



U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER: (szs)
FOLDER: K003611 - 54 pages
COMPANY: BREG, INC. (BREG)
PRODUCT: PUMP, INFUSION (FRN)
SUMMARY: Product: PAIN CARE MULTI-PORT CATHETER, MODEL 2000L

DATE REQUESTED: Mar 21, 2012

DATE PRINTED: Mar 21, 2012

Note: Printed





DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 13 2000

Ms. Kathleen Barber
Vice President of Regulatory Affairs
Breg, Incorporated
2611 Commerce Way
Vista, California 92083

Re: K003611
Trade Name: Pain Care Multi-Port Catheter
Regulatory Class: II
Product Code: FRN
Dated: November 21, 2000
Received: November 22, 2000

Dear Ms. Barber:

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 (Pre-market 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 pre-market notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic

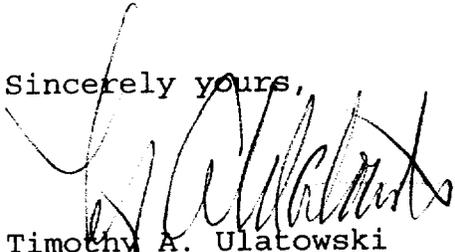
Page - Ms. Barber

Product Radiation Control provisions, or other Federal laws or regulations.

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) 594-4692. 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,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

Intended Use

BREG's PAIN CARE Multi-Port Catheter is intended to provide infusion of a local anesthetic into an intra-operative site for the post-operative management of pain.

Paloma Cisneros

(Division Sign-Off)

Division of Dental, Infection Control,

and General Hospital Devices

Number K003611

Memorandum

Date: 12-15-00

From: DMC (HFZ-401)

Subject: Premarket Notification Number(s): K003611-A1

To: Division Director: 140 / DD IGM

The attached information has been received by the 510(k) DMC on the above referenced 510(k) submission(s). Since a final decision has been rendered, this record is officially closed.

Please review the attached document and return it to the DMC, with one of the statements checked below.

Information does not change the status of the 510(k); no other action required by the DMC; please add to image file. (Prepare K-25) THIS DOES NOT APPLY TO TRANSFER OF OWNERSHIP. PLEASE BRING ANY TRANSFER OF OWNERSHIP TO POS.

Additional information requires a new 510(k); however, the information submitted is incomplete; (Notify company to submit a new 510(k); [Prepare the K30 Letter on the LAN])

Additional information requires a new 510(k); please process [This information will be made into a new 510(k)]

No response necessary (e.g., hard copy of fax for the truthful and accuracy statement, 510(k) statement).

CLIA CATEGORIZATION refers to laboratory test system devices reviewed by the Division of Clinical Laboratory Devices (HFZ-440)

Information requires a CLIA CATEGORIZATION; the complexity may remain the same as the original 510(k) or may change as a result of the additional information (Prepare a CAT letter)

Additional information requires a CLIA CATEGORIZATION; however, the information submitted is incomplete; (call or fax firm)

No response necessary

This information should be returned to the DMC within 10 working days from the date of this memorandum.

Reviewed by: SWP
Date: _____

Draft #2 : 9/8/99
Draft #3: 1/3/00

DEC 20 2000



K003611-A1

December 13, 2000

BY FEDERAL EXPRESS

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

510(k) K003611
PAIN CARE Multi-port Catheter
Amendment #1

Attn: Document Clerk

As the representative of Breg, Inc., Vista, CA I am supplying the following Amendment to 510(k) K003611, for the PAIN CARE Multi-port Catheter.

The amendment contains changes to the following pages, which were part of the original submission. The original page was not correct. Two copies are included.

- Page 6 Summaries of performance testing and risk analysis have been included
- Page 8 Modified the statement of Indication for Use

Please direct all correspondence regarding this submission to me at the above letterhead addresses. If you have any questions which may be appropriately answered by phone, then please telephone my office at (760) 599-5719 during the hours of 7:30AM - 5:00PM, PST. Thank you for your attention to this document.

Sincerely yours,

Kathleen Barber
Vice President
QA/RA

SK-37

Enclosures: 2 copies - 510(k) Amendment,

RECEIVED
Dec 15 2 57 PM '00
FDA/CDRH/ODE/DMC

Amendment#1 12/13/00

2611 Commerce Way, Vista, CA 92083

AMENDMENT NOTIFICATION FOR

510(k) K003611

Pain Care Multi-Port Catheter

Made by

BREG, INC.

2611 Commerce Way

Vista, CA 92083

Tel: (760) 599-3000

Fax (760) 598-6193

Document submitted by the official correspondent of
BREG, Inc.



Kathleen Barber
Vice President of Regulatory Affairs
BREG, Inc.

December 13, 2000

11.0 PERFORMANCE TESTING

Performance testing was completed for the following items. All tests were found to be acceptable as to the product design and none were found to adversely affect safety or efficacy.

- a. Shipping testing showed the exterior box and interior pouch to be robust. Dust drum testing found no failures.
- b. Drop testing was performed on the unit from heights of 2, 3 and 4 feet. The plastic did not shatter and the unit stayed intact.
- c. Pull testing was performed on the connections of the catheter connector, the bolus to the catheter and the catheter to a tube extension set. The connections held to a force of 10psi, and were characterized by the elongation of the catheter and not a break in the joint. These tests were performed with the catheter taped in place on the 'patient model' to duplicate the protocol most commonly seen in the operating room. See the attached graph for a summary of these test results.

12.0 SUMMARY OF DESIGN CONTROL ACTIVITIES

- a) Risk Analysis
- b) Risk analysis was performed using FMEA to identify those areas which posed the greatest failure risk in the manufacture of the **PAIN CARE Multi-Port Catheter**. Each issue was assigned a value and actions were assigned to eliminate or reduce the risk to a level that had no effect on the safety or efficacy of the product. A summary of these results is attached for review.
- c) Validation/Verification

Validation and verification was performed based upon the intended design outputs of the device from the Product Development Specification as well as upon the assurance that any areas of great risk identified by the risk analysis were corrected.

Specific examples of items that were validated include:

1. The hole drilling process was validated for repeatability. See attached summary
2. The sterilization process was validated for the **PAIN CARE Multi-Port Catheter** using AAMI, ISO and GLP standards.
3. The flow of liquid through the catheter was verified at each port location for full spectrum results. See attached photos.
4. The marking process was validated..
5. Heat Accelerated Life Testing was performed on assemblies to determine the shelf life
6. The assembly process was validated

SUMMARY OF RISK ANALYSIS

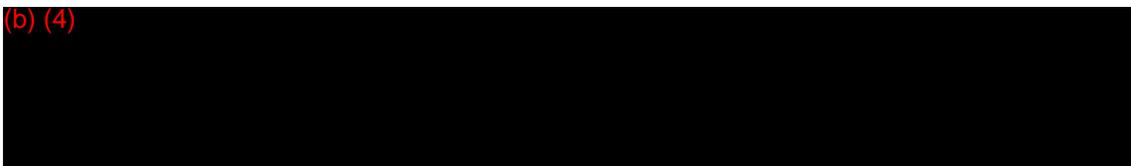
Risk analysis was performed on the Multi-port Catheter using FMEA methods for applications involving the Pain Care family of products.

