



FEB 1 1999

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Rochelle M. Mickschl  
Medical Device Representative  
Porous Media Corporation  
1350 Hammond Road  
St. Paul, MN 55110

Re: K982385  
Porous Media DPB20™ Disposable Cardiopulmonary Pre-Bypass  
Filter  
Regulatory Class: II (Two)  
Product Code: KRJ  
Dated: November 4, 1998  
Received: November 5, 1998

Dear Ms. Michkschl:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 - Ms. Rochelle M. Mickschl

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



Thomas J. Callahan, Ph.D.  
Director  
Division of Cardiovascular, Respiratory,  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure





DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

FEB 1 1999

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Rochelle M. Mickschl  
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Sincerely yours,



Thomas J. Callahan, Ph.D.  
Director  
Division of Cardiovascular, Respiratory,  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food And Drug Administration

Memorandum

From: Reviewer(s) - Name(s) J. R. M.  
Subject: 510(k) Number K982385/S1

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

- Refused to accept.
- Requires additional information (other than refuse to accept).
- Accepted for review \_\_\_\_\_
- Is substantially equivalent to marketed devices. *Approved 2/1/99*
- NOT substantially equivalent to marketed devices.

De Novo Classification Candidate?  YES  NO

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

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

This 510(k) contains:

- Truthful and Accurate Statement  Requested  Enclosed  
(required for originals received 3-14-95 and after)
- A 510(k) summary OR  A 510(k) statement
- The required certification and summary for class III devices
- The indication for use form (required for originals received 1-1-96 and after)
- Material of Biological Origin  YES  NO

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

- Confidentiality  Confidentiality for 90 days  Continued Confidentiality exceeding 90 days

Predicate Product Code with class:

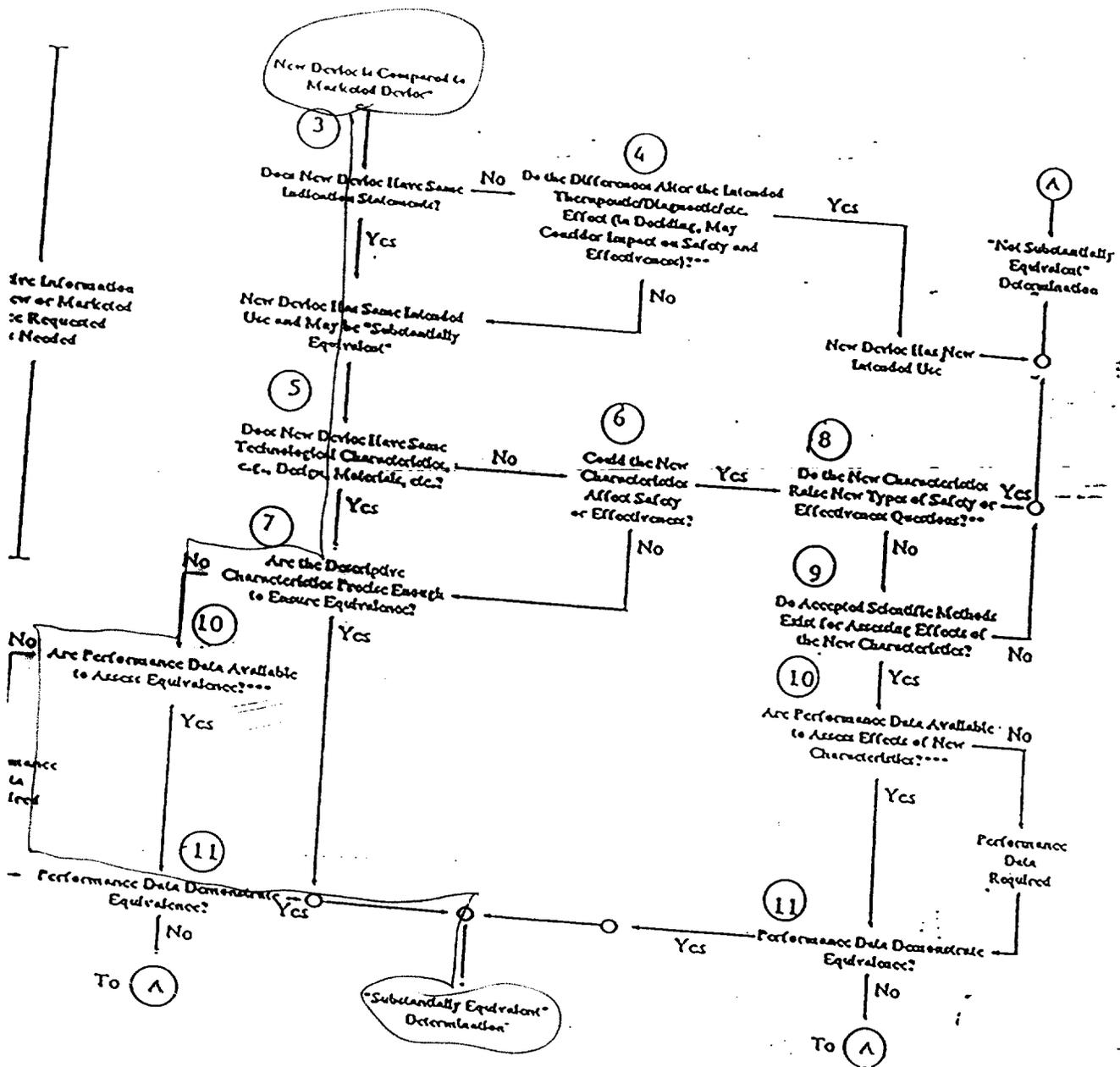
Additional Product Code(s) with panel (optional):

KRJ, II 870.4280

[Signature] (Branch Chief) ESP3 (Branch Code) 1 Feb 99 (Date)

View: [Signature] (Division Director) Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118  
[Signature] (Date) 1 Feb 99

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



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



Page 1 of 1

510(k) Number (if known): K982385

Device Name: DPB20™ Disposable Pre-bypass Filter

Indications For Use:

- THE FILTER IS INTENDED FOR USE ONLY WITH NON-CELLULAR FLUID IN THE EXTRACORPOREAL CIRCUIT PRIOR TO THE INITIATION OF CARDIOPULMONARY BYPASS.
- THE DPB20™ DISPOSABLE PRE-BYPASS FILTER HAS BEEN DESIGNED FOR SINGLE USE AND SHOULD BE DISCARDED ONCE THE CIRCUIT IS PRIMED.

*[Handwritten Signature]*  
 DIVISION SIGN-OFF  
 Division of Cardiovascular, Respiratory,  
 and Neurological Devices  
 510(k) Number K982385

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

- Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use  (Per 21 CFR 801.1091)

or

Over-The-Counter Use \_\_\_\_\_ (Optional Format 1-2-96)

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Services  
Food and Drug Administration  
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH  
Office of Device Evaluation

---

**MEMORANDUM**

**Date:** 27 January, 1999

**From:** Joydeb Roy *JR* *2/1/99*  
Physicist  
ODE/DCRND/CSPG

**To:** File:K982385/S1

**Sponsor:** Porous Media Corp.

**Device:** Porous Media DPB20 Disposable cardiopulmonary Pre-Bypass Filter

**Subject:** Original Review

**Action:** Substantial Equivalency (SE)

---

**SUMMARY OF FINDING:**

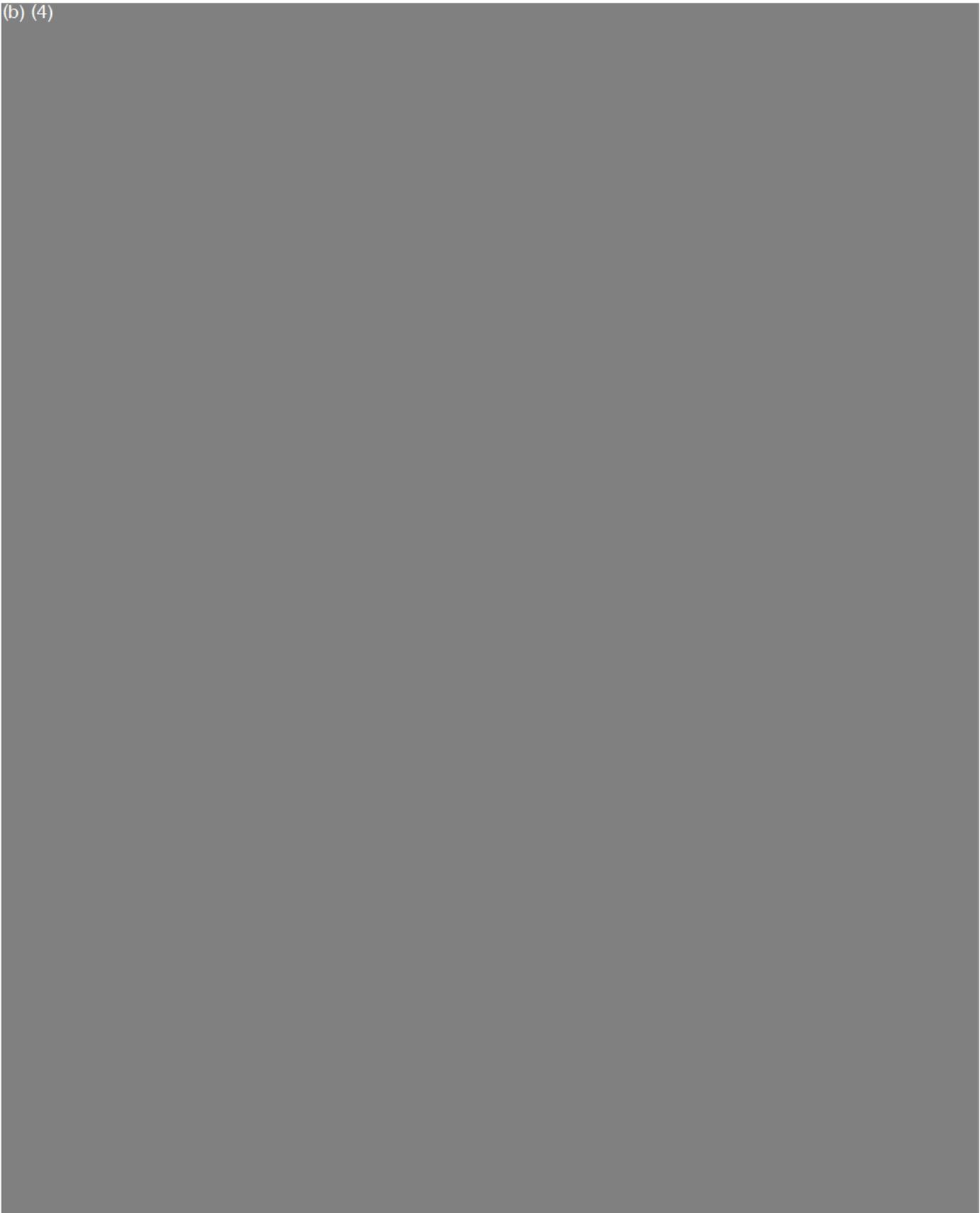
Even though the format was a little unusual, the submitter has provided the requested additional information in their response. Evaluation details are discussed in the next few pages. The following documents have now been received:

1. Performance test data (filtration efficiency, pressure drop, burst pressure, comparative testing)
2. Filtration efficiency limits on flow/flow range (validity of filtration efficiency), % removal of particulate with size
3. Average/maximum pressure drop.
4. Device description
5. Labeling, indications for use, and instruction for use

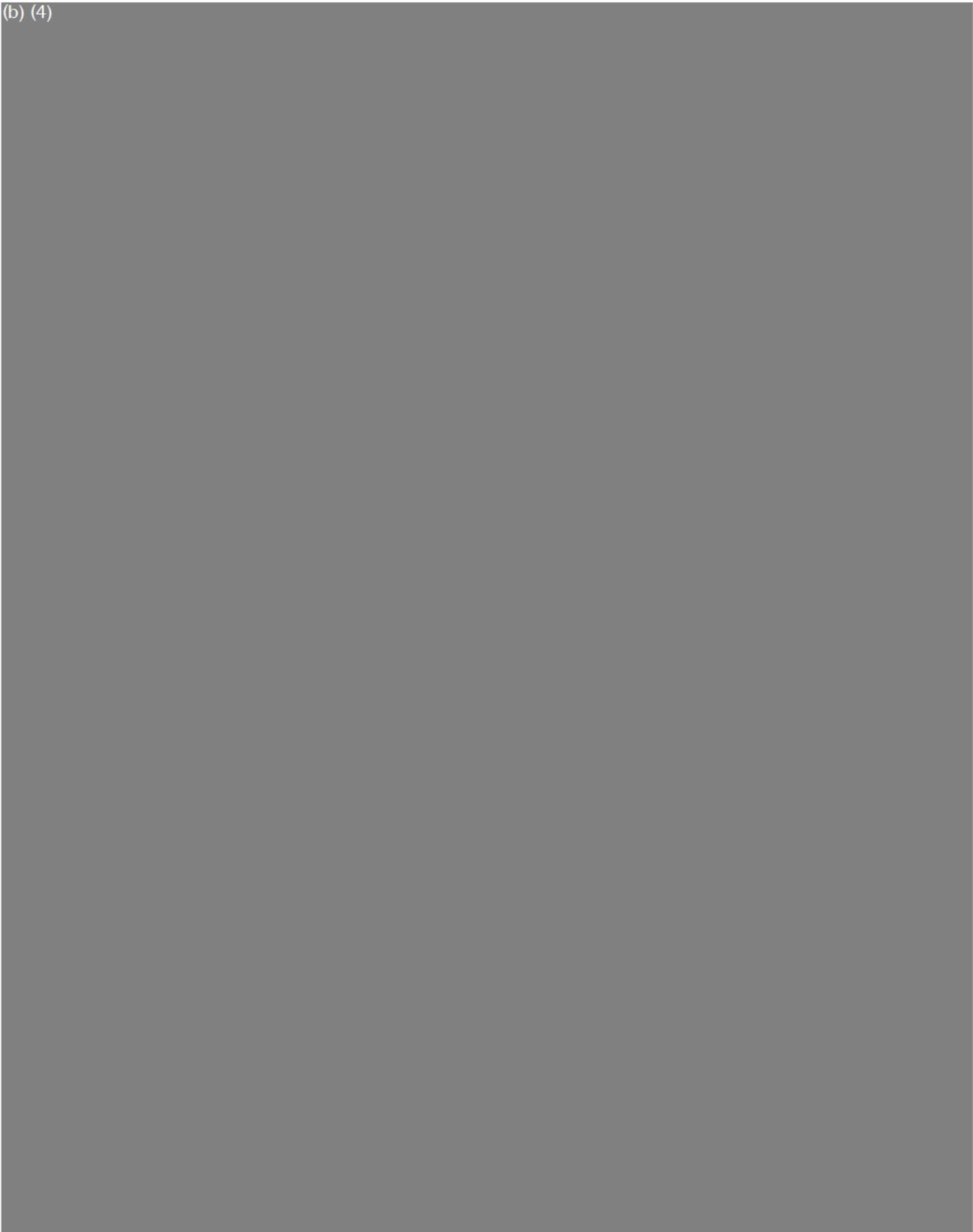
The device is judged to be substantially equivalent to the predicate device(s).

**Response to the Questions**

(b) (4)



(b) (4)



(b) (4)



**RECOMMENDATION:** Based on the information provided, and our review of that information, the device is judged substantially equivalent to the predicate (s).

