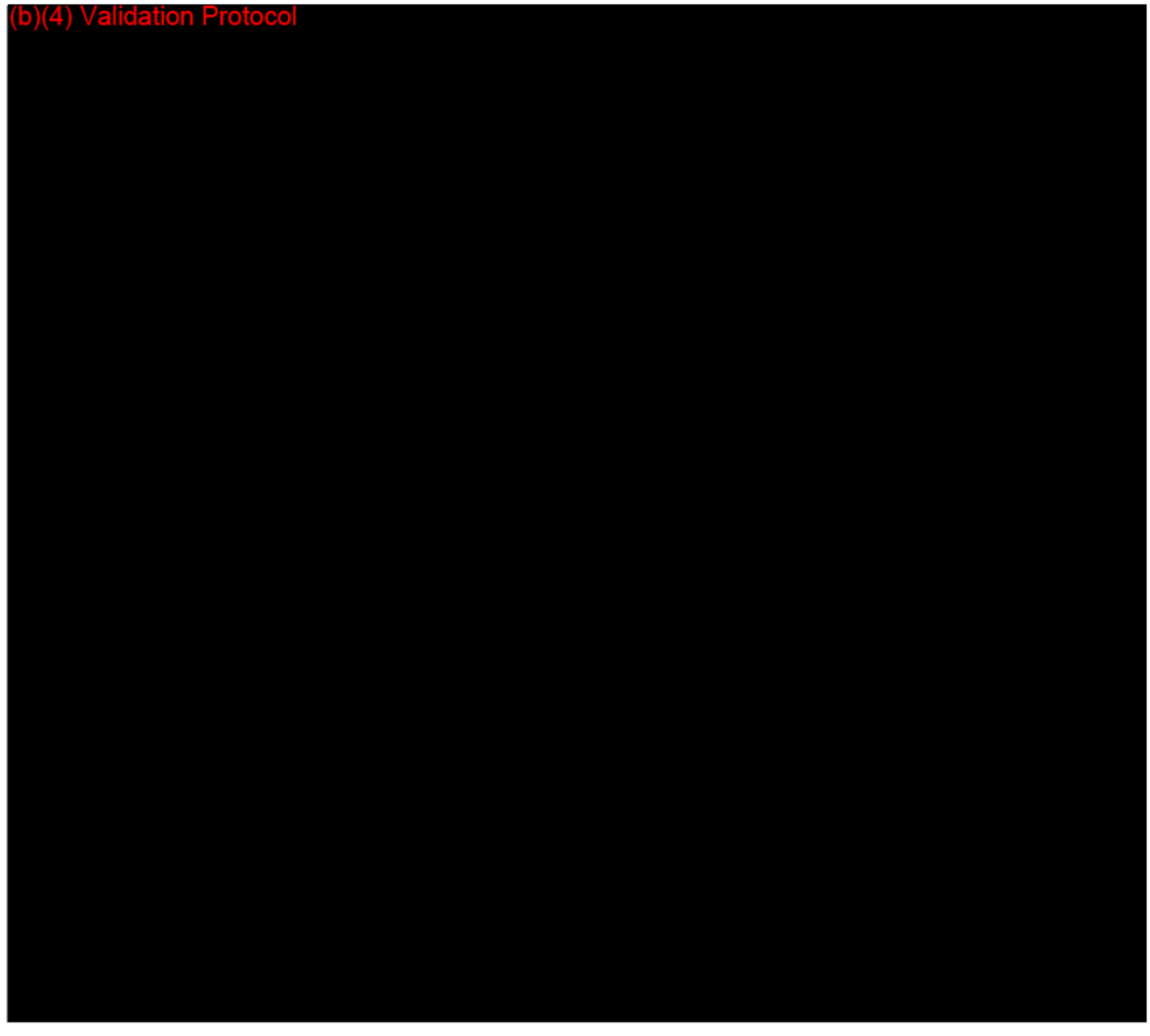

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