Two major areas were identified as concerns:

1. Improper location of marking on the catheter, which will not allow correct distances when, the catheter is inserted. This was of particular importance with the distal end of the catheter. This was addressed by validating the process and measuring a groups of 43 samples which were manufactured using the purchased marking system. In the initial run, 38 of the 43 samples were marked correctly, with 5 pieces having the last port too close to the 12 cm marking.

To correct this, a modification was made to the tooling to assure that the catheter is loaded against a stop prior to marking being done. The test was repeated with 50 additional samples and all were found to be acceptable. During this same test, the catheters in both groups were examined to verify that the distal port was open and that sterile water flowed through the catheter correctly. In both groups the catheter functioned as intended.

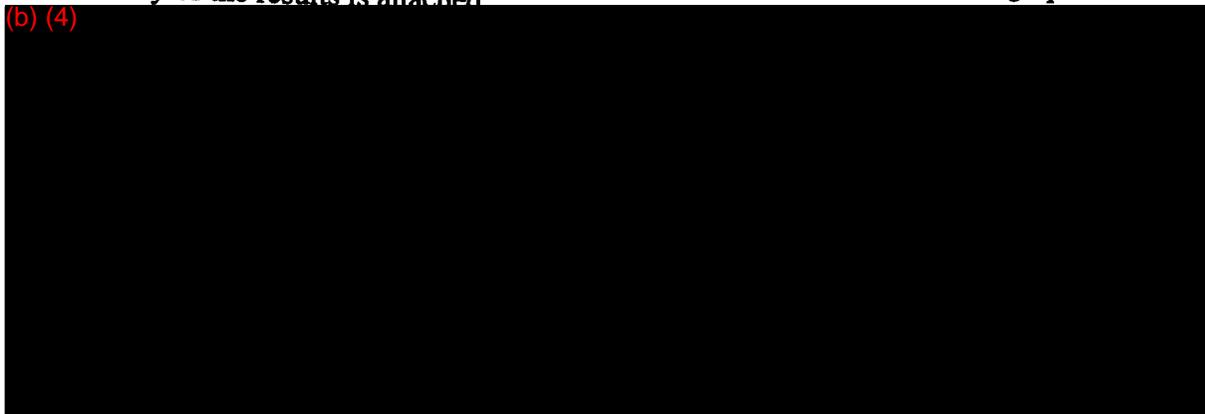
(b) (4)



2. Catheter breakage/pull-out was a concern. To assure that the catheter was strong enough to stand up to the wear and tear it would encounter in a two day insertions the following tests were run. A group of 200 catheters and connector fittings were sterilized and then assembled as per the printed instructions.

The test was divided into two groups of 100 pieces each. One was assembled dry and one group was assembled wet to simulate the conditions seen in an operating arena. Each of these sub groups was tested until breaking/pull-out from the connection and the length was measured and compared to its original length as percent. A graphical summary of the results is attached.

(b) (4)



STATEMENT OF INDICATIONS FOR USE

Intended Use

BREG's PAIN CARE Multi-Port Catheter is intended to provide infusion of a local anesthetic into an intra-operative site for the post-operative management of pain. This statement of indications for use has not changed from that of the Pain Care 2000, Pain Care 2000L and the Pain Care 3000 which have previously been approved.

6
8



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 13 2000

Ms. Kathleen Barber
Vice President of Regulatory Affairs
Breg, Incorporated
2611 Commerce Way
Vista, California 92083

Re: K003611
Trade Name: Pain Care Multi-Port Catheter
Regulatory Class: II
Product Code: FRN
Dated: November 21, 2000
Received: November 22, 2000

Dear Ms. Barber:

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 (Pre-market 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 pre-market notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic

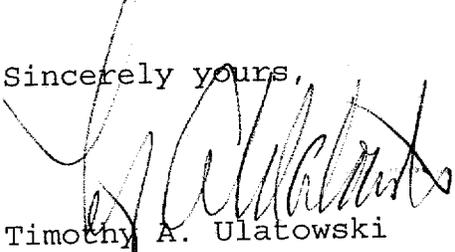
Page - Ms. Barber

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Sincerely yours,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2

STATEMENT OF INDICATIONS FOR USE

Intended Use

BREG's PAIN CARE Multi-Port Catheter is intended to provide infusion of a local anesthetic into an intra-operative site for the post-operative management of pain.

Paltina Cuervo

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices

Number K00364

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

From: 12/12/00 Reviewer(s) - Name(s) Sarah Foster

Subject: 510(k) Number 1003611

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

Refused to accept.

Requires additional information (other than refuse to accept).

Is substantially equivalent to marketed devices.

NOT substantially equivalent to marketed devices.

De Novo Classification Candidate?

YES

NO

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

Is this device subject to Postmarket Surveillance?

YES

NO

Is this device subject to the Tracking Regulation?

YES

NO

Was clinical data necessary to support the review of this 510(k)?

YES

NO

Is this a prescription device?

YES

NO

Was this 510(k) reviewed by a Third Party?

YES

NO

Special 510(k)?

YES

NO

Abbreviated 510(k)? Please fill out form on H-Drive 510(k) boilers

YES

NO

This 510(k) contains:

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

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

The required certification and summary for class III devices N/A

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):

80 FRN / Class II
(Infusion Pump accessory)

79 JCY / Class I

Review: Patricia Ciccone
(Branch Chief)