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REVIEWER: J. Roy DIVISION/BRANCH: DCRM/CPB  
 TRADE NAME: DBB20 Disposable Pre-filtration Filter COMMON NAME: CPB Filter  
 PRODUCT TO WHICH COMPARED: \_\_\_\_\_  
 (510(k) NUMBER IF KNOWN) K832594 / K940126

YES	(NO)
-----	------

1. IS PRODUCT A DEVICE? 

✓	
---	--

 - IF NO STOP
2. DEVICE SUBJECT TO 510(k)? 

✓	
---	--

 - IF NO STOP
3. SAME INDICATION STATEMENT? 

✓	
---	--

 - IF YES GO TO 5
4. DO DIFFERENCES ALTER THE EFFECT OR RAISE NEW ISSUES OF SAFETY OR EFFECTIVENESS? 

--	--

 - IF YES STOP - 
5. SAME TECHNOLOGICAL CHARACTERISTICS? 

✓	
---	--

 - IF YES GO TO 7
6. COULD THE NEW CHARACTERISTICS AFFECT SAFETY OR EFFECTIVENESS? 

--	--

 - IF YES GO TO 8
7. DESCRIPTIVE CHARACTERISTICS PRECISE ENOUGH? 

	✓
--	---

 - IF NO GO TO 10  
- IF YES STOP - 
8. NEW TYPES OF SAFETY OR EFFECTIVENESS QUESTIONS? 

--	--

 - IF YES STOP - 
9. ACCEPTED SCIENTIFIC METHODS EXIST? 

--	--

 - IF NO STOP - 
10. PERFORMANCE DATA AVAILABLE? 

	✓
--	---

 - IF NO REQUEST DATA
11. DATA DEMONSTRATE EQUIVALENCE? 

✓	
---	--



**NOTE:** IN ADDITION TO COMPLETING PAGE TWO, "YES" RESPONSES TO QUESTIONS 4, 6, 8, AND 11, AND EVERY "NO" RESPONSE REQUIRES AN EXPLANATION ON PAGE THREE AND/OR FOUR

NARRATIVE DEVICE DESCRIPTION

1. INTENDED USE: Pre 13 micron filter - single use  
- to remove particulate contamination

2. DEVICE DESCRIPTION: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. The following should be considered when preparing the summary of the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device for home use or prescription use? Does the device contain drug or biological product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

SUMMARY: Membrane filter utilizing non-cellulose  
priming solution, designed to be placed between  
the arterial and venous lines for the removal of  
particulate contamination

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

1. EXPLAIN WHY NOT A DEVICE: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

2. EXPLAIN WHY NOT SUBJECT TO 510(k): \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

3. HOW DOES THE NEW INDICATION DIFFER FROM THE PREDICATE DEVICE'S INDICATION: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

4. EXPLAIN WHY THERE IS OR IS NOT A NEW EFFECT OR SAFETY OR EFFECTIVENESS ISSUE: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

5. DESCRIBE THE NEW TECHNOLOGICAL CHARACTERISTICS: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

6. EXPLAIN HOW NEW CHARACTERISTICS COULD OR COULD NOT AFFECT SAFETY OR EFFECTIVENESS: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

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7. EXPLAIN HOW DESCRIPTIVE CHARACTERISTICS ARE NOT PRECISE ENOUGH: Test Data

incomplete

8. EXPLAIN NEW TYPES OF SAFETY OR EFFECTIVENESS QUESTIONS RAISED OR WHY THE QUESTIONS ARE NOT NEW:

Burst test, Leak test, filter efficiency

9. EXPLAIN WHY EXISTING SCIENTIFIC METHODS CAN NOT BE USED:

10. EXPLAIN WHAT PERFORMANCE DATA IS NEEDED:

11. EXPLAIN HOW THE PERFORMANCE DATA DEMONSTRATES THAT THE DEVICE IS OR IS NOT SUBSTANTIALLY EQUIVALENT:

The device compares favorably with the predicate in performance.

ATTACH ADDITIONAL SUPPORTING INFORMATION

*14*



**Porous Media**  
1350 Hammond Road  
St. Paul, MN 55110  
Phone: (651) 653-2000  
Fax: (651) 653-2230

**FAX TRANSMISSION**

**Date:** December 18, 1998  
**To:** Mr. Joydeb Roy  
Center of Devices and Radiological Health  
**Fax #:** 301-827-4351  
**From:** Rochelle Mickschl

**This transmission contains 4 page(s) including the cover sheet. If all pages are not received, please call.**

**Message:**

Dear Joydeb,

We hadn't heard a response from our last facsimile. We've attached this information again. Please let us know if further information is required. We will send this information via mail as well.

We look hearing from you soon.

Thank you and have a nice day.

CS



**POROUS MEDIA**

Porous Media Corporation  
1350 Hammond Road  
St. Paul, MN 55110  
(612) 653-2000  
(612) 653-2230 FAX

November 24, 1998

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

**RE: K982385**  
**Premarket Notification 510 (k) Submission for Porous Media DPB20™ Disposable**  
**Cardiopulmonary Pre-Bypass Filter**

Attention: Joydeb Roy, Ph. D

Dear Joydeb,

Per your request, below please find the questions addressed in our last response with corresponding FDA question numbers to answer sections, page numbers and appendices.

Question # from FDA	Answer Section	Page Number	Additional Appendices
------------------------	-------------------	----------------	--------------------------

(b)(4)

Also per your request, attached please find the test procedure for the (b)(4)

We look forward to speaking once you have an opportunity to review the aforementioned information. If you should require any additional information or if you have any questions, please contact us at (651) 653-2000 ext. 218.

Thank you.

Sincerely,

Schelle M. Mickschl  
Medical Device Representative

Enclosures

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-613; Released by CDRH on 08-29-2016

Records processed under FOIA Request # 2016-613; Released by CDRH on 08-29-2016



**POROUS MEDIA**

Porous Media Corporation  
1350 Hammond Road  
St. Paul, MN 55110  
(612) 653-2000  
(612) 653-2230 FAX

November 24, 1998

RECEIVED  
21 DEC 03 14 13  
FDA/CDRH/ODE/DMC

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

**RE: K982385  
Premarket Notification 510 (k) Submission for Porous Media DPB20™ Disposable  
Cardiopulmonary Pre-Bypass Filter**

Attention: Joydeb Roy, Ph. D

Dear Joydeb,

Per your request, below please find the questions addressed in our last response with corresponding FDA question numbers to answer sections, page numbers and appendices.

Question # from FDA	Answer Section	Page Number	Additional Appendices
------------------------	-------------------	----------------	--------------------------

(b)(4)

Also per your request, attached please find the test procedure for the (b)(4) faxed to your attention on November 10.

We look forward to speaking once you have an opportunity to review the aforementioned information. If you should require any additional information or if you have any questions, please contact us at (651) 653-2000 ext. 218.

Thank you.

Sincerely,

Rochelle M. Mickschl  
Medical Device Representative

*Handwritten initials: RM-118*

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Records processed under FOIA Request # 2016-613; Released by CDRH on 08-29-2016

Records processed under FOIA Request # 2016-613; Released by CDRH on 08-29-2016



**Porous Media**  
1350 Hammond Road  
St. Paul, MN 55110  
Phone: (651) 653-2000  
Fax: (651) 653-2230

## FAX TRANSMISSION

**Date:** November 10, 1998  
**To:** Mr. Joydeb Roy  
Center of Devices and Radiological Health  
**Fax #:** 301-827-4351  
**From:** Rochelle Mickschi

This transmission contains 2 page(s) including the cover sheet. If all pages are not received, please call.

**Message:**

Dear Joydeb,

As per our discussion today attached please find additional efficiency results that may offer assistance in your evaluation of K982385.

As you requested, we will call you during the middle of next week. If we may be of further assistance in the meantime, please contact us.

Thank you.

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(b)(4) Test Data

**FILTRATION EFFICIENCY FOR PREBYPASS FILTER BY POROUS MEDIA CORP.**



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

November 06, 1998

POROUS MEDIA CORP.  
1350 HAMMOND RD.  
ST. PAUL, MN 55110  
ATTN: ROCHELLE M. MICKSCHL

510(k) Number: K982385  
Product: POROUS MEDIA  
DPB20 SERIES  
DISPOSABLE  
PRE-BYPASS

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official.

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

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

Sincerely yours,

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

K982385/S1

**POROUS MEDIA**



Porous Media Corporation  
1350 Hammond Road  
St. Paul, MN 55110  
(612) 653-2000  
(612) 653-2230 FAX

RECEIVED

5 NOV 98 15 40

FDA/CDRH/OCE/DMC

November 4, 1998

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

**RE: K982385**  
**Premarket Notification 510 (k) Submission for Porous Media DPB20™**  
**Disposable Cardiopulmonary Pre-Bypass Filter**

Attention: Joydeb Roy, Ph. D., Betty Lemperle

We are in receipt of your response to our Premarket Notification dated October 7, 1998. Enclosed please find a copy of this document and the requested items that you've required to complete the review.

We also hope that the information we have provided will allow the FDA to reach its decision regarding substantial equivalence to predicate devices at your earliest convenience. If you should require any additional information or if you have any questions, please contact us at (651) 653-2000 ext. 236.

Thank you.

Sincerely,

Rochelle M. Mickschl  
Medical Device Representative

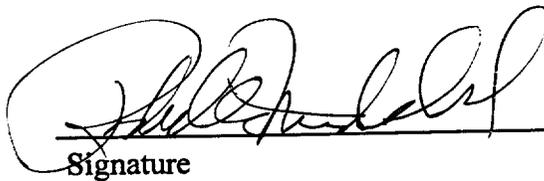
Enclosures

SK-51

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**Premarket Notification  
Truthful and Accurate Statement**

I certify that, in my capacity as a Medical Device Representative of Porous Media 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 fact has been omitted.

  
\_\_\_\_\_  
Signature

\_\_\_\_\_  
Typed Name

10/4/98

\_\_\_\_\_  
Dated

K982385

\_\_\_\_\_  
Premarket Notification [510(k) Number]

### 510K Statement

I certify that, in my capacity as a Medical Device Representative of Porous Media Corporation, I will make available all information included in this premarket notification on safety and effectiveness within 30 days of request by any person if the device described in the premarket notification submission is determined to be substantially equivalent. The information I agree to make available will be a duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding all patient identifiers, and trade secret and confidential commercial information, as defined in 21 CFR 20.61.



Signature of Certifier

Typed Name

10/4/98

Date

K982385

Premarket Notification [510(k) Number]



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

OCT 7 1998

Ms. Rochelle M. Mickschl  
Medical Device Representative  
Porous Media Corporation  
1350 Hammond Road  
St. Paul, MN 55110

Re: K982385  
Porous Media DPB20 Series Disposable  
Pre-Bypass Filter  
Dated: July 8, 1998  
Received: July 9, 1998

Dear Ms. Mickschl:

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

(b) (4)



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Page 2 - Ms. Rochelle M. Mickschl

(b) (4)



We believe that this information is necessary for us to determine whether or not this device is substantially equivalent to a legally marketed predicate device with regard to its safety and effectiveness.

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(k), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Federal Food, Drug, and Cosmetic Act (Act). You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations.

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete.

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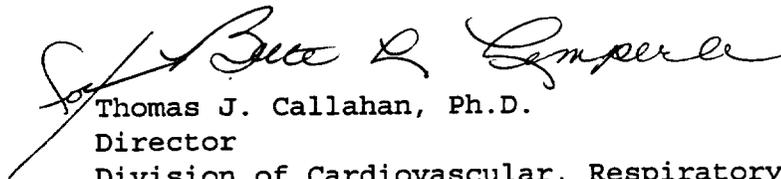
Page 3 - Ms. Rochelle M. Mickschl

The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to:

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

If you have any questions concerning the contents of this letter, please contact Joydeb Roy, Ph.D., at (301) 443-8262. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its internet address "dsmo@fdadr.cdrh.fda.gov."

Sincerely yours,



Thomas J. Callahan, Ph.D.  
Director  
Division of Cardiovascular, Respiratory,  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health .

Enclosure

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**a) Device Description**

The DPB20™ filter is designed to be placed between the arterial and venous lines for the removal of particulate contamination during the initial priming of the extracorporeal circuit with non-cellular fluids.

Please see attached exploded view drawing of the Porous Media DPB20™ Disposable Cardiopulmonary Pre-Bypass Filter (Appendix H, Drawing # 1442-2) illustrating all components and product internals. The product flows from the cap connection (inlet) to the body connection (outlet). A flow arrow will be injection-molded on the outside of the capsule to indicate flow direction to the user. As stated under materials of construction in our original submission, the membrane media consists of a high-performance polysulfone membrane constructed with polyester support layers placed upstream and downstream of the membrane. The cast polysulfone membrane produces a highly asymmetric pore structure that decreases gradually from an average of 10–20 µm on the upstream side to 0.1 µm on the downstream section, an asymmetric ratio of 100:1. The housing capsule and structural support frame are constructed from Cyrolite G-20 HIFLO®. Please see attached material specification information for the filter membrane and polymer resin for the injection-molded components (Appendix I).

The flat stock membrane and support layers are cut to size and wrapped in a cylindrical tube. This media is then placed into the cavity of an insert-molding piece of equipment that injection-molds the structural support frame around the outside diameter of the cylinder of media making the media and frame an integral part. The product flows from an inside to outside direction. The media is thermally adhered to the structural frame through the injection-molding process.

The integral piece consisting of the membrane and the support frame is placed into the capsule body (indicated on the exploded view drawing in Appendix H, Drawing # 1442-2). The ledge from the internal filter and support frame rests on the capsule body ledge. The capsule cap is then placed on top of the internal filter ledge and the three pieces are sonically welded together.

Incoming inspection testing is performed on flat stock membrane to verify porosity. Measurements are taken with Coulter® equipment to verify the minimum, maximum, mean and average pore size. After the membrane has been verified, the product is cleared for manufacturing. The assembly process is described above. Online leak testing and filter element/product integrity testing are performed on finished devices to validate membrane seal and capsule integrity.

**b) Performance Testing**

(b)(4)



**c) Filtration Rating**

(b)(4)



**d) Indications for Use**

Please see the attached revised Indications For Use form (Appendix M).

**e) Additional Proposed Labeling Information**

Please see revised labeling and instructions for use for the Adult and Pediatric filters that will be sent as an insert with each shipment (Appendix N). Following the inserts are copies of the labels that will be applied to the outside of each box. All adult and pediatric filters are provided non-sterile in bulk-packaging. The quantity per box is dependent upon an OEM or resellers requirements. A box weight maximum of 50 pounds will be applied unless otherwise specified by an OEM or reseller.

Attached please find Porous Media promotional information illustrating a variety of products offered by our Medical Technologies group (Appendix O). Detailed product information is generally provided by the OEM or reseller utilizing the DPB20™ device as a component within the finished kit.