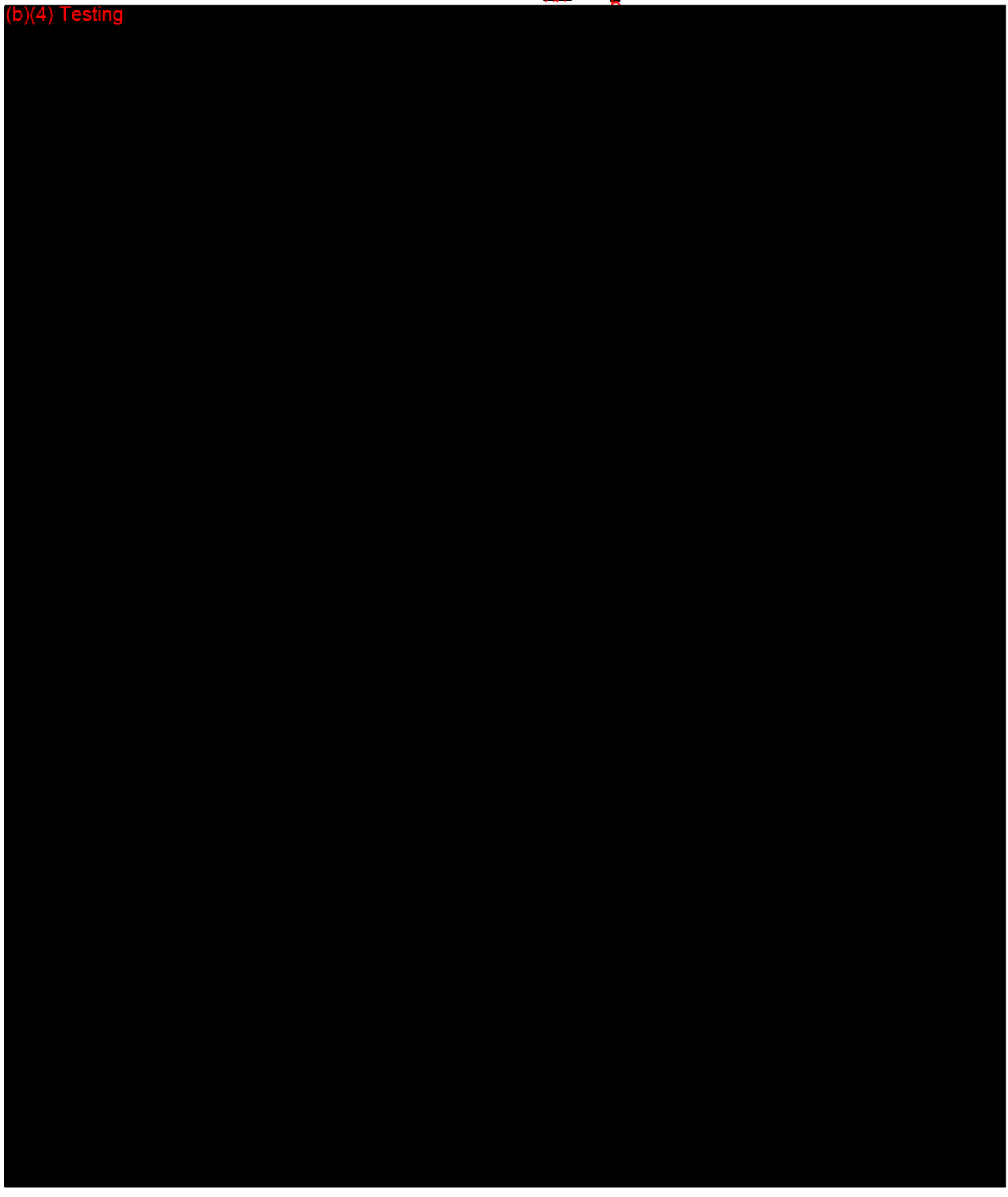
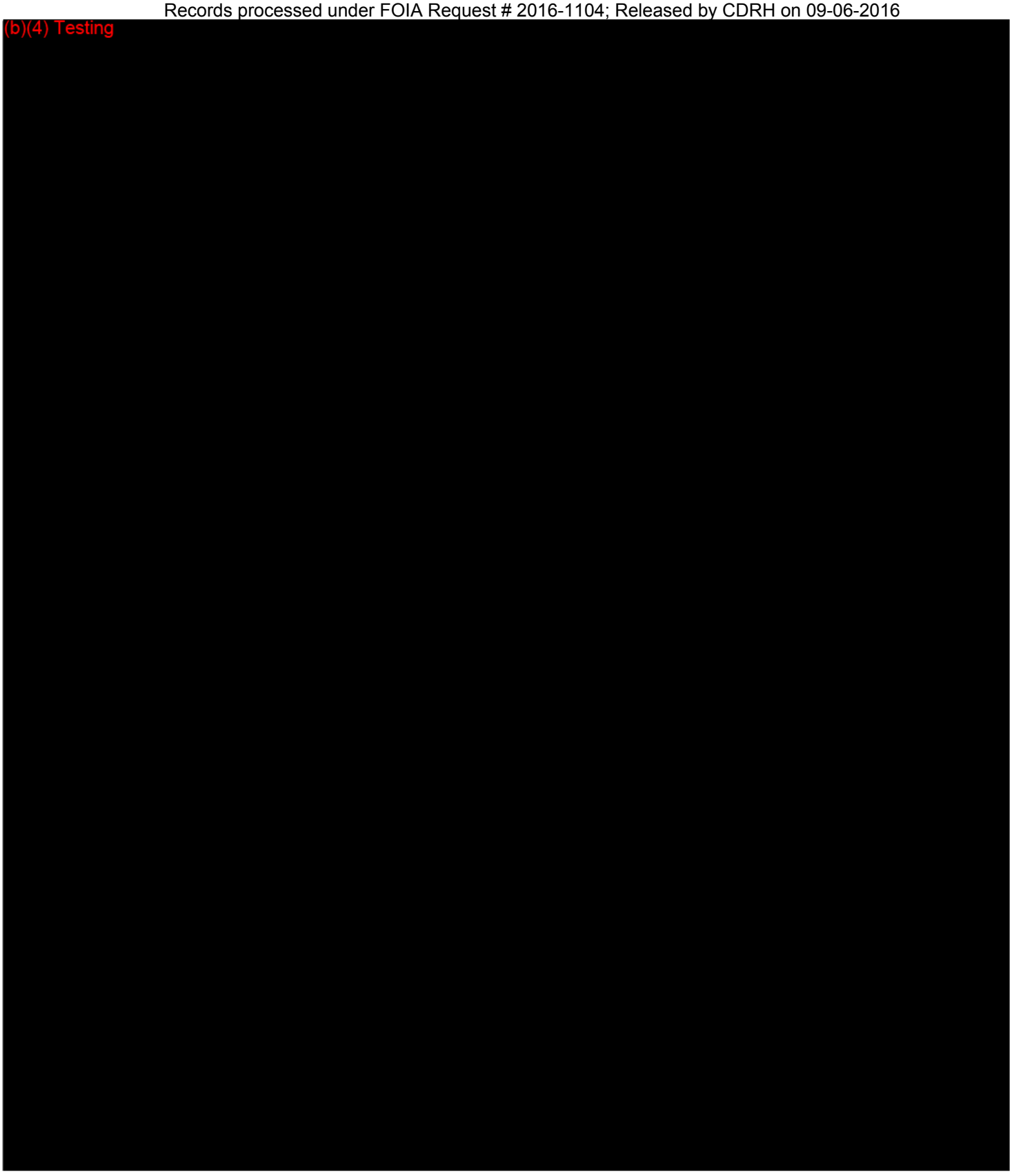