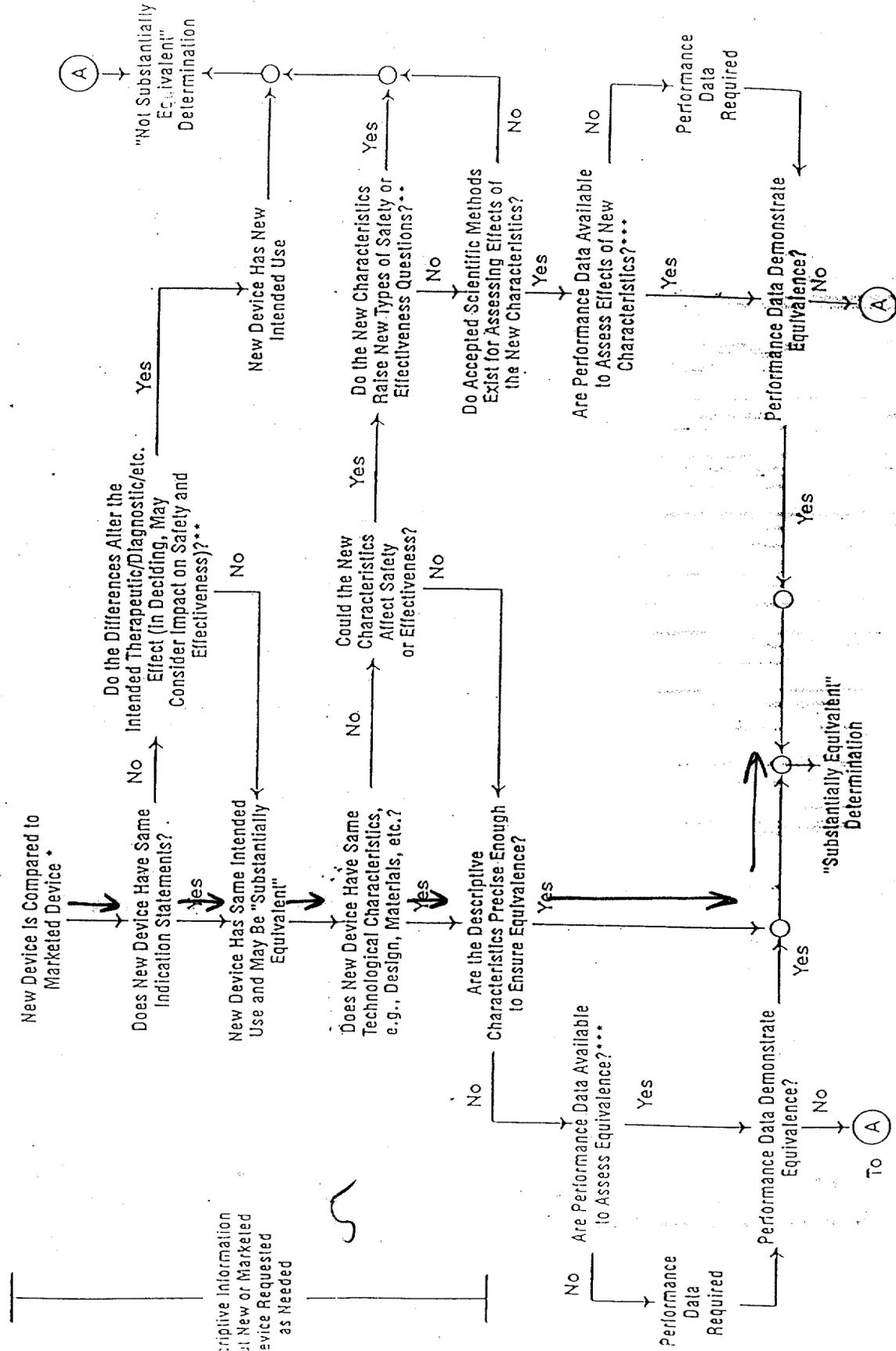
ADP/B
(Branch Code)

12/13/00
(Date)

Final Review:

[Signature] 12/13/00 4

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



510(k) Submissions Compare New Devices to Marketed Devices. FDA Requests Relationship Between Marketed and "Predicate" (Pre-App. Modified Post-Amendments) Devices is Unclear.

This Decision is Normally Based on Descriptive Information Alone, But LHM is Sometimes Required.

Other 510(k), The Center's Classification Files, or the Literature.

**SPECIAL 510(k): Device Modification
ODE Review Memorandum**

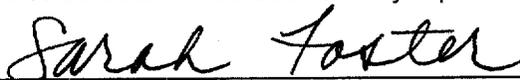
To: THE FILE

RE: DOCUMENT NUMBER K003611

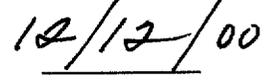
This 510(k) submission contains information/data on modifications made to the SUBMITTER'S own Class II, Class III or Class I devices requiring 510(k). The following items are present and acceptable (delete/add items as necessary):

1. The name and 510(k) number of the SUBMITTER'S previously cleared device. (For a preamendments device, a statement to this effect has been provided.)
2. Submitter's statement that the **INDICATION/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED** along with the proposed labeling which includes instructions for use, package labeling, and, if available, advertisements or promotional materials.
3. A description of the device **MODIFICATION(S)**, including clearly labeled diagrams, engineering drawings, photographs, user's and/or service manuals in sufficient detail to demonstrate that the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed**.
The purpose of this submission was to indicate the intention to manufacture and market the Breg PAIN CARE Multi-Port Catheter as an independent device. It is currently a component of the Breg, Inc. PAIN CARE 2000, PAIN CARE 2000L and the PAIN CARE 3000 infusion system kits.
4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics, and *applications of the device*.
5. A **Design Control Activities Summary** which includes:
 - a) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis
 - b) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied
 - c) A declaration of conformity with design controls. The declaration of conformity should include:
 - i) 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, and
 - ii) A statement signed by the individual responsible, that the manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.
6. A **Truthful and Accurate Statement, a 510(k) Summary or Statement and the Indications for Use Enclosure (and Class III Summary for Class III devices)**.

The labeling for this modified subject device has been reviewed to verify that the indication/intended use for the device is unaffected by the modification. In addition, the submitter's description of the particular modification(s) and the comparative information between the modified and unmodified devices demonstrate that the fundamental scientific technology has not changed. The submitter has provided the design control information as specified in The New 510(k) Paradigm and on this basis, I recommend the device be determined substantially equivalent to the previously cleared (or their preamendment) device.



(Reviewer's Signature)



(Date)

Comments:

After speaking with Bill Burdick of GHDB, we concluded that the submission for the Breg Pain-Care Multi-Port Catheter was adequate for clearance. We felt that because this device has already been legally marketed (included in a kit), and no changes have been made, it should be cleared for market as an independent device and no additional information would be necessary.

Memo

To: The File
From: Sarah Foster, Reviewer
Date: 12/13/00
Re: Document Number K003611

Memo Regarding Telephone Conversation on 12/12/00

This memo confirms the telephone conversation held on 12/12/00 between Kathleen Barber of Breg, Inc. myself, Sarah Foster of DDIGD/GHDB. I discussed with Ms. Barber the graphs she submitted in response to the request for additional Risk Analysis data. I mentioned that although this data was missing concluding statements, it was adequate for clearance. However, Ms. Barber wanted to send concluding comments regarding this data for the record. This was faxed to DDIGD on 12/12/00, and a hard copy will follow.



2611 Commerce Way
Vista, CA 92083

BY FAX: 301.480.3002
DATE: December 12, 2000
Attn: Sarah Foster
RE: Multi-Port Catheter

Thank you for your input on the phone this morning. As we discussed, have modified the Risk Analysis to include some concluding statements and attached a copy for your review. The changes are in bold.

Please let me know if these are acceptable and I will forward a hard copy of all the changes to the mail center.

If you have any questions which may be appropriately answered by phone, then please telephone my office at (760) 599-5719, during the hours of 8:30AM - 5:00PM, PST. Thank you for your attention to this document.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'K. Barber', with a long horizontal flourish extending to the right.

Kathleen Barber
Vice President of Regulatory Affairs

8

SUMMARY OF RISK ANALYSIS

Risk analysis was performed on the Multi-port Catheter using FMEA methods for applications involving the Pain Care family of products.