**f) Additional Labeling Information**

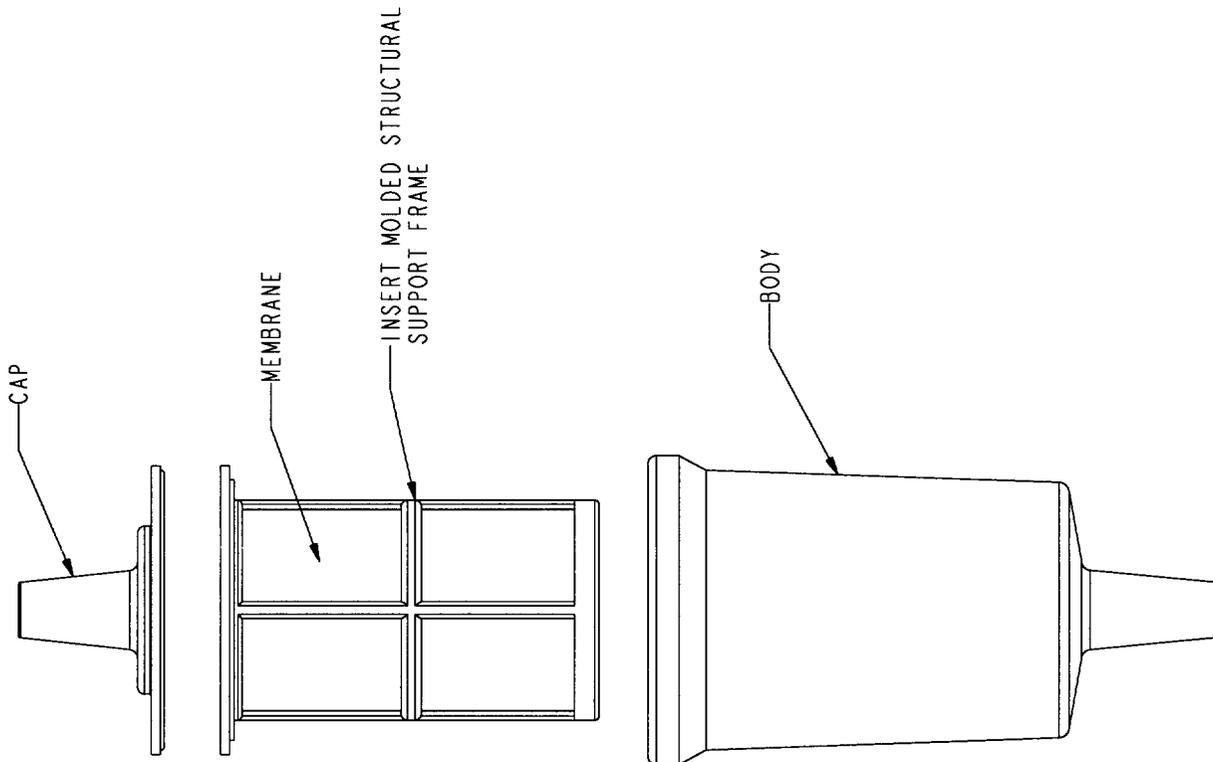
Our standard labeling and instructions for use are limited to those provided in Appendix M. Our customers (OEM's and reseller's) will package our DPB20™ within their finished kit. Our labeling and instructions for use will remain consistent for each customer.

Our product design offers the flexibility to have an OEM's or reseller's name and/or part number injection-molded directly into the capsule body. These enhancements may add additional part numbers to our basic model numbers for future differentiation but product and performance remain the same.

The DPB20™ devices are provided non-sterile. OEM's and reseller's utilizing this product will be required to perform individual sterilization validation based upon their own kit and product requirements.

**g) Appendix H**

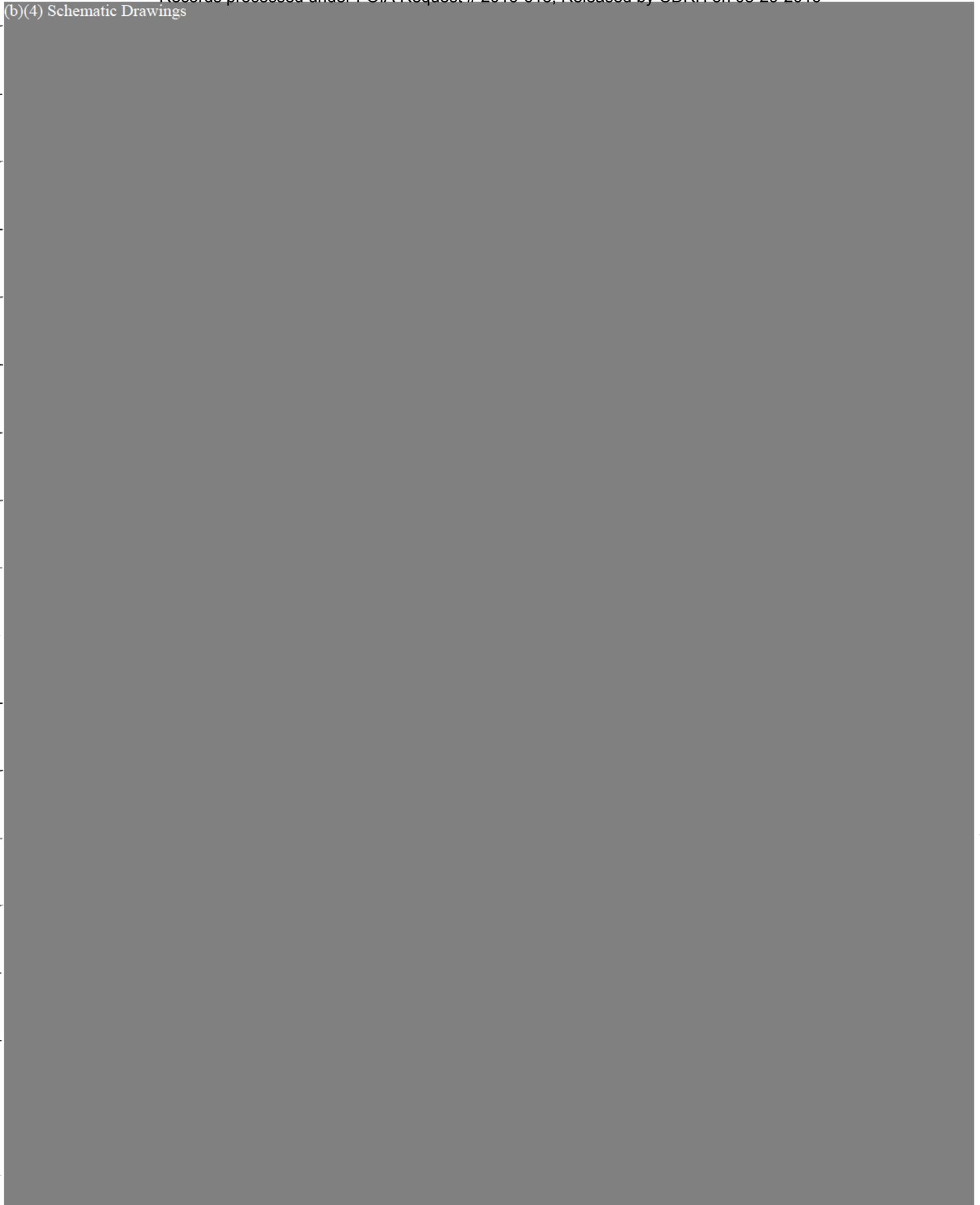
ORIGINAL DATE	10/27/1998	DRAWING NO.	1442-2	SHEET NO.	1 OF 1
DRAWN BY	CAK	CHECKED BY		APPROVED BY	
TITLE	DBP20 5 MICRON PRE-BYPASS FILTER CAPSULE				
MODEL NAME	1442				
		POROUS MEDIA CORPORATION 1350 HAMMOND ROAD, ST. PAUL, MINNESOTA 55110			
DO NOT SCALE THIS DRAWING FOR DIMENSIONS. ALL DIMENSIONS IN INCHES UNLESS SPECIFIED. DIMENSIONAL TOLERANCES UNLESS NOTED: 0.X:XX: ±0.01 X.XXX: ±0.005 ANGLES: ±0.25					



POROUS MEDIA PART NUMBER

30

(b)(4) Schematic Drawings



**h) Appendix I**



**POROUS MEDIA**  
**Medical Technologies**  
**1350 Hammond Road**  
**St. Paul, MN 55110**

**Data Specification Sheet**  
**Sulphoplast™ Membrane**

---

(b) (4)



*All materials of construction are USP VI approved*

T E C H N I C A L D A T A



# Cyrolite<sup>®</sup> GS-90

# Cyrolite<sup>®</sup> G-20

# Cyrolite<sup>®</sup> G-20 HIFLO<sup>®</sup>

ACRYLIC-BASED MULTIPOLYMER COMPOUNDS

CYROLITE GS-90, CYROLITE G-20 and CYROLITE G-20 HIFLO compounds are impact modified acrylic-based multipolymers for molding and extrusion. They have been developed for applications requiring high clarity, extra toughness, high rigidity, good environmental stress craze resistance and excellent resistance to gamma irradiation. CYROLITE GS-90 compound does not yellow after gamma sterilization. The property profiles of CYROLITE compounds have resulted in wide acceptance in the medical device industry. In addition to medical applications, the compounds have found applications in toys, appliances and a variety of large and small molded parts.

		ASTM Method	CYROLITE GS-90	CYROLITE G-20-100	CYROLITE G-20-HIFLO	
<b>Optical Properties</b>	Light Transmission (%)	D-1003	89	90	90	
	Haze (%)	D-1003	3.5	7	7	
	Refractive Index	D-542	1.515	1.515	1.515	
<b>Rheological Properties</b>	Average Melt Flow (g/10 min) @ 230°C & 5.0 kg	D-1238	7.2	2.2	12	
	<b>Mechanical Properties</b>	Tensile Strength (psi) [MPa]	D-638	7,000 [48.3]	6,800 [46.9]	6,200 [42.8]
Tensile Modulus (psi) [GPa]		D-638	0.32 [2.2]	0.32 [2.2]	0.32 [2.2]	
Tensile Elongation (%) at yield at break		D-638	3.6 6.7	4.0 9.5	3.8 9.5	
<b>Physical Properties</b>	Flexural Strength (psi) [MPa]	D-790	10,800 [74.5]	10,500 [72.4]	9,400 [64.8]	
	Flexural Modulus (x 10 <sup>6</sup> psi) [GPa]	D-790	0.33 [2.27]	0.335 [2.3]	0.31 [2.1]	
	Notched Izod (ft.-lb/in. of notch) [J/m] on 1/4" [6.35mm] bar	73°F [23°C]	D-256	2.0 [107]	1.9 [101]	1.9 [101]
		32°F [0°C]			1.1 [59]	1.1 [59]
	Compressive Strength (psi) [MPa]	D-695	—	11,500 [79.3]	11,500 [79.3]	
	Rockwell Hardness (M scale)	D-785	30	39	27	
	Deflection Temperature (°F @ 264 psi) [°C]	D-648	163 [73]	186 [86]	186 [86]	
Vicat Softening Point (°F) [°C]	D-1525	210 [99]	214 [101]	214 [101]		
Specific Gravity	D-792	1.11	1.11	1.11		
Water Absorption (% max)	D-570	0.3	0.3	0.3		
Mold Shrinkage (in/in & mm/mm)	—	0.004-0.006	0.004-0.007	0.004-0.007		
Bulk Density (g/cc loose)	D-1895	0.65	0.65	0.65		
Coefficient of Linear Expansion (in/in/°F, 32-212°F) [mm/mm/°C, 0-100°C]		D-696	0.00004 [0.000072]	0.0000514 [0.0000925]	0.0000514 [0.0000925]	

**i) Appendix J**

Records processed under FOIA Request # 2016-613; Released by CDRH on 08-29-2016

# U.S. FILTER

**U.S. FILTER/FILTRATION** TELEPHONE 847-468-1405  
1430 DAVIS ROAD FACSIMILE 847-468-1571  
ELGIN, IL 60123 USA TOLL FREE 1-800-FILTERS

Here are the summary report of the efficiency test of MMM5 membrane for Porous Media:

**Procedures and Results:**

(b) (4)



42

(b) (4)