(b)(4) Testing



Neurocath Expert

(b)(4), (b)(6) Testing

Validation Protocol # (b .rev (

(b)(4) Testing

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Della Hammond

Subject: 510(k) Number K081942

To: The Record

Please list CTS decision code SE

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

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*	✓	
510(k) Summary / 510(k) Statement	*Attach Summary*	✓	
Truthful and Accurate Statement.	*Must be present for a Final Decision*	✓	
Is the device Class III?			✓
If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		✓
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			✓
Is this a combination product? (Please specify category N, see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			✓
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			✓
Is this device intended for pediatric use only?			✓
Is this a prescription device? (If both prescription & OTC, check both boxes.)		✓	
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?		✓	
Is clinical data necessary to support the review of this 510(k)?			✓
Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If not, then applicant must be contacted to obtain completed form.)			✓
Does this device include an Animal Tissue Source?			✓
All Pediatric Patients age<=21			✓
Neonate/Newborn (Birth to 28 days)			✓
Infant (29 days -< 2 years old)			✓
Child (2 years -< 12 years old)			✓
Adolescent (12 years -< 18 years old)			✓
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥21 (different device design or testing, different protocol procedures, etc.)			✓

Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)	✓
Nanotechnology	✓
Is this device subject to Section 522 Postmarket Surveillance? (Postmarket Surveillance Guidance, http://www.fda.gov/cdrh/osb/guidance/316.html) *Contact OSB.*	✓
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html) *Contact OC.*	✓

Regulation Number	**Class***	**Product Code**
882.5550	2	JXG

(*If unclassified, see 510(k) Staff)

Additional Product Codes:

Review: David Krause for NRO G-S D B 8/11/2008
(Branch Chief) (Branch Code) (Date)