Two major areas were identified as concerns:

1. Improper location of marking on the catheter, which will not allow correct distances when, the catheter is inserted. This was of particular importance with the distal end of the catheter. This was addressed by validating the process and measuring a groups of 43 samples which were manufactured using the purchased marking system. In the initial run, 38 of the 43 samples were marked correctly, with 5 pieces having the last port too close to the 12 cm marking.

To correct this, a modification was made to the tooling to assure that the catheter is loaded against a stop prior to marking being done. The test was repeated with 50 additional samples and all were found to be acceptable. During this same test, the catheters in both groups were examined to verify that the distal port was open and that sterile water flowed through the catheter correctly. In both groups the catheter functioned as intended.

(b) (4)

2. Catheter breakage/pull-out was a concern. To assure that the catheter was strong enough to stand up to the wear and tear it would encounter in a two day insertions the following tests were run. A group of 200 catheters and connector fittings were sterilized and then assembled as per the printed instructions.

The test was divided into two groups of 100 pieces each. One was assembled dry and one group was assembled wet to simulate the conditions seen in an operating arena. Each of these sub groups was tested until breaking/pull-out from the connection and the length was measured and compared to its original length as percent. A graphical summary of the results is attached.

(b) (4)

Memo

To: The File
From: Sarah Foster, Reviewer
Date: 12/12/00
Re: Document Number K003611

Memo Regarding Telephone Conversation on 12/06/00

This memo confirms the telephone conversation held on 12/05/00 between Kathleen Barber of Breg, Inc. myself, Sarah Foster of DDIGD/GHDB. I asked Ms. Barber if the Breg PAIN CARE Multi-Port Catheter was intended to be used only with the Breg PAIN CARE infusion devices, or other infusion devices as well. This was unclear in the labeling. Ms. Barber informed me that the subject device is intended to be used with the Breg infusion devices as well as other infusion devices compatible with the catheter. She also said that the labeling will be changed to reflect this indication.

Sarah Foster 12/12/00

Memo

To: The File
From: Sarah Foster, Reviewer
Date: 12/12/00
Re: Document Number K003611

Memo Regarding Telephone Conversation on 12/08/00

This memo confirms the telephone conversation held on 12/05/00 between Kathleen Barber of Breg, Inc. myself, Sarah Foster of DDIGD/GHDB. I explained to Ms. Barber that her Risk Analysis information included in her submission was not adequate, and requested that she send in a more detailed risk analysis along with the results. I also requested a statement verifying that the indications for use have not been changed from those in the predicate device. Ms. Barber faxed this information to DDIGD on 12/11/00, and a hard copy will follow.

Sarah Foster 12/12/00



2611 Commerce Way
Vista, CA 92083

BY FAX: 301.480.3002

DATE: 12/11/2000

Attn: Sarah Foster

RE: Multi Port Catheter ~~XXXXXXXXXX~~

Thank you for your telephone call of Friday, December 11, 2000.

As you requested, I have attached the following:

- Page 8: The statement of Indications for Use has been modified to indicate that the Multi-port Catheter has the same indication as that of the original device
- Page 6: Summaries of performance testing and risk analysis have been included

If you have any questions which may be appropriately answered by phone, then please telephone my office at (760) 599-5719, during the hours of 8:30AM - 5:00PM, PST. Thank you for your attention to this document.

Sincerely yours,


Kathleen Barber
Vice President of Regulatory Affairs

STATEMENT OF INDICATIONS FOR USE

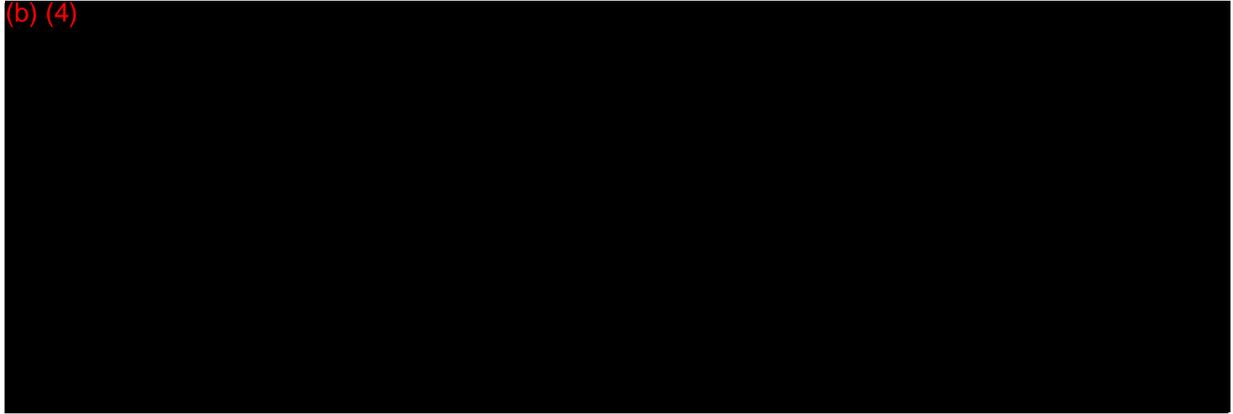
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11.0 PERFORMANCE TESTING

Performance testing was completed for the following items. All tests were found to be acceptable as to the product design and none were found to adversely affect safety or efficacy.

(b) (4)



12.0 SUMMARY OF DESIGN CONTROL ACTIVITIES

- a) Risk Analysis
- b) Risk analysis was performed using FMEA to identify those areas which posed the greatest failure risk in the manufacture of the **PAIN CARE Multi-Port Catheter**. Each issue was assigned a value and actions were assigned to eliminate or reduce the risk to a level that had no effect on the safety or efficacy of the product. A summary of these results is attached for review.
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3. The flow of liquid through the catheter was verified at each port location for full spectrum results. See attached photos.
4. The marking process was validated..
5. Heat Accelerated Life Testing was performed on assemblies to determine the shelf life
6. The assembly process was validated