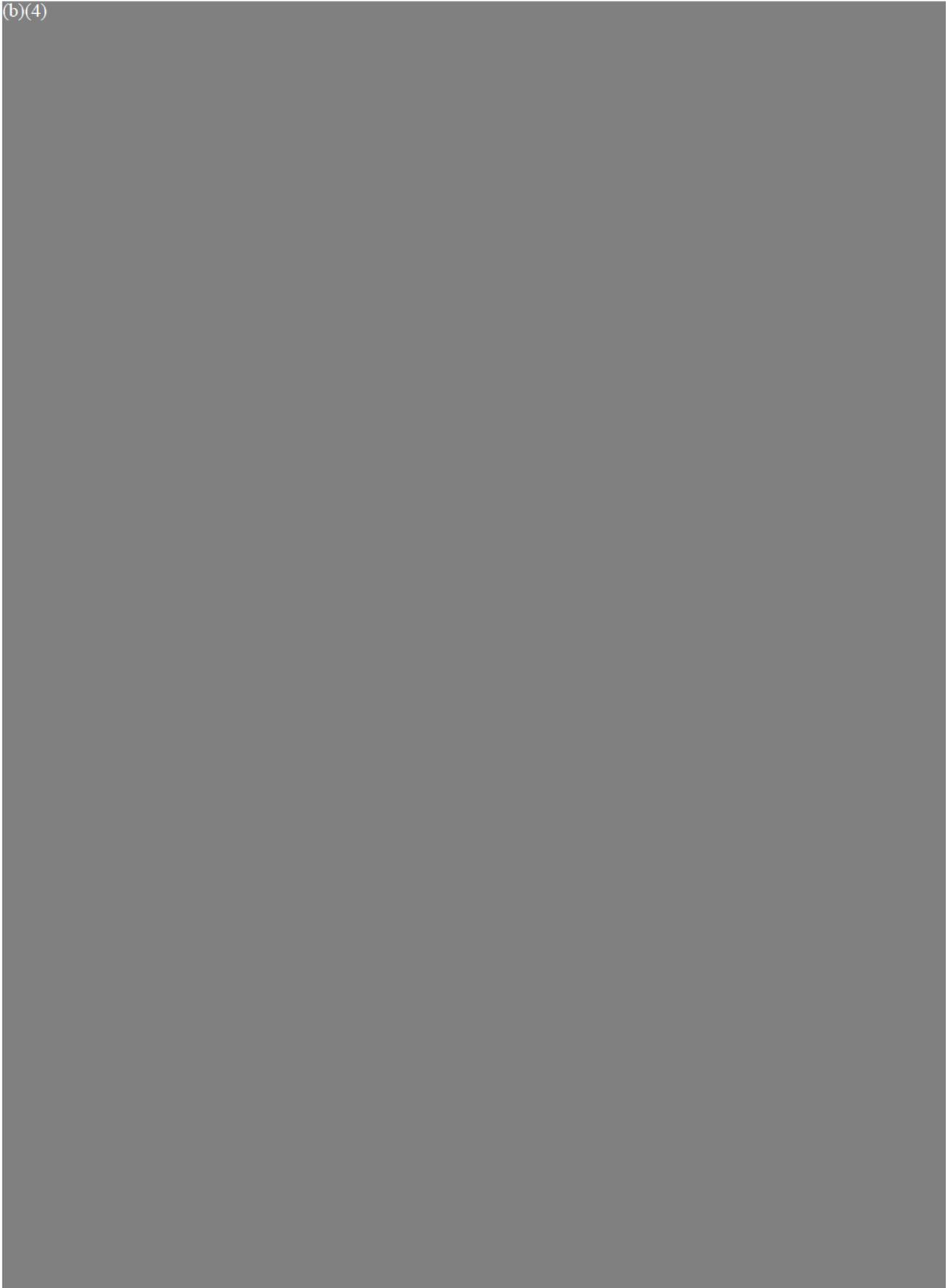
**j) Appendix K**

**Performance Test Data**  
**for Porous Media DPB20™ Prebypass Filter**

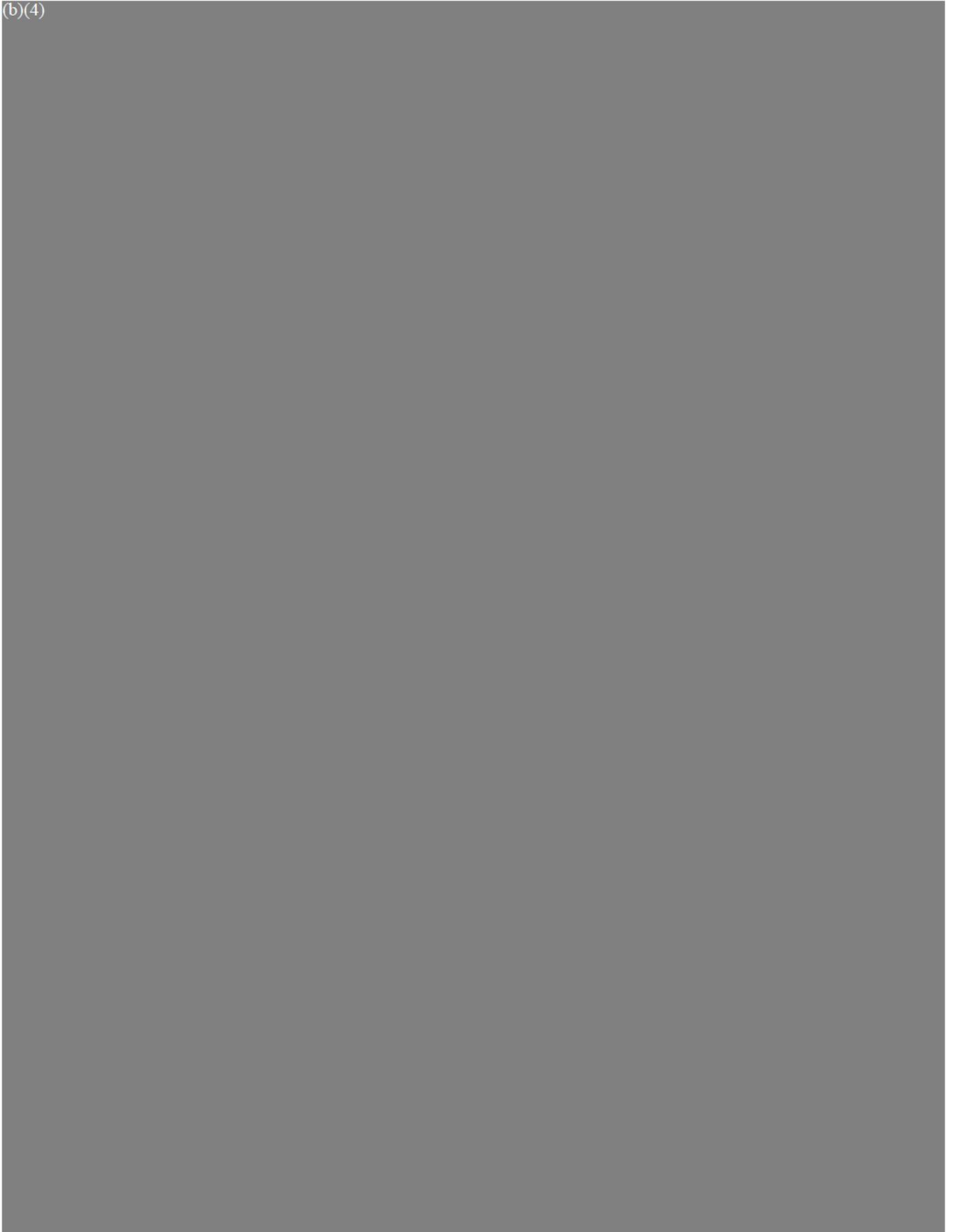
The enclosed information is the property of Porous Media Corporation and is furnished in confidence solely for the purpose of evaluating Porous Media technology. It is not to be copied, communicated or distributed without the expressed written consent of Porous Media Corporation.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4)



(b)(4)



**k) Appendix L**

48

## **Standard Testing Procedure**

(b)(4)



Records processed under FOIA Request # 2016-613; Released by CDRH on 08-29-2016

Records processed under FOIA Request # 2016-613; Released by CDRH on 08-29-2016

**l) Appendix M**

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Page 1 of 1

510(k) Number (if known):           K982385          

Device Name:           DPB20™ Disposable Pre-bypass Filter          

Indications For Use:

- THE FILTER IS INTENDED FOR USE ONLY WITH NON-CELLULAR FLUID IN THE EXTRACORPOREAL CIRCUIT PRIOR TO THE INITIATION OF CARDIOPULMONARY BYPASS.
- THE DPB20™ DISPOSABLE PRE-BYPASS FILTER HAS BEEN DESIGNED FOR SINGLE USE AND SHOULD BE DISCARDED ONCE THE CIRCUIT IS PRIMED.

---

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

- Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use            or Over-The-Counter Use             
(Per 21 CFR 801.1091) (Optional Format 1-2-96)

53

**m) Appendix N**

54 25



## **POROUS MEDIA**

Porous Media Corporation  
1350 Hammond Road  
St. Paul, MN 55110  
(612) 653-2000  
(612) 653-2230 FAX

### **Porous Media DPB20™ - Adult Prebypass Filter Model No. DPB2011S500**

#### **Description**

The DPB20™ is a filter designed to be placed between the arterial and venous lines for the removal of particulate contamination during the initial priming of the extracorporeal circuit with non-cellular fluids

#### **Indications**

Porous Media DPB20™ pre-bypass filter is indicated for cardiopulmonary procedures utilizing non-cellular priming solution.

#### **Warnings**

Do not use with blood or blood products.  
Please follow instructions for use.  
Intended for single use only.  
Do not reuse.  
Do not re-sterilize.  
Do not exceed 6 lpm flow rate.

**Important:** Remove pre-bypass filter from circuit before cardiopulmonary bypass.

#### **Contraindications**

The DPB20™ is not designed, sold or intended for use except as indicated.

#### **Specifications**

Filter Media	5.0 micron
Flow Direction	Flow only in direction indicated on the housing
Maximum Flow Rate	6 lpm
Inlet/Outlet Port Configuration	Non-barbed and adaptable to either 3/8" or 1/2" tubing.
Priming Volume	180 ml

#### **Instructions for Use**

1. Connect the filter between the arterial and venous line observing sterile technique in accordance with the direction orientation indicated on the filter.
2. Prime the extracorporeal circuit with non-blood, non-cellular solutions.
3. Slowly recirculate the priming solution and purge air from the filter.
4. Increase pump to recommended full flow and continue to recirculate.
5. After recirculation, stop pump, clamp tubing distal and proximal to the filter and remove filter.
6. Dispose of filter.

#### **Caution:**

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

		<b>Porous Media</b> 1350 Hammond Road St. Paul, MN 55110	
POROUS MEDIA PART NUMBER: <b>DPB2011S500</b>			
			
QUANTITY:		U.O.M.:	
		<b>EACH</b>	
LOT#:		DATE:	
<b>XXXXXXXXXX</b>		<b>11/03/08</b>	
			

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## **POROUS MEDIA**



Porous Media Corporation  
1350 Hammond Road  
St. Paul, MN 55110  
(612) 653-2000  
(612) 653-2230 FAX

### **Porous Media DPB20™ - Pediatric Prebypass Filter Model No. DPB2022S500**

#### **Description**

The DPB20™ is a filter designed to be placed between the arterial and venous lines for the removal of particulate contamination during the initial priming of the extracorporeal circuit with non-cellular fluids

#### **Indications**

Porous Media DPB20™ pre-bypass filter is indicated for cardiopulmonary procedures utilizing non-cellular priming solution.

#### **Warnings**

Do not use with blood or blood products.

Please follow instructions for use.

Intended for single use only.

Do not reuse.

Do not re-sterilize.

Do not exceed 6 lpm flow rate.

**Important:** Remove pre-bypass filter from circuit before cardiopulmonary bypass.

#### **Contraindications**

The DPB20™ is not designed, sold or intended for use except as indicated.

#### **Specifications**

Filter Media	5.0 micron
Flow Direction	Flow only in direction indicated on the housing
Maximum Flow Rate	6 lpm
Inlet/Outlet Port Configuration	Non-barbed and adaptable to either 1/4" or 3/8" tubing
Priming Volume	180 ml

#### **Instructions for Use**

1. Connect the filter between the arterial and venous line observing sterile technique in accordance with the direction orientation indicated on the filter.
2. Prime the extracorporeal circuit with non-blood, non-cellular solutions.
3. Slowly recirculate the priming solution and purge air from the filter.
4. Increase pump to recommended full flow and continue to recirculate.
5. After recirculation, stop pump, clamp tubing distal and proximal to the filter and remove filter.
6. Dispose of filter.

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

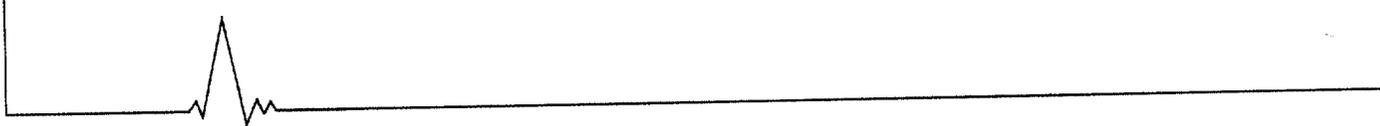
		<b>Porous Media</b> 1350 Hammond Road St. Paul, MN 55110	
POROUS MEDIA PART NUMBER: <b>DPB2022S500</b>			
			
QUANTITY:		U.O.M.:	
		<b>EACH</b>	
LOT#:		DATE:	
<b>XXXXXXXXXX</b>		<b>11/03/98</b>	
			

58

**n) Appendix O**

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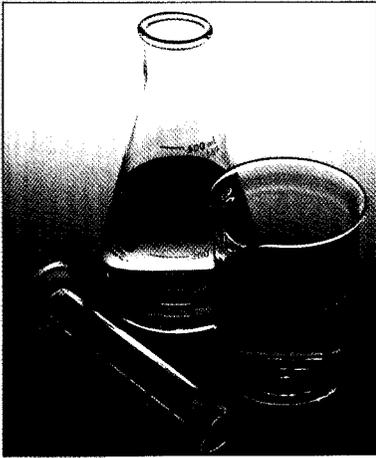




Porous Media Corporation designs and manufactures high-performance filter media and related filtration products and separation technologies. These are used in the separation of liquids, solids or gases from liquids or gases in a wide array of industries including medical, fluid process, pneumatics, instrumentation, oil and gas, lubrication and hydraulics, and transportation industries.

Porous Media's medical devices are a reflection of its guiding corporate philosophies. Innovative technologies. An uncompromising commitment to quality. Unparalleled service. Exceptional value. And an overwhelming passion for understanding the specific needs and expectations of the customer.

These have been the driving forces that transcend across all disciplines within Porous Media. Advanced ideas and improvements that continually come together into extraordinary products and technical support. This is what makes the decision to utilize Porous Media so simple.



## INNOVATION

In today's highly competitive medical environment, yesterday's solutions aren't enough. It's why we place such an emphasis on innovation. An aggressive R&D effort is supported by our STAR™ (Scientific, Testing, Analysis and Research) Laboratories. Scientists and engineers of STAR™ Laboratories develop and refine filter media and membranes, optimize filtration characteristics and create medical device designs which provide the highest level of performance, efficacy and repeatability.

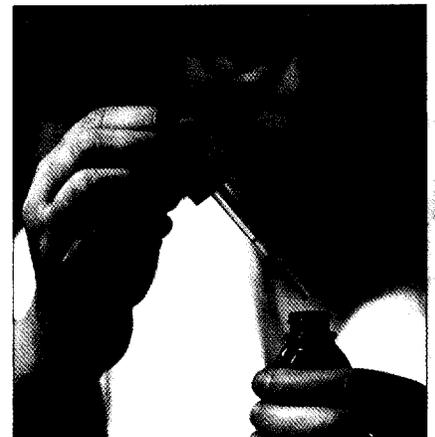
We also realize that many of the best innovations are user-driven. That's why we practice *holistic innovation*. Individuals from research and development, engineering, manufacturing, marketing and quality assurance work together in integrated teams in developing and bringing new products to market. This leads to better definitions of project requirements, reduced product development cycle times, lower development costs and faster speed-to-market product introductions. It has also led to a host of advancements for critical medical filtration applications.

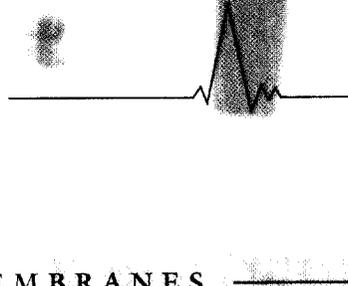
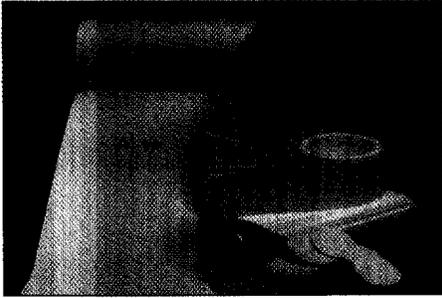
This result is products which aren't intended just to compete, but to set the standards by which every other medical filtration device has to be measured.

## TECHNICAL SUPPORT

More than ever, users are looking for companies who provide not just products, but also offer technical support when making the best decision possible from a myriad of choices. Behind every Porous Media product is an entire company waiting to help you. Teams of engineers, scientists, chemists, marketing and customer service associates are dedicated to understanding the specific needs and requirements of your application, and providing a product or service which not only meets but exceeds those expectations.

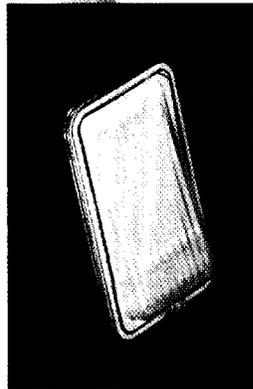
In addition, we offer regulatory assistance for 510K approval applications and our scientists and engineers also work hand in hand with independent laboratory facilities to validate test procedures and results.





## MEDIA AND MEMBRANES

A wide range of media and membranes are available. Standard grades, with or without hydrophobic, hydrophilic or other surface treatments, are available to tailor the media or membrane to the specific requirements of the application.



## SURGICAL DEVICES

A plethora of surgical protection devices are available to provide protection and bacteria removal for procedures including laser surgery, insufflation, fluid irrigation, ophthalmic surgery, liposuction and many more.

## IV THERAPY

For safe removal of microembolisms, particulate contaminants and lipids, IV products are available with various membrane grades and efficiencies.

## HYDROPHOBIC BARRIERS

A variety of disks and capsule configurations provide cross-contamination protection for patients and extend the life of expensive medical equipment.

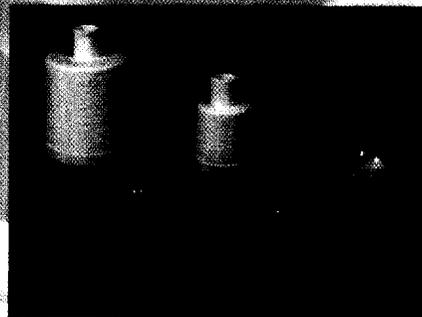


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## STERILE AIR, GAS AND FLUID

High-efficiency capsules and devices provide bacteria-free air, gas and fluid delivery to patients to ensure a complication-free recovery for the patient and protection for the hospital staff. These devices are available in a variety of configurations from small to large flow applications.