Final Review:
(Division Director) (Date)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES **MEMORANDUM**

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

Premarket Notification [510(k)] Review
Traditional/Abbreviated

K081942

Date: August 8, 2008
To: The Record
From: Della Hammond, MPH, Microbiologist, GSDB, DGRND
Office: ODE
Division: DGRND
510(k) Holder: Vygon Neuro
Device Name: Neurocath Ag
Contact: Courtney Smith 2495 General Armistead Avenue, Norristown, PA 19403
Phone: 610-539-9300
Fax: 610-539-9333
Email: csmith@vygonus.com

***SPECIAL** **SE**

I. Purpose and Submission Summary

The 510(k) holder would like to introduce the Neurocath Ag into interstate commerce.

The firm is submitting a SPECIAL for a change in material from silicone to polyurethane impregnated with AgION™ (silver ions). The device is intended for use as a means of temporary external diversion, pressure monitoring and collection of cerebrospinal fluid. The catheters incorporate silver ions for the purpose of radiopacity. The firm previously submitted an application for this device with a claim that the silver impregnated catheter for neurological implantation is effective in reducing or preventing device-related infections, thus all claims for antimicrobial efficacy or the preventing of device-related infections has been removed. It was determined that the firm needed clinical data to support the claim that a silver impregnated catheter for neurological implantation is effective in reducing or preventing a device - related infection. This submission was not submitted to re-introduce that claim, but to remove the claim of antimicrobial efficacy. The proposed device is comparable to the predicate Fifth Ventricle Drainage Catheter, K800168 and identical to the pre-amendment device, the Holter Drainage Catheter. An *Affidavit* is provided in Section 3 from a former employee of the Holter Company which is currently Vygon US LLC to which the employee is currently employed. The employee describes that while employed by the Holter Company his responsibilities included the assembly and packaging for the batch compounding of silicone and silver powder. Mr. Munro attest that invoices and shipping records of the Holter Company are no longer available. See Section 3 for additional details provided in the Affidavit.

The proposed device is an external drainage catheter used to drain CSF from the ventricles to an externalized drainage bag. The proximal end is intended to be implanted in the ventricles, while the distal end is intended to be externalized and connected to an external drainage system. The catheter releases silver ions from their internal and external surfaces. The device is single use.

Differences

The firm contends the only change between the predicate devices, **K800168, K853365**, and the pre-amendment device is the change in material from barium impregnated silicone and silver impregnated silicone, to polyurethane, impregnated with silver ions. *(13)*

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Chemical Composition Testing
Vygon has conducted chemical composition testing on the proposed Neurocath Ag and the pre-amendment device. The results show that the pre-amendment device (b)(4) (b)(4) (b)(4)

The firm has provided labeling from a pre-amendment device and a company that is no longer in business, the Holter Company, a division of Extracorporeal Medical Specialties, Inc., King of Prussia, Pa. and a second predicate, the Fifth Ventricle Drainage Catheter, K800168. See Section 3 of the submission.

The proposed device shares similar features and functions with the corresponding pre-amendment device, the Holter Drainage Catheters with regard to function, indications, materials, sterilization, and labeling. Therefore, I find the proposed device to be substantially equivalent to the predicate.

III. Administrative Requirements

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

III. Device Description

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

Device Description
The proposed device is an external drainage catheter used to drain CSF from the ventricles to an externalized drainage bag. The proximal end is intended to be implanted in the ventricles, while the distal end is intended to be externalized and connected to an external drainage system. The catheter releases silver ions from their internal and external surfaces. The device is single use.

Accessories included are a stainless steel stylet, stainless steel trocar, male luer connector, compression hub, and suture wing *(5-2)*

The firm reports that no other catheter device is currently on the market that uses silver ions in a catheter to be utilized for radiopacity. *(15)* The catheter is available with 3 holes off-set at 120° or 16 holes, in lengths of 32cm, 23.5cm, and 15.5cm. The firm states similar external drainage catheters have been manufactured and distributed by Vygon. *(15)*

Vygon has conducted chemical composition testing on the proposed Neurocath Ag and the pre-amendment device. The results are as follows:

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Device	% Silver Composition
Holter Ventricular Drainage Catheters (pre-amendment)	(b)(4)
Neurocath Ag	(b)(4)

Engineering drawings are provided as Section 5 of the submission.

A Risk Analysis is provided as Section 5 of the submission.

Declaration of Conformity provided as page 20 of the submission.