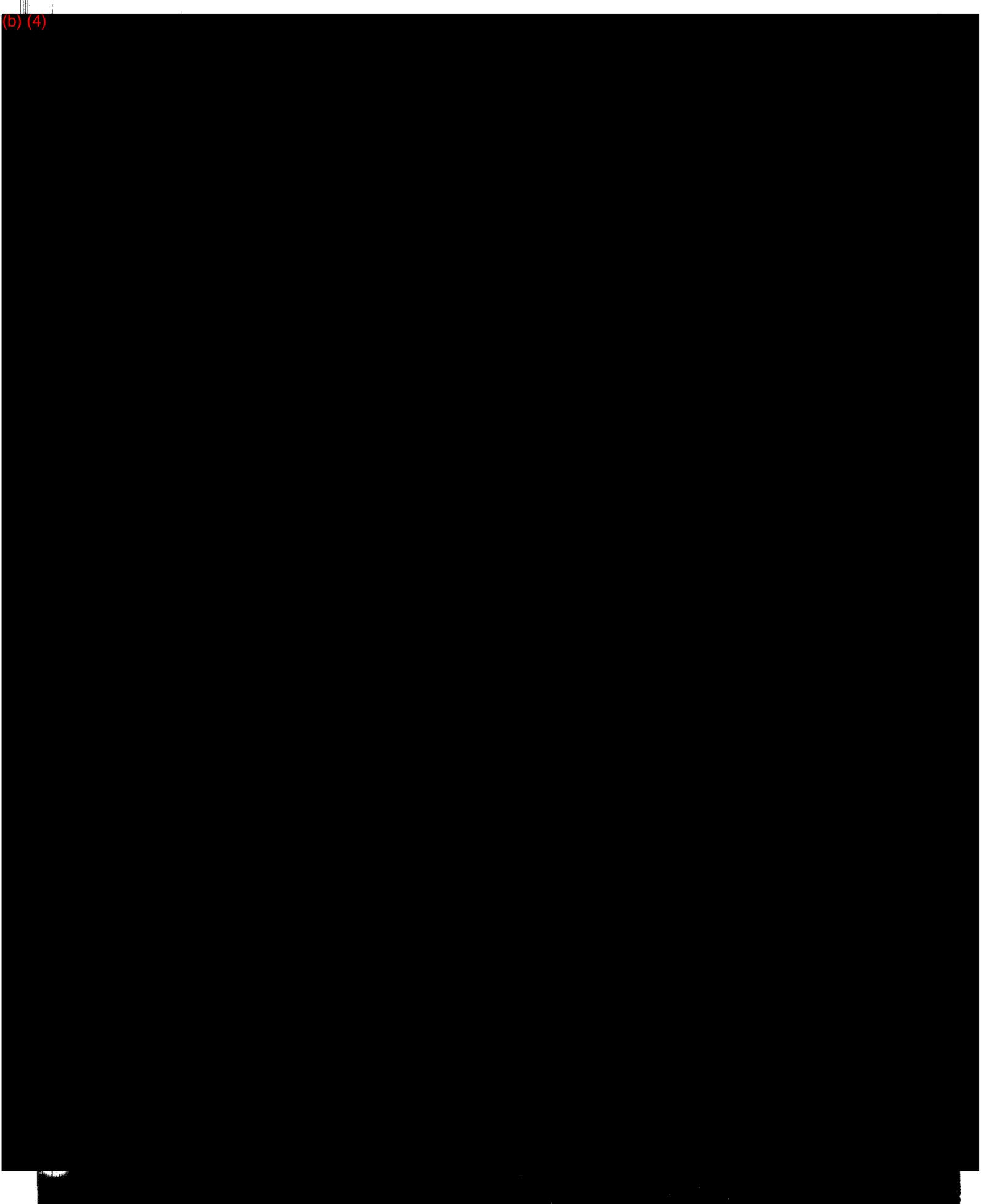
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Two major areas were noted as concerns:

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2. Catheter breakage/pull-out. To assure that the catheter was strong enough to stand up to the wear and tear it would encounter in a two day insertions. A group of 200 catheters with connectors attached were sterilized and then assembled as per the printed instructions. The test group was broken into two sub groups of 100 each. One was assembled dry and one was assembled wet to simulate the conditions seen in an operating arena. Each of these sub groups was tested until breaking/pull-out from the connection and the length was measured and compared to its original length as a percent. A graphical summary of the results is attached.



(b) (4)

Screening Checklist

For all Premarket Notification 510(k) Submissions

Device Name:						K						
Submitter (Company):												
Items which should be included (circle missing & needed information)						S P E C I A L	A B B R E V I A T E D	T R A D I T I O N A L	✓ IF ITEM IS NEEDED AND IS MISSING			
						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 # 2,3		GO TO # 2,4,5		GO TO #2, 5		
2. GENERAL INFORMATION: REQUIRED IN ALL 510(K) SUBMISSIONS								✓ IF ITEM IS NEEDED				
Financial Certification or Disclosure Statement for 510(k)s with a Clinical Study 807.87(i)						NA		YES		NO		AND IS MISSING
						SPECIALS		ABBREVIATED		TRADITIONAL		
						YES	NO	YES	NO	YES	NO	
a) trade name, classification name, establishment registration number, 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						NA						
d) compliance with Section 514 - performance standards						NA						
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)												
l) 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						NA						
vi) safety characteristics						NA						
m) If kit, kit certification												
3. "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								* If no - STOP not a special				

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FOR USE OF MODIFIED DEVICE AS DESCRIBED IN ITS LABELING HAVE NOT CHANGED*				
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.			

	SPECIALS		ABBREVIATED		TRADITIONAL		✓ IF ITEM IS NEEDED AND IS MISSING
	YES	NO	YES	NO	YES	NO	
4. ABBREVIATED 510(K): SPECIAL CONTROLS/CONFORMANCE TO RECOGNIZED STANDARDS - PLEASE FILL OUT THE STANDARDS ABBREVIATED FORM ON THE H DRIVE							
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						

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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			

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: _____

Reviewer: _____
Concurrence by Review Branch: _____

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

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K _____

Reviewer: _____

Division/Branch: _____

Device Name: _____

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

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

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

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1. Intended Use:
2. Device Description: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device 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.

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

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

ATTACH ADDITIONAL SUPPORTING INFORMATION

Internal Administrative Form

	YES	NO
1. Did the firm request expedited review?		
2. Did we grant expedited review?		
3. Have you verified that the Document is labeled Class III for GMP purposes?		
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.		

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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

November 22, 2000

BREG, INC.
2611 COMMERCE WAY
VISTA, CA 92083
ATTN: KATHLEEN BARBER

510(k) Number: K003611
Received: 22-NOV-2000
Product: PAIN CARE MULTI-PORT
CATHETER, MODEL
2000L

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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K003611



2611 Commerce Way
Vista, CA 92083

BY PRIORITY MAIL

November 21, 2000

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

SK-8

Attn.: Document Clerk

I am the representative of Breg, Inc., Vista, CA. As required by section 510(k) of the FDC Act, 1976 and the Safe Medical Devices Act of 1990, I hereby submit a **Special 510(k) Premarket Notification** (enclosed) to indicate the intention of Breg, Inc. to manufacture and introduce into commercial distribution a medical device named the **PAIN CARE 2000L**. The information required by 21 CFR807.87 is included in the enclosed 510(k) notification.

I believe this submission is subject to review and approval of the ODE, Division of Dental, Infection Control and General Hospital Devices.

Please direct all correspondence regarding this submission to the letterhead address. If you have any questions, which may be appropriately answered by phone, then please telephone my office at (760) 599-5719, during the hours of 8:30AM - 5:00PM, PST. Thank you for your attention to this document.

Sincerely yours,

Kathleen Barber
Vice President of Regulatory Affairs

Enclosures: 2 copies of 510(k) with cover letter attached

NOV 23 2000
11 23 2000
11 23 2000

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Special 510(k) NOTIFICATION

for the

Pain Care Multi-Port Catheter

Made by

BREG, INC.