## RESPIRATORY DEVICES

A variety of breathing circuit filters for ventilators and anesthesia applications provide bacteria and viral removal with efficiencies greater than 99.999%. Inspiratory and expiratory breathing circuit filters, HME's (Heat & Moisture Exchanger), HEPA disposable devices and respiratory filter capsules are available in various configurations and efficiencies. Custom OEM devices can also be provided utilizing either Electrete™ (electrostatically charged media) or Ultraphobic™ hydrophobic filter media.

ADDITIONALLY, A WIDE ARRAY OF PRODUCTS AND DEVICES ARE AVAILABLE FOR OTHER APPLICATIONS:

Sterile Water Delivery

Cardiovascular Filtration

Endotoxin Removal

Oxygen Concentrator Devices

Blood Filtration

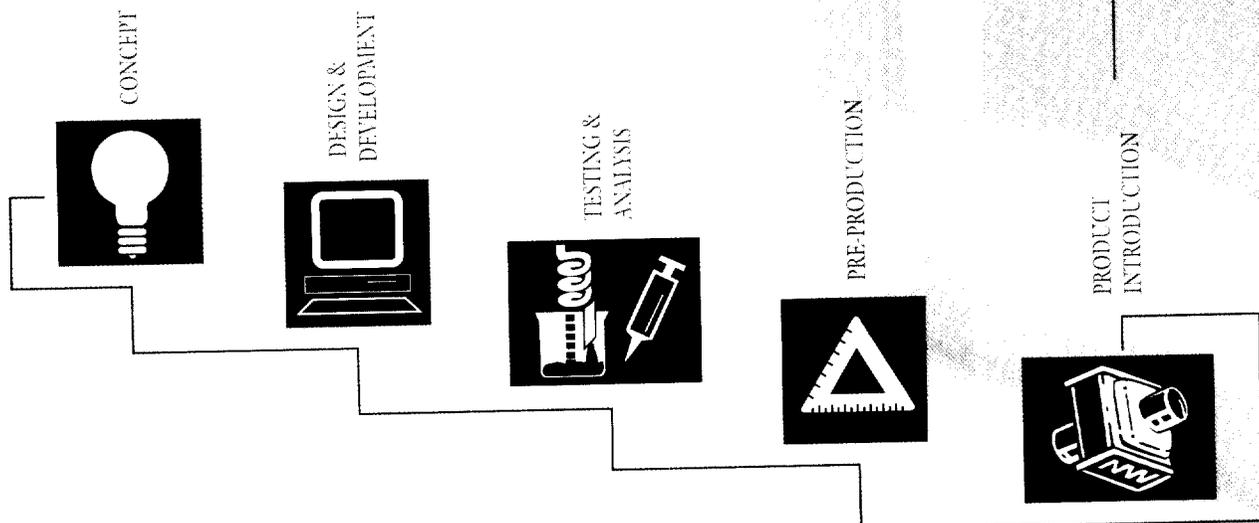
Medical Suction

HPLC

## ASC™ PROGRAM

Each company's specific needs are unique. And as a result, they typically aren't interested in generic solutions. That's why we created our ASC™ (Application-Specific Customization) Program. A team of Porous Media associates work together with an OEM's key personnel to develop customized filtration products and devices specifically for the individual requirements of the OEM's application. The result is a filtration device which provides exactly the performance necessary for the application. Products are designed as part of the equipment, thereby enhancing the OEM's name-brand recognition and reputation for providing quality.

While customized products usually mean long development times, Porous Media's market-driven philosophy has given the term "speed-to-market" a whole new meaning. Team engineering, rapid prototyping methods and flexible manufacturing systems take a concept all the way from design through prototyping and on to final production within weeks.



## QUALITY

At Porous Media, quality means the continuous pursuit of excellence. Our corporate values of QRS (Quality, Respect and Service) ensure every associate is dedicated to producing superior quality products and delivering exceptional service.

As a GMP manufacturer, our quality assurance program and clean room procedures strictly conform to all applicable FDA device regulations. Special quality assurance procedures can also be implemented to apply to customer requirements. As part of the program, testing, documentation and validation are available to the OEM for their reference.

## ECONOMIC VALUE

Today's medical market is demanding economic solutions to reduce overall costs which conventional filtration and separation technologies don't provide. The technical and creative expertise of Porous Media scientists and engineers, combined with new technological breakthroughs and Porous Media's ASC™ program, are utilized to optimize each medical device for the specific requirements of the application in order to provide the best cost/performance ratio. Automation is used whenever possible to provide improved reliability, increased productivity while minimizing costs. It all adds up to exceptional economic value.



**POROUS MEDIA CORPORATION**

Medical Technologies Division • 1350 Hammond Road • St. Paul, MN 55110

Phone: (612) 653-2000 • Fax: (612) 653-2230

Questions? Contact FDA/CDRH/OCE/DIV 1 at CDRH-FOI-STATUS@fda.hhs.gov or 301-796-8118

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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

OCT 7 1998

Ms. Rochelle M. Mickschl  
Medical Device Representative  
Porous Media Corporation  
1350 Hammond Road  
St. Paul, MN 55110

Re: K982385  
Porous Media DPB20 Series Disposable  
Pre-Bypass Filter  
Dated: July 8, 1998  
Received: July 9, 1998

Dear Ms. Mickschl:

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

(b) (4)



Page 2 - Ms. Rochelle M. Mickschl

(b) (4)



We believe that this information is necessary for us to determine whether or not this device is substantially equivalent to a legally marketed predicate device with regard to its safety and effectiveness.

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(k), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Federal Food, Drug, and Cosmetic Act (Act). You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations.

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete.

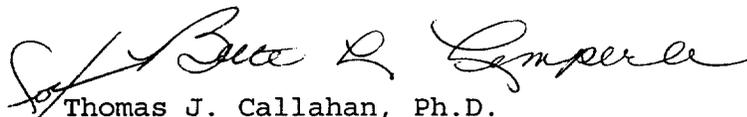
Page 3 - Ms. Rochelle M. Mickschl

The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to:

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

If you have any questions concerning the contents of this letter, please contact Joydeb Roy, Ph.D., at (301) 443-8262. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its internet address "dsmo@fdadr.cdrh.fda.gov."

Sincerely yours,



Thomas J. Callahan, Ph.D.  
Director  
Division of Cardiovascular, Respiratory,  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

Page 4 - Ms. Rochelle M. Mickschl

cc: HFZ-401 DMC  
 HFZ-404 510(k) Staff  
 HFZ-450 Division  
 D.O.

Prepared by: Jroy:erj:10/6/98:FINAL

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
450	Bl/for JR	7 OCT						
450	Rempel	7 OCT						

U.S. GPO 1986-169-089

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Ms. Rochelle M. Mickschl  
Medical Device Representative  
Porous Media Corporation  
1350 Hammond Road  
St. Paul, MN 55110

Re: K982385  
Porous Media DPB20 Series Disposable  
Pre-Bypass Filter  
Dated: July 8, 1998  
Received: July 9, 1998

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Page 2 - Ms. Rochelle M. Mickschl

(b) (4)



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Page 3 - Ms. Rochelle M. Mickschl

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Rockville, Maryland 20850

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Sincerely yours,

Thomas J. Callahan, Ph.D.  
Director  
Division of Cardiovascular, Respiratory,  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food And Drug Administration

Memorandum

1: Reviewer(s) - Name(s) Joyles J  
Subject: 510(k) Number K982385

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

- Refused to accept.
  - Requires additional information (other than refuse to accept). *3/20/98*
  - Accepted for review \_\_\_\_\_
  - Is substantially equivalent to marketed devices.
  - NOT substantially equivalent to marketed devices.
- De Novo Classification Candidate?  YES  NO
- Other (e.g., exempt by regulation, not a device, duplicate, etc.)

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

This 510(k) contains:

- Truthful and Accurate Statement  Requested  Enclosed  
(required for originals received 3-14-95 and after)
- A 510(k) summary OR  A 510(k) statement
- The required certification and summary for class III devices
- The indication for use form (required for originals received 1-1-96 and after)
- Material of Biological Origin  YES  NO

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

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

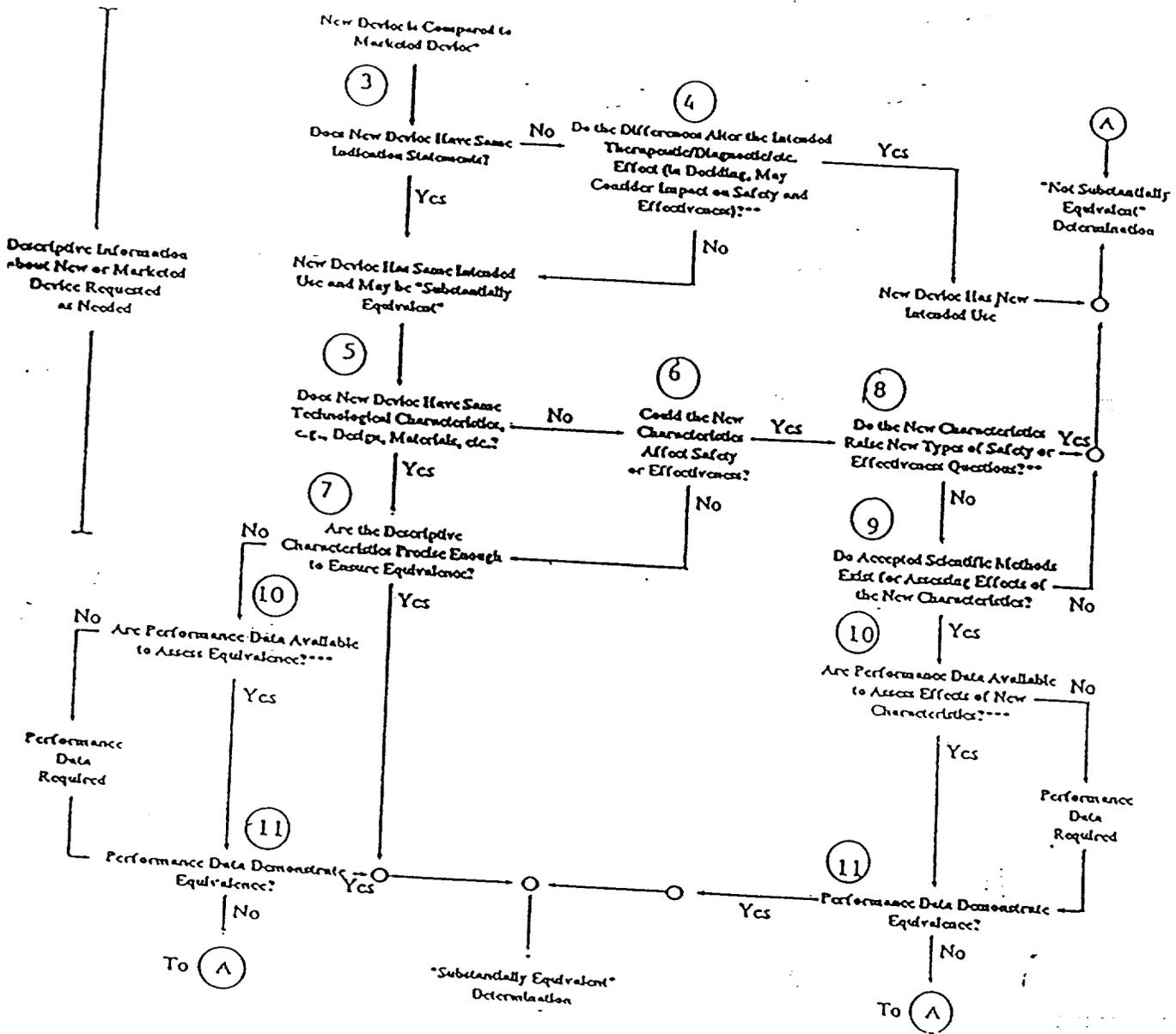
Predicate Product Code with class: \_\_\_\_\_ Additional Product Code(s) with panel (optional): \_\_\_\_\_

Review: \_\_\_\_\_  
(Branch Chief) (Branch Code) (Date)

Final Review: \_\_\_\_\_  
(Division Director) (Date)

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



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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Services  
Food and Drug Administration  
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH  
Office of Device Evaluation

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**MEMORANDUM**

**Date:** 14 September, 1998

**From:** Dr. Joydeb Roy *JR*  
Physicist  
DCRND/CSPG *30  
100-98*

**To:** File:K982385

**Sponsor:** Porous Media Corp.

**Device:** Porous Media DPB20 Disposable cardiopulmonary Pre-Bypass Filter

**Subject:** Original Review

**Action:** **Additional Information (AI)**

---

**SUMMARY OF FINDING:**

The following deficiencies were noted:

Performance test data missing: No test data for filtration efficiency, limits on flow/flow range (validity of filtration efficiency), % removal of particulates with size, average/maximum pressure drop, and comparative testing of predicate(s). The description and the labeling and the instruction for use is inadequate. In addition, the submission is also not well organized.

A deficiency letter is being prepared for mailing.

**Review Elements**

1. **Administrative Information:**

Truthful and Accurate Statement:	The truthful and accurate statement provided
Indications for Use Statement:	The required indication for use form provided.
Summary of Safety and Effectiveness:	The 510(k) statement of safety and effectiveness provided.
Predicate Device:	K832594/K940126/K831286
Panel/Class/Code/CFR:	II/870.4280
Reason for submission:	New Device
Reference Documents:	
Device sample:	

***Missing Information:*** *None*

2. **Indications for Use:**

The device is indicated for the following:  
The device will be used to filter the non-hermetic priming solution prior to introducing blood into the cardiopulmonary pre-bypass circuit. The product is a short term single use disposable device. The product will be used for both adults and pediatric patients. The device is identical for adults and pediatric use except for smaller inlet size for the pediatric

The filter device has been designed to remove particulate contamination from the extracorporeal circuit during the initial priming and debubbling.

NOTE: The indication for use form is not very precise (page 36).

***Missing Information:*** *Modification required*

3. **Labeling:**

Labeling information provided. It includes information on label size, Lot#, caution statement, warnings, instructions for use provided. The device will be sold by or on order of a physician.

However, copies of proposed/ actual package labels, container labels not provided.

NOTE: Labeling is inadequate. Additional information will be required.

NOTE: The instructions for use does not specify the average or nominal time the device will be in use .or what criteria will be used to know whether the all components to be removed have been removed.

*Predicate labeling for Bentley RF10 Re-circulation Filter, also provided.*

***Missing Information:*** *Labels, Promotional material,*

4. **Description:**

The device is a multilayered-filter. The filter media utilized within the device is a 5.0micro-m polysulfone membrane. The support layer is polyester melt blown media. The support layers are placed up and downstream to provide additional support for for the membranebut more importantly to act as handling material during the manufacturing process. The sealed capsule filter housing material is injection-molded from Cyrolite G-20 HIFLO manufactured by CYRO Industries. Filter media is hermetically sealed to the housing to prevent the possibility of contamination bypassing filter media. Flow arrows will be injection molded into the housing. The device utilizes non-barbed inlet and outlet port configurations similar to AVecor/bentley devices.

The device is a filter for removing particulate contamination from the extra-corporeal circuit during the initial priming and de-bubbling of non-cellular fluids prior to cardiopulmonary bypass. The device is designed for single use and is to be removed and discarded once the circuit is primed. The filter size: ½” to 3/8” (adults) and ¼” to 3/8” (pediatric).