Certification testing for Ag is provided in Section 3 of the submission. Test Certificate for the Holton Company or pre-amendment device does not identify a product. On August 8, 2008, in a phone conversation with the holder of the submission, Ms. Courtney Smith, Regulatory Affairs Manager, Vygon US LLC, Ms. Smith stated that the pre-amendment device was not available; therefore, pieces of the pre-amendment device (Holton device) were used for Ag composition and comparison testing.

The Risk Analysis method used to assess the impacts of the modifications was a (b)(4) (b)(4) (b)(4) are provided as Section 5 of the attached faxed copy. This reviewer agrees with the Risk Analysis conducted by the firm and the methods used to identify all of the risks associated with each modification and the impact assessment of the modifications made in the design of the proposed device.

(b)(4) testing was conducted and the results and protocol are provided in Section 5 of the submission.
(b)(4) testing was conducted and the results and protocol are provided in Section 5 of the submission.
(b) testing was conducted and the results and protocol are provided in Section 5 of the submission.

II. Indications for Use

The Neurocath Ag catheter is designed to be temporarily implanted (less than 30 days) for the drainage of cerebrospinal fluid (CSF) to reduce and control increased intracranial pressure (ICP).

III. Predicate Device Comparison

The firm is claiming substantial equivalence to the Fifth Ventricle Drainage Catheter, K800168 and K870660, and the *pre-amendment device* . The firm contends the only difference between the predicate devices, K800168 (and K870660), and the pre-amendment device is the change in material from barium impregnated silicone, and silver impregnated silicone, to polyurethane, impregnated with silver ions. *(13)*

Substantial Equivalence Table.

	Neurocath Ag	Fifth Ventricle Drainage Catheter K800168 / K870660	Holter Drainage Catheters (pre-amendment)
Usable Length (cm)	15.5, 23.5, 32	15, 23.5, 35	15, 23.5, 35
Class	II	II	----
Sterility	EO	EO	EO
Materials	Polyurethane impregnated w/ silver ions Stylet – (b) Stainless Steel	Silicone	Silicone impregnated w/ silver
% Silver Composition	(b)(4)		(b)(4)

IV. Labeling

Adequate labeling is provided as SECTION 2 of the submission.

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V. **Sterilization/Shelf Life/Reuse** *(16)*

Terminal Sterilization Method: chamber EO sterilization
SAL: 10^{-6}
Standard: AAMI/ANSI/ISO 11135: 2007 (21)
EO residual levels: (b)(4)
Packaging: (b)(4)
(b)

Shelf Life

Five years. (5-2)

VI. **Biocompatibility** *(18)*

The sponsor has provided all required biocompatibility data for a limited duration skin surface contact device, i.e., (b)(4) for the Neurocath Ag catheter. The test article provided by the sponsor was identified as a MULTICATH 3L AgION tube (b)(4) On August 8, 2008, in a phone conversation with the holder of the submission, Ms. Courtney Smith, Vygon Neuro Regulatory Affairs Manager, Vygon US LLC, indicated that the MULTICATH AgION device in which the biocompatibility data is provided in this submission is a device that has been cleared by FDA. Ms. Courtney Smith stated that the MULTICATH 3L AgION device is identical in materials to the proposed Neurocath Ag and biocompatibility testing was conducted in 2007 and submitted for the proposed Neurocath Ag catheter.

The firm certifies that the materials used in the construction of the proposed device both in direct patient contact meet all of the ISO 10993-1 1997 requirements and current FDA ISO guidelines. Testing results are provided for the polyurethane coating in Section 4 of the submission.

VIII. **Software**

Version:	**n/a**	
Level of Concern:		
		Yes / No
Software description:		
Device Hazard Analysis:		
Software Requirements Specifications:		
Architecture Design Chart:		
Design Specifications:		
Traceability Analysis/Matrix:		
Development:		
Verification & Validation Testing:		
Revision level history:		
Unresolved anomalies:		

VII. **Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety**

N/A

VIII. **Performance Testing – Bench**

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(b)(4) testing was conducted and the results and protocol are provided in Section 5 of the submission.
(b)(4) testing was conducted and the results and protocol are provided in Section 5 of the submission.
(b) testing was conducted and the results and protocol are provided in Section 5 of the submission.
(b)(4) testing was conducted and the results and protocol are provided in Section 5 of the submission.