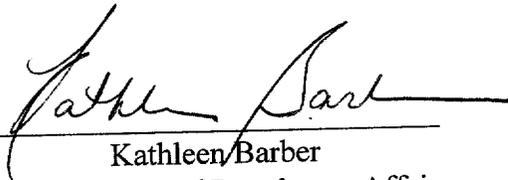
2611 Commerce Way

Vista, CA 92083

Tel: (760) 599-3000

Fax (760) 598-6193

Document submitted by the official correspondent of
BREG, Inc.



Kathleen Barber

Vice President of Regulatory Affairs

BREG, Inc.

November 17, 2000

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1. MANUFACTURER/FDA REGISTRATION

The manufacturer of the device is:

BREG, Inc.
2611 Commerce Way
Vista, CA 92083-8309
Tel: (760) 599-3000
Fax: (760) 598-6193

The FDA Registration Number is 2028253. Contract Sterilization will be provided by Sterigenics, Corona, CA whose FDA Registration Number is 2029275.

BREG currently holds 510(k)s on the following products:

Polar Pump Model 500	K913729	Polar Pad	K914434
Polar Pad Sterile	K920581	Polar Care Model 500/5000	K961855
Polar Cub	K942410	Polar Care 300	K963596
Flexmate K500	K950755	Pain Care 2000	K983454
Pain Care 2000L	K002321	Pain Care 3000	K002073

2. DEVICE NAME

The common name of the device is "Catheter".

The proprietary name of the product is **Pain Care Multi-Port Catheter**.

3. CLASSIFICATION

Classification is found in **21 CFR 880.5725**, General Hospital Devices.

Accessories, Pump, Infusion,

- (a) Identification. An infusion pump is a device used in a health care facility to pump fluids into a patient in a controlled manner. The device may use a piston pump, a roller pump, or a peristaltic pump and may be powered electrically or mechanically. The device may also operate using a constant force to propel the fluid through a narrow tube which determines the flow rate. The device may include means to detect a fault condition, such as air in, or blockage of the infusion line and to activate an alarm.

This is an accessory to the Pain Care 2000, Pain Care 2000L and the Pain Care 3000. It is currently used in these devices and packed as part of the kit. Approval of this submission will allow the sale of this unit as a stand alone device.

- (b) Classification. Class II (performance standards)

4. STANDARDS

There are no mandatory or voluntary standards that govern the device under Section 514. Review of the Federal Register finds no proposed or ongoing process for development of standards at this time.

The **PAIN CARE Multi-Port Catheter** will be manufactured under QSR as well as ISO9001:1994 standards. Sterility and biocompatibility are discussed separately.

5. LABELING/USE INSTRUCTIONS

Labeling is contained as Attachment 1, while Use Instructions are Attachment 2.

6. SUBSTANTIAL EQUIVALENCE

BREG's new **PAIN CARE Multi-Port Catheter** is a catheter device which is intended to be used with Infusion systems which are currently on the market.. It is currently a component of the Breg, Inc. Pain Care 2000, Pain Care 2000L and the Pain Care 3000 product kits. The 510(k) numbers for these devices are mentioned in section 1.. Other manufacturers of Infusion devices, such as Sgarlotta and I-Flow could use the Multi-Port Catheter, if it were packaged individually for sale.

The **PAIN CARE Multi-Port Catheter** is substantially equivalent to the I-Flow Soaker Catheter, K994374 and the I-Flow IntraOp Catheter, K991543.

7. DESCRIPTION

BREG's **PAIN CARE Multi-Port Catheter** consists of a 16GA catheter which has been drilled with holes along the length. The locations of the holes are marked so that the health professional who inserts the catheter can be sure that the unit is fully inserted into the wound site. Anesthetic flows out of all the holes along the length of the catheter. The end of the catheter is inserted into a Luer lok device which attaches the catheter to the infusion device.

There are two models of the **PAIN CARE Multi-Port Catheter**, the MP-220 and the MP-130. They are differentiated by the placement of the hole patterns. Both devices are available in two different lengths -One is 24 inches in length and will be marketed with the Pain Care 2000 and the Pain Care 2000L and other patient controlled pain infusion devices.. The second one is 54 inches in length and will be marketed with the Pain Care 3000 and other continuous flow pain infusion devices.

8.0 BIOCOMPATABILITY:

The components of the **PAIN CARE Multi-Port Catheter** are listed on Diagram 1. All materials in the fluid path have been tested and conform to the FDA Biocompatibility

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Guidance 95-1 as well as to the ISO-10993-1 biomaterial-testing program for medical devices.

The device has not been tested for pyrogenicity as no water is used in the assembly process.

9.0 STERILITY ASSURANCE:

The type of sterilization is Cobalt 60 gamma radiation performed by Sterigenics International, Corona, CA 91720, to achieve a sterility assurance level of 10 to the -6. The dosage range is 2.5 to 4.0 kg.

The sterility validation methodology used to initially establish our dose requirements and our ongoing quarterly audits complies with the following specifications: (1) USP Sect. 71; (2) ISO-11135; and (3) ANSI/AAMI Method 1.

Parts will be packed into industry recognized sterilization pouches designed for radiation applications which are heat sealed prior to sterilization. This package is a commercially available radiation pouch manufactured by Kenpak. It consists of a Tyvek type material side and a clear poly side. This same pouch is in use with Breg, Inc. product Pain Care 2000, K983454.

10.0 KITS, PACKS or TRAYS

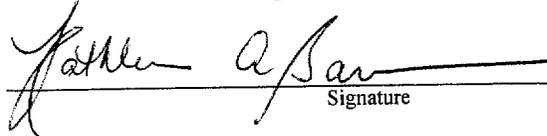
The **PAIN CARE Multi-Port Catheter** system is packed as a kit which contains the following elements:

- 1 16 GA IV Catheter Introduction Needle
- 1 16 GA IV Multi-Port Catheter Set(s)
- 1 Instruction

The **PAIN CARE Multi-Port Catheter** is the subject of this 510(k) submission and is discussed in detail.

The 16GA Epidural Catheter has been found to be SE through the premarket notification process for the uses in which the kit is to be intended. These catheters are purchased in bulk and reprocessed by the addition of luer connectors, defined lengths and drilled hole patterns and gamma sterilization.

For the other elements above, I certify that these devices have been found to be substantially equivalent through the premarket notification process for the uses for which the kit is to be intended. I further certify that these devices/components are not purchased in "bulk", but are purchased in finished form, i.e. they are packaged, labeled, etc., consistent with their premarket notification status.