The following predicate device(s) have been listed:  
Gish Biomedical Pre-Bypass Filter, Model EC-PBF  
Avecor Cardiovascular, Pre-Bypass Filter  
Bentley Laboratories, RF-10 Recirculation Filter  
Willaim Harvey H-600 Pre-Bypass Filter  
Delta Medical Industries, PB-005

The description of the filter is not detailed. A detailed diagram with layers of materials will be needed.

NOTE: Biocompatibility results are included.

**NOTE: Product drawing provided, but it does not show/describe layered materials, internal construction.**

**NOTE: This submission is not well organized or formatted. For example, the information is not organized into proper sections, and the sections are not separated with dividers. No description, performance testing section. Product drawing is not placed with the description.**

NOTE: The company states that they will resell /distribute their device to other companies.

**Missing Information:**

**Drawing, detailed description, formatting**

**5. Comparative Information:**

A table of comparison with the predicate device(s) provided.

The porous media for the device is Polysulfone and the Housing material is Cyrolite G-20 HIFLO. The porous media for the Avecor (K940126)/ Bentley(K790361) device(s) is PVC Copolymer and the Housing is Cyrolite. For the Gelman (K812539) device the filter media is PVC CoPolymer/Nylon Support and the Housing is Polypropylene. The filter material used in the device is different. Housing material is similar to the Avecor /William Harvey device. The pre size is 5.0 micron for msot predicates except for Pall Corp. and Gelman Sciences.

The device is different in the following respects:

NOTE: Polysulfone materials are said to be used in a variety of other medical devices including IV Drug Therapy (Gelman Sciences), IV-4 Filter (K934691, Gelman), Polysulphone and Polyethersulfone materials have also been used in many devices.

NOTE: Polysulfone (class) materials have been known to have been used in several classes of devices. A structure/chemical/thermal stability information provided for the polysulfone family of polymers.

NOTE: The submitter states that a comparison of properties of the predicate(s) with the device has been performed.

**Missing Information:**

**Comparative analysis**

**6. Performance Testing:**

(b)(4)



(b)(4)



7. ***Clinical Study***  
No clinical study performed or required..

*Missing Information:* *None*

8. ***Animal Study:***  
No animal study performed or required.

*Missing Information:* *None*

9. ***Material Specification and Biocompatibility Testing:***

(b) (4)



10. ***Sterility, and Packaging:***  
The product will be bulk packaged, non-sterile. The device will be supplied to other manufacturers.
-

The device is a single use disposable device.

NOTE: Packaging and sterility details to be followed by other manufacturers/ resellers.

*Missing Information:*

*List Details*

**II. Software and Firmware:**

*N/A*

*Missing Information:*

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**Information Matrix:**

REVIEW ELEMENTS	YES	NO	DEFICIENCY
Administrative			
Labeling	Yes		
Description			
Comparative Information			
Performance Testing	Yes		
Environmental Testing			
Clinical Testing			
Animal Testing			
Biocompatibility Testing			
Sterility Testing			
Packaging	Yes		
Software Testing			
Special Features			
Standards/Guidance			
Any Other Issue			
Recommendation	AI		
Letter			
Comments:			

Deficiency Letter:

K-3  
CANNOT DETERMINE EQUIVALENCY LETTER  
- NEED MORE INFORMATION

Ms. Rochelle M.Mickschl  
Medical Device Representative  
Porous Media Corp.  
1350 Hammond Road  
St. Paul, MN 55110

Re: K982385  
Trade Name: Porous Media DPB20 Series Disposable  
Pre-Bypass Filter  
Dated: July 8, 1998  
Received: July 9, 1998

Dear Ms. Mickschl:

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

(b) (4)



(b) (4)



We believe that this information is necessary for us to determine whether or not this device is substantially equivalent to a legally marketed predicate device with regard to its safety and effectiveness.

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(k), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Federal Food, Drug, and Cosmetic Act (Act). You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations.

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete.

The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to:

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

If you have any questions concerning the contents of this letter, please contact [DIVISION REPRESENTATIVE] at (301) 594-[ ]. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its internet address "dsmo@fdadr.cdrh.fda.gov".

Sincerely yours,

[Division Director]

Office of Device Evaluation  
Center for Devices and  
Radiological Health

cc: HFZ-401 DMC  
HFZ-404 510(k) Staff  
HFZ- Division  
D.O.

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## *Internal Administrative Form*

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

## Screening Checklist For all Premarket Notification 510(k) Submissions

Device Name: <i>Porus Media DBW Device disposable prehydrant filter</i> K 982385						
Submitter (Company): <i>Porus Media Corp</i>						
Items which should be included (circle missing & needed information)	SPECIAL		ABBREVIATED		TRADITIONAL	
	YES	NO	YES	NO	YES	NO
1. Cover Letter clearly identifies Submission as: a) "Special 510(k): Device Modification" b) "Abbreviated 510(k)" c) Traditional 510(k)	GO TO # 2,4		GO TO # 3,4,5		GO TO # 4,5	✓ IF ITEM IS NEEDED AND IS MISSING
2. "SPECIALS" - ONLY FOR MODIFICATIONS TO MANUFACTURER'S OWN CLASS II, III OR RESERVED CLASS I DEVICE						
a) Name & 510(k) number of legally marketed (unmodified) predicate device						
b) STATEMENT - INTENDED USE AND INDICATIONS FOR USE OF MODIFIED DEVICE AS DESCRIBED IN ITS LABELING HAVE NOT CHANGED*					* If no - STOP not a special	
c) STATEMENT - FUNDAMENTAL SCIENTIFIC TECHNOLOGY OF THE MODIFIED DEVICE HAS NOT CHANGED*					* If no - STOP not a special	
d) Design Control Activities Summary						
i) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis						
ii) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied						
iii) A declaration of conformity with design controls. The declaration of conformity should include:						
1) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met						
2) A statement signed by the individual responsible, that manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.					<i>JD</i>	

→ → → CONTINUE TO SECTION 4 ← ← ←

	SPECIALS		ABBREVIATED		TRADITIONAL		✓ IF ITEM IS NEEDED AND IS MISSING
	YES	NO	YES	NO	YES	NO	
	<b>3. ABBREVIATED 510(K): SPECIAL CONTROLS/CONFORMANCE TO RECOGNIZED STANDARDS</b>						
a) For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type							
b) If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.							
c) For a submission, which relies on a recognized standard, a declaration of conformity to the standard. The declaration should include the following:							
i) An identification of the applicable recognized consensus standards that were met							
ii) A specification, for each consensus standard, that all requirements were met, except for inapplicable requirements or deviations noted below							
iii) An identification, for each consensus standard, of any way(s) in which the standard may have been adapted for application to the device under review, e.g., an identification of an alternative series of tests that were performed							
iv) An identification, for each consensus standard, of any requirements that were not applicable to the device							
v) A specification of any deviations from each applicable standard that were applied							
vi) A specification of the differences that may exist, if any, between the tested device and the device to be marketed and a justification of the test results in these areas of difference							
vii) Name/address of test laboratory/certification body involved in determining the conformance of the device with applicable consensus standards and a reference to any accreditations for those organizations							
d) Data/information to address issues not covered by guidance documents, special controls, and/or recognized standards							

→ → → CONTINUE TO SECTION 4 ← ← ←

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4. GENERAL INFORMATION: REQUIRED IN ALL 510(K) SUBMISSIONS							✓ IF ITEM IS NEEDED AND IS MISSING
	SPECIALS		ABBREVIATED		TRADITIONAL		
	YES	NO	YES	NO	YES	NO	
a) trade name, classification name, establishment registration number, address of manufacturer. device class					✓		
b) OR a statement that the device is not yet classified	FDA - may be a classification request; see coordinator						
c) identification of legally marketed equivalent device					✓		
d) compliance with Section 514 - performance standards					✓		
e) address of manufacturer					✓		
f) Truthful and Accurate Statement					✓		
g) Indications for Use enclosure					✓		
h) SMDA Summary or Statement (FOR ALL DEVICE CLASSES)					✓		
i) Class III Certification & Summary (FOR ALL CLASS III DEVICES)					-		
j) Description of device (or modification) including diagrams, engineering drawings, photographs, service manuals					✓		
k) Proposed Labeling:							
i) package labeling (user info)					✓		
ii) statement of intended use					✓		
iii) advertisements or promotional materials					✓		
i) MRI compatibility (if claimed)					✓		
m) Comparison Information (similarities and differences) to named legally marketed equivalent device (table preferred) should include:							
i) labeling					✓		
ii) intended use					✓		
iii) physical characteristics					✓		
iv) anatomical sites of use					✓		
v) performance (bench, animal, clinical) testing					✓		
vi) safety characteristics					✓		
n) If kit, kit certification					✓		

5. Additional Considerations: (may be covered by Design Controls)						
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:						✓
i) component & material						✓
ii) identify patient-contacting materials						✓
iii) biocompatibility of final sterilized product						✓
b) Sterilization and expiration dating information:						
i) sterilization method						✓
ii) SAL						✓
iii) packaging						✓
iv) specify pyrogen free						✓
v) ETO residues						✓
vi) radiation dose						✓
c) Software validation & verification:						
i) hazard analysis						-
ii) level of concern						
iii) development documentation						
iv) certification						

Items shaded under "NO" are necessary for that type of submission. Circled items and items with checks in the "Needed & Missing" column must be submitted before acceptance of the document.

Passed Screening  Yes  No  
 Date: 7/20/98

Reviewer: J. Ray  
 Concurrence by Review Branch: \_\_\_\_\_

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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, 1998

POROUS MEDIA CORP.  
1350 HAMMOND RD.  
ST. PAUL, MN 55110  
ATTN: ROCHELLE M. MICKSCHL

510(k) Number: K982385  
Received: 09-JUL-1998  
Product: POROUS MEDIA DPB20  
SERIES DISPOSABLE  
PRE-BYPASS FILTER

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

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

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

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

Sincerely yours,

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

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15982385



**POROUS MEDIA**

Porous Media Corporation  
1350 Hammond Road  
St. Paul, MN 55110  
(612) 653-2000  
(612) 653-2230 FAX

July 8, 1998

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

RECEIVED

9 JUL 98 09 56

FDA/CDRH/OCE/DAC

**RE: Premarket Notification 510 (k) Submission for Porous Media DPB20™ Disposable Cardiopulmonary Pre-Bypass Filter**

Attention: Document Mail Clerk

As required by Federal Register Notice 21, No. 807 and section 510(k) of the Federal, Food, Drug and Cosmetic Act, Porous Media Corporation is providing 90 day notice of our intent to introduce into interstate commerce for commercial distribution a new cardiopulmonary pre-bypass filter. We believe this device is substantially equivalent to other similar devices currently marketed. Enclosed please find a copy of our 510 (k) PreMarket Notification for this product.

The Porous Media DPB20™ disposable pre-bypass filters, which are the subject of this notification, are substantially equivalent in design, material composition, function and performance to the following:

- a. Gish Biomedical Pre-Bypass Filter, Model EC-PBF
- b. AVecor Cardiovascular, Pre-Bypass Filter
- c. Bentley Laboratories, RF-10 Recirculation Filter
- d. William Harvey H-600 Pre-Bypass Filter
- e. Delta Medical Industries, PB-005

Porous Media has performed extensive in-house testing within our Scientific, Testing, Analysis and Research (STAR™) Laboratories coupled with the verification of external independent testing laboratories to validate our performance claims. We've also performed numerous tests validating pressure drop, priming volume and structural integrity. In addition, several technical papers have been published for the application of pre-bypass filters. In trying to keep this submission to a reasonable length, we will gladly submit these documents, if required, under separate cover.

Porous Media manufacturing process and procedures conforms to the Quality System Regulation (21 CFR 820) required as a GMP manufacturer.

SK-3

CV  
II

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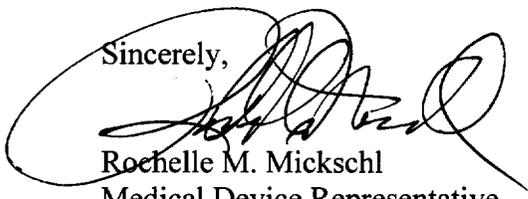
Our company will be supplying this product to other manufacturers and resellers of oxygenators and accessories. This product will be provided non-sterile.

Porous Media believes that the following information which includes biocompatibility testing, performance specifications, and labeling information will be most helpful for the FDA to reach a favorable decision as to the substantial equivalence of this product to currently marketed devices. Porous Media Corporation appreciates the efforts and cooperation of the Food and Drug Administration in this matter.

We also hope that the information we have provided will allow the FDA to reach its decision regarding substantial equivalence to predicate devices within 90 days of this submission. If you should require any additional information or if you have any questions, please contact us at (612) 653-2000 ext. 236.

Thank you.

Sincerely,



Rochelle M. Mickschl  
Medical Device Representative

*Enclosures*

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**510 (k) Submission**

**Porous Media DPB20™ Disposable Cardiopulmonary Pre-Bypass  
Filter**

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**Device Name**

**a) Common/ Usual Name**

Cardiopulmonary Pre-bypass Filter

**b) Proprietary Name**

Porous Media DPB20™ Series Disposable Pre-bypass Filter

**c) Establishment Registration Number**

2132517 Porous Media's manufacturing facility is located at 1350 Hammond Road, St.Paul, MN 55110.

**d) Classification**

FDA has classified cardiopulmonary pre-bypass filters in Class II as pertaining to 21 CFR classification code 870.4280.

**e) Performance Standards**

None established.

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## Proposed Labeling and Instructions for Use

Below, please find labeling information that will accompany the Porous Media DPB20 pre-bypass filter. We feel that this is representative of printed data that will sufficiently describe to the user, the device, the directions for use, warnings and its intended use. Also, claims relevant to the filter's retention of particles, disposability, warnings, flow capacity will be clearly indicated.

Porous Media will be manufacturing and private labeling the DCB20™ disposable pre-bypass filter for other resellers or manufacturers, who in turn, resell our device under their name. All manufacturers and resellers will be made aware of all instructions for use, warnings and intended uses.

Products that Porous Media supplies to other manufacturers and resellers for use within their customized kits will be provided non-sterile.

### Porous Media DPB20™ Series Cardiopulmonary Pre-bypass Filters

Porous Media P/N

DPB2011S500

1/2" to 3/8"

DPB2022S500

1/4" to 3/8" For Pediatric applications

#### **Caution:**

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

#### **Warnings:**

Do not use with blood or blood products.

Please follow instructions for use.

Do not reuse.

Do not re-sterilize.

**Important:** Remove pre-bypass filter from circuit before cardiopulmonary bypass. /

#### **Indications:**

Porous Media DPB20™ pre-bypass filter is indicated for cardiopulmonary procedures utilizing non-cellular priming solution.

## **Instructions for Use DPB20™ Pre-bypass Filter**

Porous Media would like to reiterate that the DPB20™ Pre-bypass Filter may be manufactured by Porous Media for other resellers or manufacturers, who in turn, resell our device under their name. If Porous Media manufactures the filter for another reseller or manufacturer, the company name "Porous Media" and product trade name "DPB20™ " may be replaced with the reseller's or manufacturer's company name and filter trade name. Porous Media will verify that all labeling and instructions for use be incorporated by the manufacturer or reseller private labeling the product.

### **Instructions**

1. Connect the filter between the arterial and venous line observing sterile technique in accordance with the directional orientation indicated on the filter.
2. Prime the extracorporeal circuit with non-blood, non-cellular solutions.
3. Slowly recirculate the priming solution and purge air from the filter.
4. Increase pump to recommended full flow and continue to recirculate.
5. After recirculation, stop pump, clamp tubing distal and proximal to the filter and remove filter.
6. Dispose of filter.