IX. Performance Testing – Animal

(b)(4)

X. Performance Testing – Clinical

XI. Substantial Equivalence Discussion

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

Note: See http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4148/FLOWCHART%20DECISION%20TREE%20.DOC for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

1. Explain how the new indication differs from the predicate device's indication:

2. Explain why there is or is not a new effect or safety or effectiveness issue:

3. Describe the new technological characteristics:

4. Explain how new characteristics could or could not affect safety or effectiveness:

5. Explain how descriptive characteristics are not precise enough:

6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:

7. Explain why existing scientific methods can not be used:

8. Explain what performance data is needed:

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

XII. Deficiencies

(b)(4) [redacted]

XIII. Contact History

The firm was contacted by this reviewer to provide the following:

From: Hammond, Della
Sent: Tuesday, August 05, 2008 9:23 AM
To: 'csmith@vygonus.com'
Subject: K081942 - Neurocath Ag Catheter

Dear Ms. Smith,

I have reviewed your notification of intent to market the device referenced above. To complete the review, please provide the following:

(b)(4) [redacted]

If you wish, you may email your response back to me, or fax your response to the fax number provided below. Please do not hesitate to contact me should you have any questions.

08/06/08:

From: Courtney Smith [mailto:csmith@vygonus.com]
Sent: Wednesday, August 06, 2008 1:09 PM
To: Hammond, Della
Subject: RE: K081942 - Neurocath Ag Catheter

Dear Ms. Hammond,

(b)(4) [redacted]

Best Regards,

XIV. Recommendation: SE

Regulation Number: 21 CFR 882.5550
Regulation Name: Central nervous system fluid shunts and components
Regulatory Class: Class II
Product Code: JXG

David Krause for NRO
Branch Chief

8/11/2008
Date

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Indications for Use

510(k) Number (if known): K081942

Device Name: Neurocath Ag

Indications For Use:

The Neurocath Ag catheter is designed to be temporarily implanted (less than 30 days) for the drainage of cerebrospinal fluid (CSF) to reduce and control increased intracranial pressure (ICP).

Prescription Use ____X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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K081942

VYGON

US Vygon us, LLC, 2495 General Armistead Avenue, Norristown, PA 19403, USA
Office Phone: 610 539-9300 800482-2662 Office Fax: 610 539-8333

PREMARKET NOTIFICATION
510(k) SUMMARY
(As Required By 21 CFR 807.93)

Date of Preparation: June 20, 2008

Applicant:	Vygon Neuro 2495 General Armistead Ave. Norristown, PA 19403
Contact Individual:	Courtney Smith, Regulatory Affairs Manager 610-539-9300 Ext. 110
Trade Name:	Neurocath Ag
Common Name:	External Drainage Catheter
Regulation Number:	882.5550
Product Code:	JXG
Classification Name:	Shunt, Central Nervous System and Components
Classification:	Class II
Predicate Device Name:	Fifth Ventricle External Drainage Catheter (K800168/ K870660), Extracorporeal Ventricular Catheters (preamendment)
Device Description:	The Neurocath Ag is an external drainage catheter composed of polyurethane and impregnated with the silver ions for the purpose of radiopacity. The catheter is available with 3 holes off-set at 120°, or 16 holes, in lengths of 32, 23.5, and 15.5cm. Biocompatibility and performance testing demonstrates the safety and efficacy of these devices. The Neurocath Ag is supplied with a stainless steel stylet (for introducing it into the ventricle), a stainless steel subgaleal trochar (for tunneled catheter placement), a male luer connector, a slitted wing and a compression hub (for connecting the catheter to the tubing set). The Neurocath Ag catheter is available individually or packaged with the tubing set.

The Neurocath Ag catheters are as follows:

Description	Reference
Neurocath Ag Catheters	8335.xxx

Intended Use: The Neurocath Ag catheter is designed to be temporarily implanted (less than 30 days) for the drainage of cerebrospinal fluid (CSF) to reduce and control increased intracranial pressure (ICP).

Technology Characteristics: The fundamental scientific technology of the Neurocath Ag is substantially equivalent to the predicate devices.

Summary of Design Control Activities:
Biocompatibility testing of the material demonstrate that it is non-irritant and non-toxic. Performance testing demonstrates that the changes do not affect safety or efficacy. Risk Assessment was conducted in compliance with ISO 14971.

Conclusion: The only change between the predicate device (Fifth Ventricle Drainage Catheter K800168 and K853365) and the preamendment predicate device and the Neurocath Ag is the change in material from barium impregnated silicone and silver impregnated silicone, respectively, to polyurethane impregnated with silver ions. Biocompatibility testing, performance testing and risk assessment demonstrate that the Neurocath Ag is safe and effective to use, when used in accordance with the supplied instructions for use.