Signature

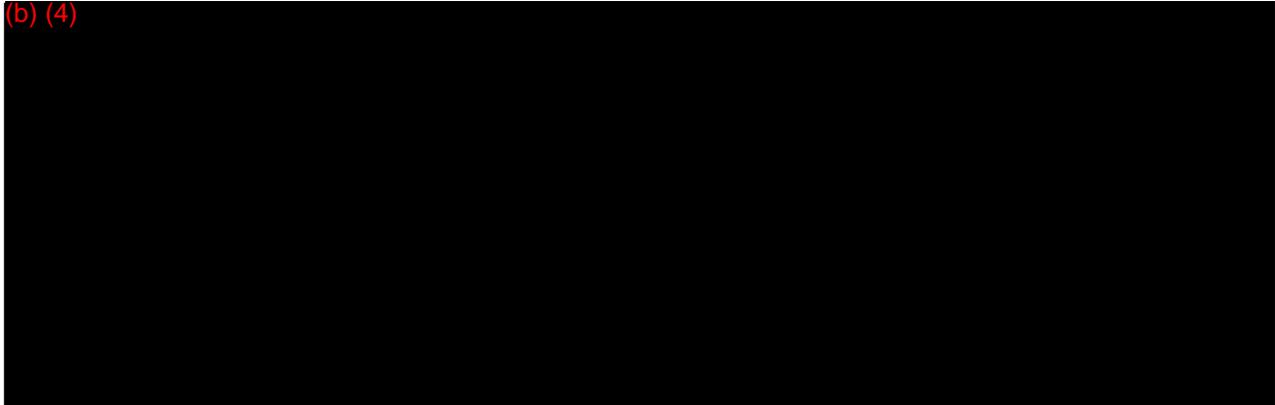
11/17/2000

Date

11.0 PERFORMANCE TESTING

Performance testing was completed for the following items. All tests were found to be acceptable as to the product design and none were found to adversely affect safety or efficacy.

(b) (4)



12.0 SUMMARY OF DESIGN CONTROL ACTIVITIES

a) Risk Analysis

b) Risk analysis was performed using FMEA to identify those areas which posed the greatest failure risk in the manufacture of the **PAIN CARE Multi-Port Catheter**. Each issue was assigned a value and actions were assigned to eliminate or reduce the risk to a level that had no effect on the safety or efficacy of the product. The results of this analysis are available for review in the BREG, Inc. Engineering department.

c) Validation/Verification

Validation and verification was performed based upon the intended design outputs of the device from the Product Development Specification as well as upon the assurance that any areas of great risk identified by the risk analysis were corrected.

Specific examples of items that were validated include:

1. The hole drilling process was validated for repeatability.
2. The sterilization process was validated for the **PAIN CARE Multi-Port Catheter** using AAMI, ISO and GLP standards.
3. The flow of liquid through the catheter was verified at each port location for full spectrum results.
4. The marking process was validated..
5. Heat Accelerated Life Testing was performed on assemblies to determine the shelf life
6. The assembly process was validated

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DECLARATION OF CONFORMITY

1. As required by risk analysis, all verification and validation activities for the Pain Care 2000L were performed by the BREG, Inc. Engineering staff. The results demonstrate that the predetermined acceptance criteria were met.
2. BREG, Inc. is a FDA registered manufacturing facility and is in compliance with all the design control procedure requirements as specified in 21 CFR 820.30 and the results are available for review.


Kathleen Barber
Vice President, RA/QA

11/17/2000

STATEMENT OF INDICATIONS FOR USE

Intended Use

BREG's **PAIN CARE Multi-Port Catheter** is intended to provide infusion of a local anesthetic into an intra-operative site for the post-operative management of pain.

Comparative Analysis of Multiple Port Catheters Used with Infusion Pumps

Device Name	Manufacturer	Type	Duration	Applications	Contraindications	Benefits
Pain Care Multi-Port Catheter	Breg, Inc.	16GA catheter with luer fittings, with hole pattern along distance; various lengths, will meet the ANSI specifications for conical connections	2-3 Days	To provide infusion of a local anesthetic into an intra-operative site for the post operative management of pain.	Not designed for epidural, subcutaneous or vascular drug delivery. Not for blood, blood products or TPN use.	Direct pain relief w/o side effects of narcotics, decreased breakthrough pain, reduced hospital stay, earlier ambulation.
Soaker Catheter K994374	I-Flow.	20GA catheter with luer fittings, with hole pattern along distance, various lengths will meet the ANSI specifications for conical connections	2-3 Days	To provide continuous or intermittent delivery of local anesthetics to surgical wound sites	Not designed for epidural, subcutaneous or vascular drug delivery. Not for blood, blood products or TPN use.	Direct pain relief w/o side effects of narcotics, decreased breakthrough pain, reduced hospital stay, earlier ambulation.

MATERIALS APPROVED SAMPLE

PART NO. 1.80820 DESC: Package Label MP220-24 REV: A DATE: 9/7/00
ECO No. 000908B DCD Release Date: 9/19/2000

 **BREG**TM
Breg, Inc., 2611 Commerce Way, Vista, CA 92083 U.S.A.
PART NO. 10460
CONTENTS / INHALT /
CONTENU / CONTENIDO: 1

MP 220-24

Multi-Port Catheter
16 Ports • 220 mm Tip to Last Port • 24 Inches Total Length
For Single Patient Use Only

Contents of Unopened,
Undamaged Package are:

STERILE

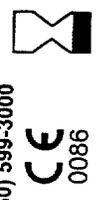
CONTENTS:
1 each - MP 220-24 Multi-Port Catheter
1 each - Catheter Introducer Needle
1 each - Catheter Connector



SEE DIRECTIONS FOR USE. CAUTION: FEDERAL LAW (U.S.A.) RESTRICTS THIS DEVICE TO
SALE BY OR ON THE ORDER OF A HEALTHCARE PROFESSIONAL

E/U Authorized Representative
M.D.S.S.
Burchardstrasse 1
D-30163 Hanover
Germany

To Reorder Call:
(800) 321-0607
(760) 599-3000



PATENTS PENDING
P/N 1.80820 Rev. A 9/00

ATTACHMENT 1

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12

MATERIALS APPROVED SAMPLE

PART NO.

1-80830

DESC: *Package Label, MP220-54*

REV: A

DATE: 9/7/00

ECO No.

000908B

DCD Release Date:

9/19/2000



BREGTM
Breg, Inc., 2611 Commerce Way, Vista, CA 92083 U.S.A.

PART NO. 10470
CONTENTS / INHALT /
CONTENU / CONTENIDO: 1

MP 220-54

Multi-Port Catheter

16 Ports • 220 mm Tip to Last Port • 54 Inches Total Length
For Single Patient Use Only

Contents of Unopened,
Undamaged Package are:

STERILE R

CONTENTS:
1 each - MP 220-54 Multi-Port Catheter
1 each - Catheter Introducer Needle
1 each - Catheter Connector



SEE DIRECTIONS FOR USE. CAUTION: FEDERAL LAW (U.S.A.) RESTRICTS THIS DEVICE TO
SALE BY OR ON THE ORDER OF A HEALTHCARE PROFESSIONAL

EU Authorized Representative
MDSS
Burckhardtstrasse 1
D-30163 Hanover
Germany

To Reorder Call:
(800) 321-0607
(760) 599-3000



CE
0086

PATENTS PENDING
P/N 1.80830 Rev. A 9/00

Attachment 1

MP 220 Multi-Port Catheter Directions



FEDERAL (U.S.A.) LAW RESTRICTS THIS DEVICE TO BE SOLD BY THE ORDER OF A HEALTHCARE PROFESSIONAL

Pain Care only?