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## Device Description

### a) Intended Use

The DPB20™ Series Pre-bypass Filters were developed to remove particulate contamination from the extracorporeal circuit during the initial priming and debubbling of non-cellular fluids prior to cardiopulmonary bypass. The device is designed for single use and is removed and discarded once the circuit is primed.

As with the predicate devices, Porous Media's pre-bypass filter will be used to filter the non-hermetic priming solution prior to introducing blood into the cardiopulmonary pre-bypass circuit. The purpose of the filter is to reduce contaminants present in the cardiopulmonary circuitry prior to beginning cardiopulmonary bypass. This product is a short-term use device.

The DPB20™ can be utilized for both adult and pediatric applications. The products are identical with the only difference being the size of the inlet and outlet connections.

### b) Materials of Construction

(b) (4)



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**c) Packaging**

Because we are manufacturing this product for other manufacturers and resellers, this product will be bulk packaged, non-sterile. All manufacturers/resellers will be required to follow all labeling and instructions ~~for use~~.

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## Performance Specifications

Below please find our performance claims for filtration efficiencies and pressure drop.

<b>Porous Media DPB20™</b>	
<b>Retention Rating</b>	> 96% @ 5.0 μm
<b>Maximum Differential Pressure (Saline)</b>	No Greater than 100 mm Hg @ 6 lpm

Various procedures within manufacturing will be performed to verify that all products meet published specifications. A sample from each completed lot will be integrity tested prior to shipment.

/s/

### Substantial Equivalence Comparison

Per the request of the FDA below please find a table below indicating properties found with each product based upon information available.

	Product Code	Rated Flow	Ref. Pore Size	Referenced Pressure	Materials Of Construction
Porous Media	DPB20™	6 lpm	5.0 µm		(b) (4)
Gish Biomedical (K832594)	EC-PBF	6 lpm	5.0 µm		
Avecor Cardiovascular (K940126)		6 lpm	5.0 µm	No greater than 100 mm Hg @ 6 lpm	
Delta Medical (K803101)	PB-005	NS	5.0 µm Nominal		
Bentley (K790361)	RF-10	6 lpm	5.0 µm	1000 mm Hg (Max.)	
William Harvey	H-600	6 lpm	5.0 µm		
Gelman Sciences (K812539)	4500003	NS	3.0 µm	750 mm Hg Max.	
Pall Corp. (831286)	Ultipor® Prebypass Plus™	6 lpm	0.2 µm		

#### a) Product Similarities

As shown above, indicated on the attached information and verified from our comparative laboratory test data, the combined characteristics of the 5.0 µm products are substantially equivalent to the Porous Media DBP20™ filter device devices. Other products with lower micron sizes are referenced to illustrate the plethora of products available for this application.

As with other various pre-bypass filters, the DBP20™ device is manufactured with a 5.0 µm filter medium that is thermally adhered to a structural frame and placed within a sealed capsule with inlet and outlet ports. Filter media is hermetically sealed to the housing to prevent possibility of contamination bypassing filter media. The material of the capsule housing is a Cyrolite G-20 HIFLO®. This material is currently utilized within other pre-bypass filters

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including; AVecor Cardiovascular and William Harvey. As with other products currently available, we are fusing the media to a support frame that is then placed into a capsule. This allows our product to provide positive sealing without introducing adhesives.

As with other devices, the product flows inside to outside. Flow arrows will be injection-molded into the housing so the user is clear as to the flow direction.

Porous Media utilizes non-barbed inlet and outlet port configurations similar to other products commercially available (AVecor Cardiovascular K940126, Bentley RF-10 K790361).

The instructions, indications for use, and labeling for pre-bypass filters have been standardized over time. As shown, our DPB20™ adheres to all standard labeling requirements for this product.

**b) Product Differences**

(b)(4)



**c) Conclusion**

Porous Media has evaluated the design, materials, indications for use, performance specifications in addition to a comparative analysis of test results of the Porous Media DPB20™, William Harvey H-600 pre-bypass filter and the AVecor pre-bypass filter in the application. After careful review we find that the Porous Media DPB20™ is substantially equivalent to other products commercially available.

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**Appendices**

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**a) DBP20™ Product Drawing**

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(b)(4) Schematic Drawings



**b) Properties of Polysulfones**

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Properties of Polysulfones

(b) (4)



118

**c) USP Class VI Biocompatibility Test Results for Materials of Construction**

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Records processed under FOIA Request # 2016-613; Released by CDRH on 08-29-2016

Records processed under FOIA Request # 2016-613; Released by CDRH on 08-29-2016

Records processed under FOIA Request # 2016-613; Released by CDRH on 08-29-2016

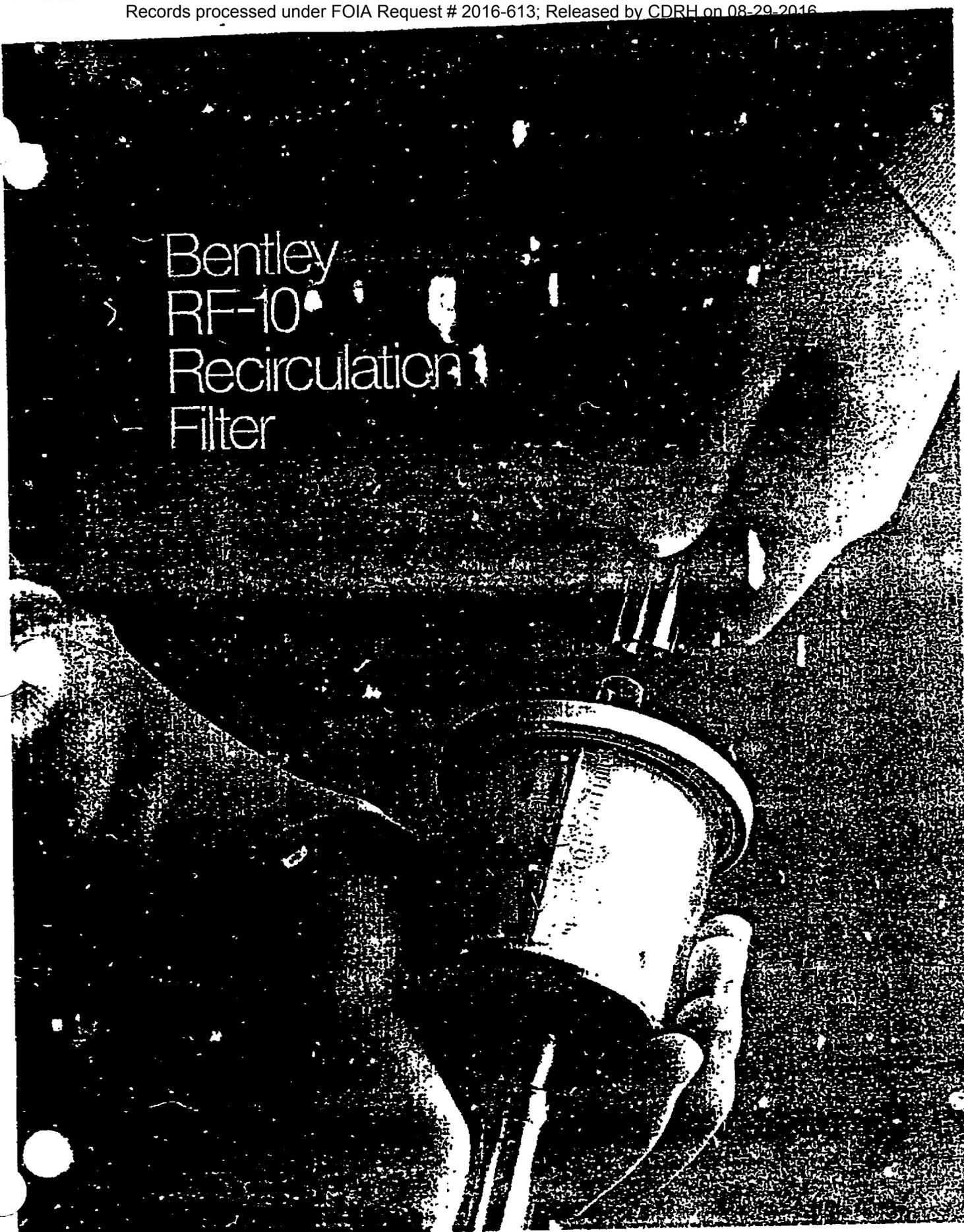
Records processed under FOIA Request # 2016-613; Released by CDRH on 08-29-2016

Records processed under FOIA Request # 2016-613; Released by CDRH on 08-29-2016

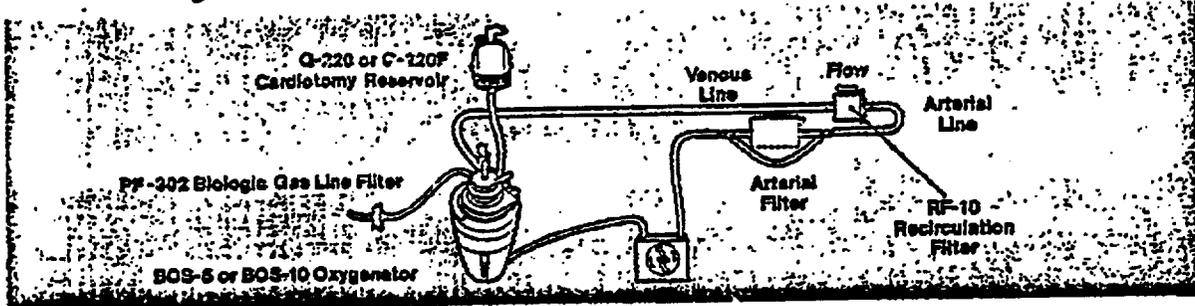
Records processed under FOIA Request # 2016-613; Released by CDRH on 08-29-2016

**d) Product Labeling/Brochures for Predicate Devices**

Bentley  
RF-10  
Recirculation  
Filter



# Bentley RF-10 Recirculation Filter



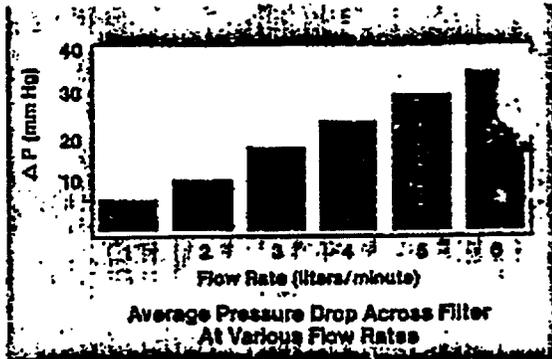
The RF-10 contains a 5 micron filter element. Its purpose is for use in the arterial-venous recirculation line (refer to circuit drawing above). During the initial priming and debubbling (recirculation) of the arterial and venous lines, the RF-10 can remove potential microemboli which may occasionally be present in the various components of the extracorporeal circuit.

Since the filter element is 5 microns, the RF-10 cannot be used in association with blood components. A totally non-blood prime must be used when utilizing the RF-10. Once the recirculation process has been completed, the RF-10 must be removed from the circuit. The barbless RF-10 connectors will allow for filter removal from the tubing without creating inner tubing wall abrasion. This will eliminate the need to cut the filter out of the tubing. The act of cutting the tubing may produce the very debris which you are trying to eliminate.

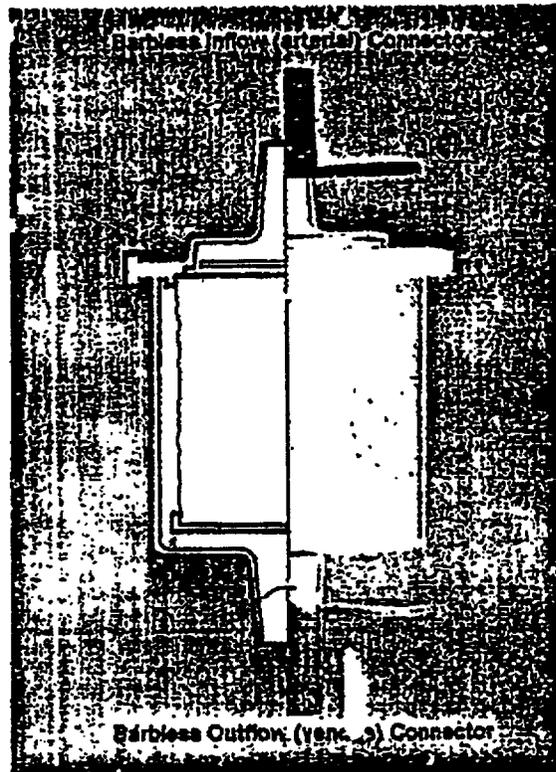
**Specifications:**

- Size: a) Overall length = 12.38 cm
- b) Maximum diameter = 7.54 cm
- Priming Volume: 180 ml
- Weight: .0544 kg.
- Inflow (arterial) Connector:  $\frac{3}{8}$ " = 9.5 mm
- Outflow (venous) Connector:  $\frac{1}{2}$ " = 12.7 mm

- Packaged:**
- 6 units per unit carton
  - 15.87 x 15.87 x 21.59 cm
  - 4 unit cartons per master
  - 32.07 x 32.07 x 21.75 cm



The pressure drop chart (shown above) indicates the average pressure drop across the RF-10 filter, at various flow rates. The actual pressure drop varies slightly according to the amount of gas occupying the filter area. The RF-10 has been tested up to 20 p.s.i. (over 1000 mm Hg) line pressure without separation of the tubing (Bentley tubing) from the barbless RF-10 connectors.

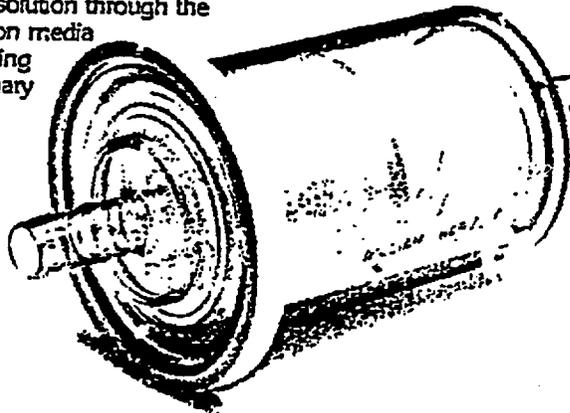


BENTLEY LABORATORIES, INC.

BENTLEY LABORATORIES EUROPE

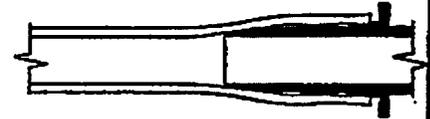
### A solution to a long recognized problem - the H-600 Pre-bypass Filter.

Particulate contamination in cardiopulmonary bypass is well documented.<sup>6,7,8</sup> The H-600 disposable pre-bypass filter permits removal of foreign body material accumulated in the extracorporeal circuit. This is accomplished by high flow circulation of the prime solution through the H-600 5-micron media prior to initiating cardiopulmonary bypass.

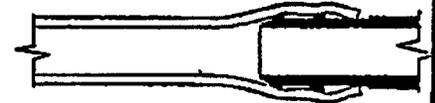


### Reduced turbulence with William Harvey Connectors

William Harvey connectors fit snugly. There is no gap between the tube wall and the outer barb surfaces. All injection mold parting lines are outside of the blood path.



William Harvey Connectors



Conventional connectors

1. Wilkinson, R.F.: A comparative scanning electron microscope study of polyvinyl chloride and urethane-coated tubing used in blood circulation, unpublished. Electron Microscope Laboratory, Hancock Foundation.
2. Guess, W.L., Jacob, J., Autiani, J.: A study of polyvinyl chloride blood bag assemblies, 1. Alteration or contamination of ACD solutions, *Drugs Intel*, 1, 120 1967.
3. Marcel, Y.L., Noel, S.P.: A plasticizer in lipid extracts of human blood, *Chem. Phys. Lipids*, 4, 417 1970.
4. Hubban, L.C., Kletschke, H.D., Olsen, D.A., Rasmussen, E.H., Clausen, E.W., Robinson, A.R.: Spallation using roller pumps and its clinical implications. Presented AMSECT National Meeting, August 1, 1975 Portland, Oregon.
5. Hodge, R., Leverett, B., Akers, W.H.: Abrasion of pump sets in roller pumps. Report No. 6503, Bio-Medical Engineering Laboratory, Rice University, Houston, Texas 1965.
6. Reed, C.C., Pomagnoli, A., Taylor, D.E., Clark, D.K.: Particulate matter in bubble oxygenators, *J. Thorac. Cardiovasc. Surgery*, Vol. 68 No. 6 Dec. 1974.
7. Gerecke, W.B., Crosthwait, R.W., and Angel, R.T.: Particulate contamination in cardiopulmonary bypass: importance of delivery systems and intravenous fluids. In press 1973.
8. Austen, W.G., and Howry, D.H.: Ultrasound to detect bubbles or Particulate matter during cardiopulmonary bypass, *J. Surg. Res.* 5:283, 1965.



WILLIAM HARVEY™

William Harvey, Division of C.R. Bard, Inc., 1125 South Village Way, Santa Ana, CA 92705 • Telephone 714/835-2422.

Attachment #4

# PRE-BYPASS FILTER Cat.No.PB-005

It is recognized\* that debris may be present in components of the pulmonary bypass circuit. (\*Reed, C.C., Pomagnoli, A., Taylor, Clark, D.K., Particulate matter in bubble oxygenators. J. Thoracic and Cardiovascular Surgery, Vol. 68, No. 6, Dec. 1974)

The PB-005 filter can be used to reduce the chances of debris from entering the extracorporeal circuit prior to commencing cardiopulmonary bypass while the non-cellular priming liquid is being recirculated.

**WARNING: This filter must not be used for blood!**

Filter rating: 5 microns nominal

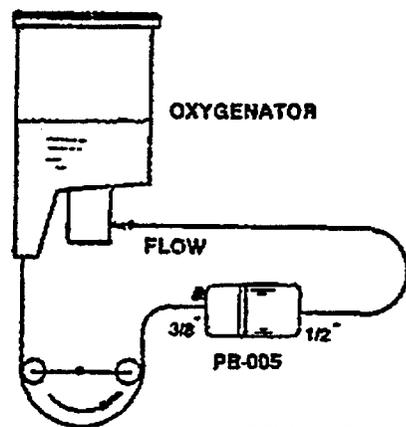
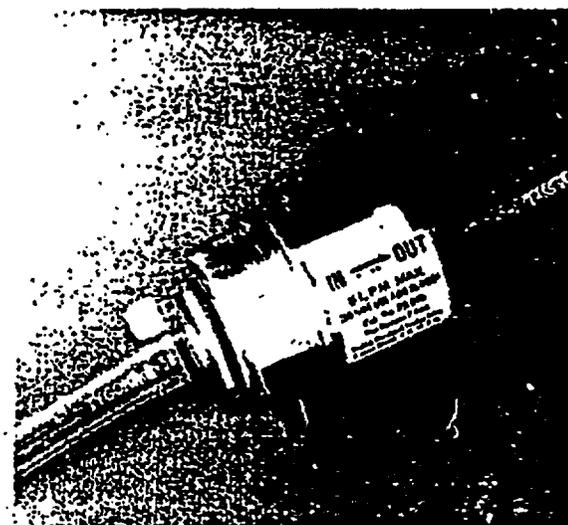
Fittings: 3/8" (inlet), 1/2" (outlet)

The LUER fitting on the inlet side facilitates the removal of air from the filter housing.

\$7.95 each, standard packaging: 25 units per box.

### INSTRUCTIONS FOR USE:

1. Remove filter from bag using aseptic technique. Discard the nipples.
2. Insert into the circuit. 3/8" to arterial side. 1/2" to venous line.
3. Prime the system with non-cellular fluid.
4. Start the pump, observing the flow direction. Flow must be towards 1/2 inch outlet fitting. Do not exceed 6 liters per minute.
5. Open the LUER fitting partially to permit air to escape into the atmosphere from the inlet side.
6. Tilt the outlet fitting upwards to allow air from the filter housing to move towards the venous inlet of the oxygenator.
7. Recirculate as usual. When procedure is completed remove the filter from the circuit making sure its contents do not drain back into the line.
8. Discard the filter.



**DISPOSABLE - Do not reuse! STERILE - when seal is not broken.**  
Caution: Federal law restricts this device to sale by or on order of a licensed physician.

Warranty: DELTA MEDICAL INDUSTRIES warrants that reasonable care has been used in the manufacture of this product. This warranty is in lieu of and excludes all other warranties not expressly set forth therein whether express or implied by operation of law or otherwise including but not limited to any implied warranties of merchantability or fitness because handling, storage, sterilization and installation of this product as well as other factors relating to the patient, his diagnosis, treatment, surgical procedures and other

matters beyond DELTA MEDICAL INDUSTRIES control directly affect this product and the results obtained from its use. DELTA MEDICAL INDUSTRIES shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this product other than replacement of it. D.M.I. neither assumes nor authorizes any other person to assume for it any other or additional liability or responsibility in connection with the product.

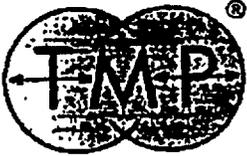
Model No. **PB-005**  
**PRE-BYPASS FILTER**

JE BY:



**DELTA MEDICAL INDUSTRIES**  
1579 SUNLAND LANE COSTA MESA, CA 92626

REPRESENTED IN YOUR AREA BY:



Texas Medical Products, Inc.

10940 SO. WILCREST DRIVE  
HOUSTON, TEXAS 77099 713-933-7766  
TWX 9108804055

February 6, 1981

TMP PREBYPASS FILTER

Directions for Use

1. Remove from package.
2. Place in extracorporeal circuit observing sterile technique in accordance with the direction of flow indicated on filter.
3. Introduce prime to circuit.
4. Recirculate with pump, gradually increasing to full flow.
5. Maintain full flow for at least one minute.
6. Stop pump, clamp tubing proximal and distal to filter and remove from circuit.
7. DO NOT recirculate with blood or any other cellular primes.
8. This TMP Prebypass Filter MUST BE REMOVED prior to initiation of cardiopulmonary bypass.

CAUTIONS AND WARNINGS

1. Do not resterilize.
2. Do not reuse this product. It is disposable and intended for one use only.

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MASTER SHIPPING CARTON

**Caution.**

---

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

---

Contents are sterile, non-pyrogenic if package is unopened and undamaged.

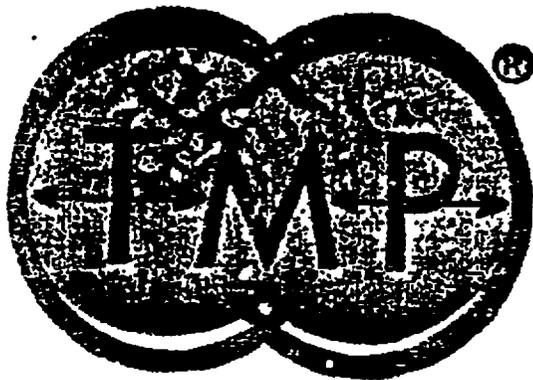
**Report damage now.**

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In case of damage, call carrier's agent at once for inspection and request inspection report. If this precaution is not taken, we cannot assist you in recovering the amount of the claim against the carrier.

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Returned goods must be via the same carrier.



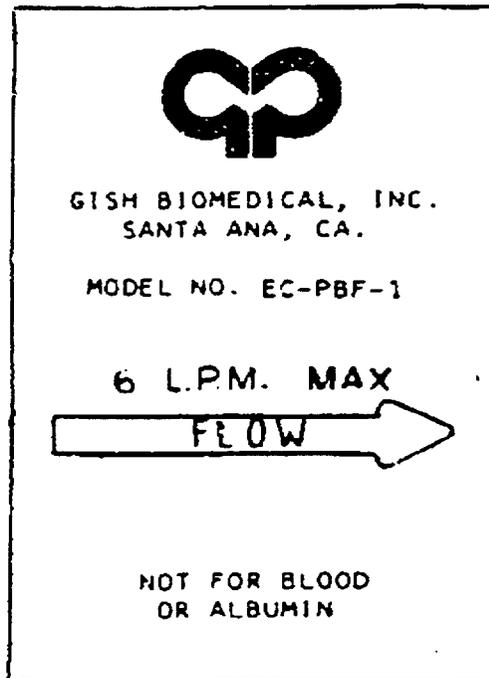
**Texas Medical  
Products, Inc.**

Houston, Texas 77025

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**BEST AVAILABLE COPY**

PRODUCT LABEL



GISH PREBYPASS  
FILTER

EC-PBF SERIES WITH 5 MICRON FILTER

↳ material?

DIRECTIONS FOR USE

1. Remove filter from package.
2. Using aseptic technique, remove nozzle covers, and connect filter in the extracorporeal circuit in the correct direction for flow.
3. Prime the circuit with non-cellular fluid.
4. Slowly recirculate with pump, and purge air from the filter.
5. Increase pump flow to 4 liters, and continue to recirculate.
6. Stop pump, and clamp tubing proximal and distal to the filter, and remove filter.
7. Discard filter.

CAUTIONS

- ✓ 1. Do not reuse.
- ✓ 2. Do not resterilize.
3. Do not use with blood or cellular prime solutions.
4. Do not exceed 6 liters per minute.

✓ WARNING: Do not use this filter to filter blood or any other fluid.

CAUTION: Do not use this filter to filter blood or any other fluid.

GISH BIOMEDICAL INC  
Sunnyvale, CA 92703

A-14203

BEST AVAILABLE COPY

PALL  
PREBYPASS PLUS™  
0.2 MICRON FILTER FOR  
PULMONARY CARDIOPULMONARY  
BYPASS CIRCUITS

Recorder No. PP 3002

WARNING: NOT FOR USE WITH BLOOD  
OR BLOOD PRODUCTS -  
FOLLOW INSTRUCTIONS FOR  
USE.

Pall Biomedical Products Corp.  
2200 Northern Blvd.  
East Hills, NY 11548

**BEST AVAILABLE COPY**

**BEST AVAILABLE COPY**

DS

DESCRIPTION:

The Pall Prebypass Plus™ 0.2 micron filter is a sterile, non-pyrogenic, disposable filter designed to be used during the priming and recirculation phase in cardiopulmonary bypass equipment. It is designed for the removal of particulate and bacterial contamination down to 0.2 micrometers.

INDICATION:

The Pall Prebypass Plus filter is indicated for any cardiopulmonary bypass procedure employing a cell-free priming solution.

CONTRAINDICATIONS:

Do not use this device with blood or blood products. The 0.2 micron pores will preclude passage of red blood cells.

PRECAUTIONS:

Read and follow directions.

STERILE, NON-PYROGENIC, DISPOSABLE, DO NOT REUSE.

The contents of this package are certified as sterile according to U.S.P. IX standards. Since this product was vacuum sterilized, the smallest pinhole will cause the package to lose the skin-tight appearance of its wrapper. Consider only unopened, undamaged, vacuum-tight packages as sterile before use.

*same process as these other filters*

CAUTION:

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

INSTRUCTIONS FOR USE:

Position prebypass filter in the circuit to permit recirculation of all of the priming solution through the device. A typical location is in the arterial line near the arterio-venous connector. Orient filter so that the priming solution enters on the side marked "IN". Be sure that the vent cap is closed.

Introduce priming solution into the circuit, and recirculate at about 1 liter/minute to fill filter. To complete prime, gradually increase to clinical flowrate.

Recirculate for several minutes, then stop pump and clamp arterial and venous lines.

IMPORTANT:

Remove prebypass filter from circuit before instituting cardiopulmonary bypass.

PALL BIOMEDICAL PRODUCTS CORP.  
2200 Northern Blvd.  
East Hills, New York 11548

Telex # 968855

Reorder No. PP-3802

**BEST AVAILABLE COPY**

**e) Indications for Use Enclosure**

*P7*

Page 1 of 1

510(k) Number (if known): \_\_\_\_\_

Device Name: DPB20™ Disposable Pre-bypass Filter

Indications For Use:

**CONTENTS:**

Disposable 5.0 µm DPB20™ Pre-bypass Filters

**CAUTION:**

FEDERAL (U.S.A.) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON ORDER OF A PHYSICIAN.

**INDICATIONS:**

- THIS DISPOSABLE PRE-BYPASS FILTER HAS BEEN DESIGNED FOR SINGLE USE TO REMOVE PARTICULATE CONTAMINATION FROM THE EXTRACORPOREAL CIRCUIT DURING THE INTIAL PRIMING AND DEBUBBLING ~~FROM~~ OF NON-CELLULAR FLUIDS PRIOR TO CARDIOPULMONARY BYPASS.
- THIS DEVICE IS DESIGNED FOR SINGLE USE AND SHOULD BE DISCARDED ONCE THE CIRCUIT IS PRIMED.
- FILTER EFFICIENCY OF 96% @ 5.0 µm.

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

- Concurrence of CDRH, Office of Device Evaluation (ODE)

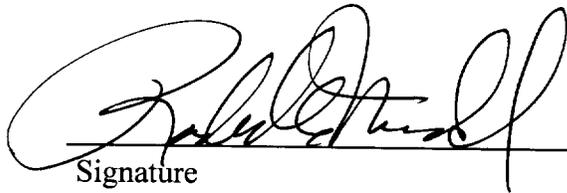
Prescription Use \_\_\_\_\_ or Over-The-Counter Use \_\_\_\_\_  
(Per 21 CFR 801.1091)

(Optional Format 1-2-96)

**f) Truth in Accurate Statement**

**Premarket Notification  
Truthful and Accurate Statement**

I certify that, in my capacity as a Medical Device Representative of Porous Media 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 fact has been omitted.



Signature

Typed Name

Dated

Premarket Notification [510(k) Number]

**g) 510K Statement**

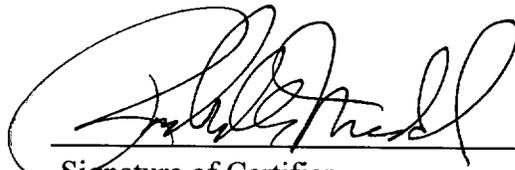


## **POROUS MEDIA**

Porous Media Corporation  
1350 Hammond Road  
St. Paul, MN 55110  
(612) 653-2000  
(612) 653-2230 FAX

### **510K Statement**

I certify that, in my capacity as a Medical Device Representative of Porous Media Corporation, I will make available all information included in this premarket notification on safety and effectiveness within 30 days of request by any person if the device described in the premarket notification submission is determined to be substantially equivalent. The information I agree to make available will be a duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding all patient identifiers, and trade secret and confidential commercial information, as defined in 21 CFR 20.61.

  
\_\_\_\_\_  
Signature of Certifier

\_\_\_\_\_  
Typed Name

\_\_\_\_\_  
Date

\_\_\_\_\_  
Premarket Notification [510(k) Number]