BREG's Multi-Port Catheter System is designed to provide greater perfusion of medication when used with the Pain Care line of products. The MP 220 has the following features: (Figure 1)

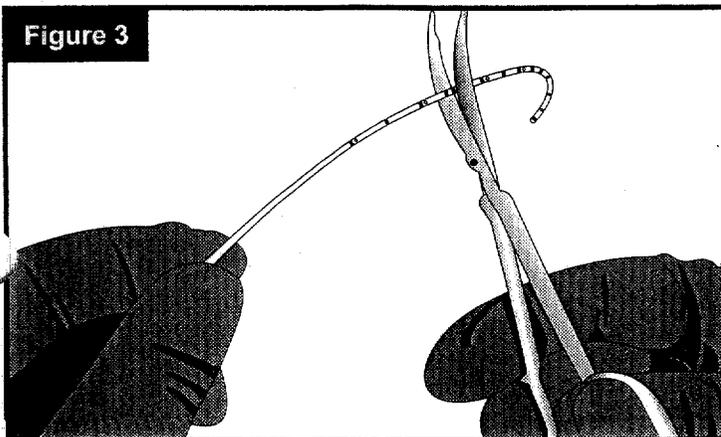
- 16 Lateral Ports Spanning 220 mm from Tip
- 180 Degree Port Orientation
- Progressive Port Separation Permitting Optimal Flow Pattern
- Open End Design Permitting "Cut to Length"
- Last Catheter Marking Proximal to Last Port

Cutting The Catheter To Length

BREG's Multi-Port Catheter can be cut to any appropriate length. This permits the user to insert all of the ports, some of the ports, or none of the ports into the wound site. To do this: (Figures 3 & 4)

- Determine the length of ports necessary.
- With a pair of scissors, cut the desired length by cutting on the appropriate catheter marking. (This ensures that the cut is not made on a port)
- Insert the catheter, using the standard procedure. (Be sure that the last catheter marking is well into the wound site) (Figure 2)

Figure 3



MP 220

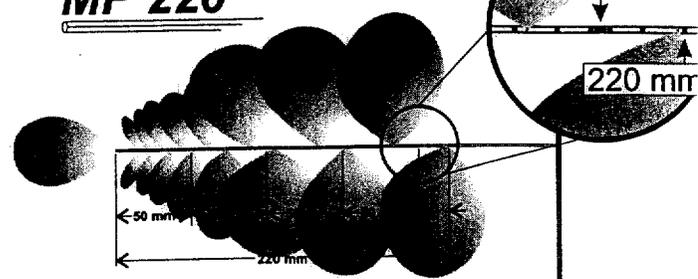


Figure 1

WARNING: The last port (last catheter marking) **MUST** be well below the skin and into the wound site to prevent leaking. The catheter can be cut to the appropriate length prior to insertion.

Figure 2

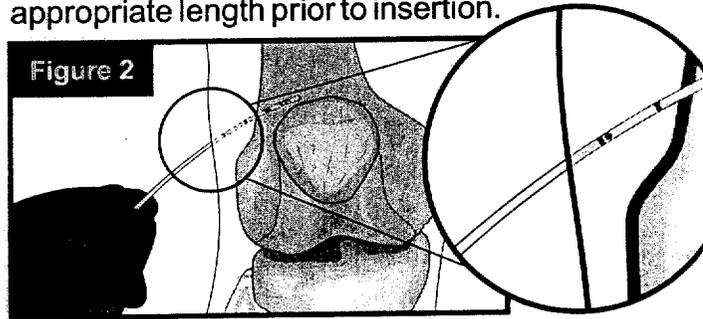
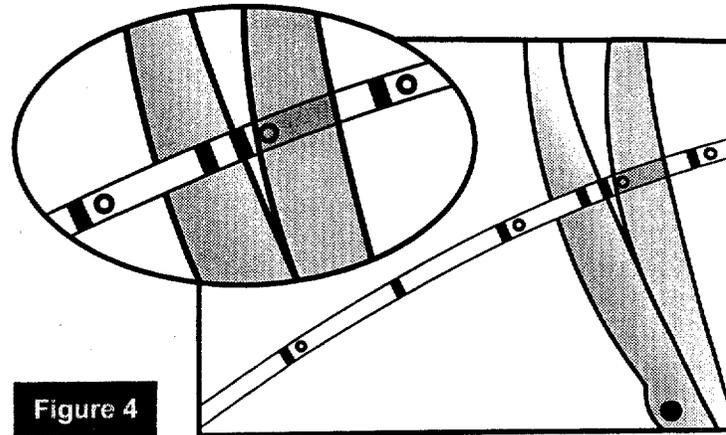


Figure 4



WARNINGS

1. The MP Multi-Port Catheter System is designed to be applied by a licensed health care provider.
2. All medication used with the MP Multi-Port Catheter System is to be prescribed by a licensed physician.
3. Use sterile technique at all times during implantation of the catheter, while completing all connections to the infusion pump, and upon removal of the catheter. If sterile technique is violated, a possible risk of infection exists.
4. Single patient use only. Discard after use.
5. Do not re-sterilize.
6. Medications with known allergies or complications arising from medication used with the MP Multi-Port Catheter System should be used in accordance with the instructions from the drug manufacturer.
7. Not meant for vascular, epidural, or chemo therapy.
8. Do not implant the MP Multi-Port Catheter into the vascular system. Possible drug toxicity exists.
9. Patients with known allergies or complications arising from medication used with the MP Multi-Port Catheter System should not use the MP Multi-Port Catheter System. The physician must be contacted immediately if any adverse reactions occur such as breathing difficulty, heart rate fluctuations, rash, hives, excessive sweating, or nausea.



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E/U Authorized Representative
MDSS
Burckhardtstrasse 1
D-30163 Hannover
Germany

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Premarket Notification

510(k) Statement

As required by 21 CFR 807.93

I certify that, in my capacity as Vice President of Quality and Regulatory Affairs for BREG, Inc., and as their official correspondent that I will make available all information included in their 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.



Kathleen Barber
November 17, 2000

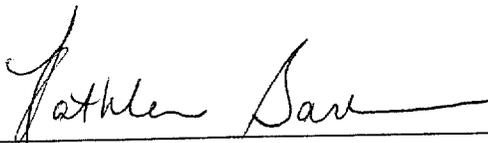
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PREMARKET NOTIFICATION

TRUTHFUL AND ACCURATE STATEMENT

I certify that, in my capacity as Vice President of Quality Assurance and Regulatory Affairs of BREG, Inc., I believe to the best of my knowledge, that data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.



Kathleen Barber
November 17, 2000

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