



# U.S. Department of Health & Human Services

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Food and Drug Administration

## SAVE REQUEST

**USER:** (szs)  
**FOLDER:** K013928 - 37 pages  
**COMPANY:** BREG, INC. (BREG)  
**PRODUCT:** PUMP, INFUSION, ELASTOMERIC (MEB)  
**SUMMARY:** Product: PAIN CARE 3200

**DATE REQUESTED:** Mar 21, 2012

**DATE PRINTED:** Mar 21, 2012

**Note:** Printed





Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

DEC 03 2001

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

Re: K013928  
Trade/Device Name: Pain Care 3200  
Regulation Number: 880.5725  
Regulation Name: Infusion Pump  
Regulatory Class: II  
Product Code: MEB  
Dated: November 26, 2001  
Received: November 28, 2001

Dear Ms. Barber:

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

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

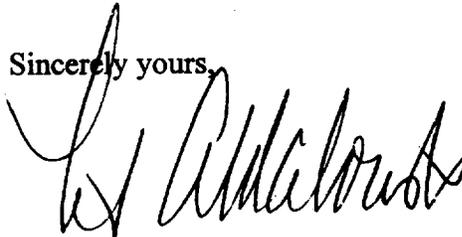
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. 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 Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsamain.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

K013928

**STATEMENT OF INDICATIONS FOR USE**

**Intended Use**

BREG's Pain Care 3200 has the same intended use as BREG's Pain Care 3000. Both units are intended to provide continuous infusion of a local anesthetic into an intra-operative site for the post-operative management of pain.

The purpose of BREG's Pain Care 3000 and 3200 is to provide a delivery mechanism of local anesthetic maintenance doses in order to sustain pain relief that is initially established by the bolus of local anesthetic that is injected intra-operatively (loading dose).

*Roberto Cruz*  
(Division Sign-Off)  
Division of Dental, Infection Control,  
and General Hospital Devices  
510(k) Number K013928

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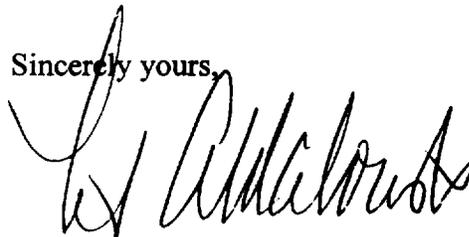
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Sincerely yours,



Timothy A. Ulatowski  
Director

Division of Dental, Infection Control  
and General Hospital Devices  
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K013928

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*Patricia Curran*  
\_\_\_\_\_  
(Division Sign-Off)  
Division of Dental, Infection Control,  
and General Hospital Devices  
510(k) Number K013928

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Memorandum

From: 11/30/01 Reviewer(s) - Name(s) Sarah Foster

Subject: 510(k) Number 1013928

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

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

De Novo Classification Candidate?

YES  NO

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

- Is this device subject to Postmarket Surveillance?  YES  NO
- Is this device subject to the Tracking Regulation?  YES  NO
- Was clinical data necessary to support the review of this 510(k)?  YES  NO
- Is this a prescription device?  YES  NO
- Was this 510(k) reviewed by a Third Party?  YES  NO
- Special 510(k)?  YES  NO
- Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers  YES  NO

This 510(k) contains:

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

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

The required certification and summary for class III devices 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):

CLASS II / 80 MEB 880.5125

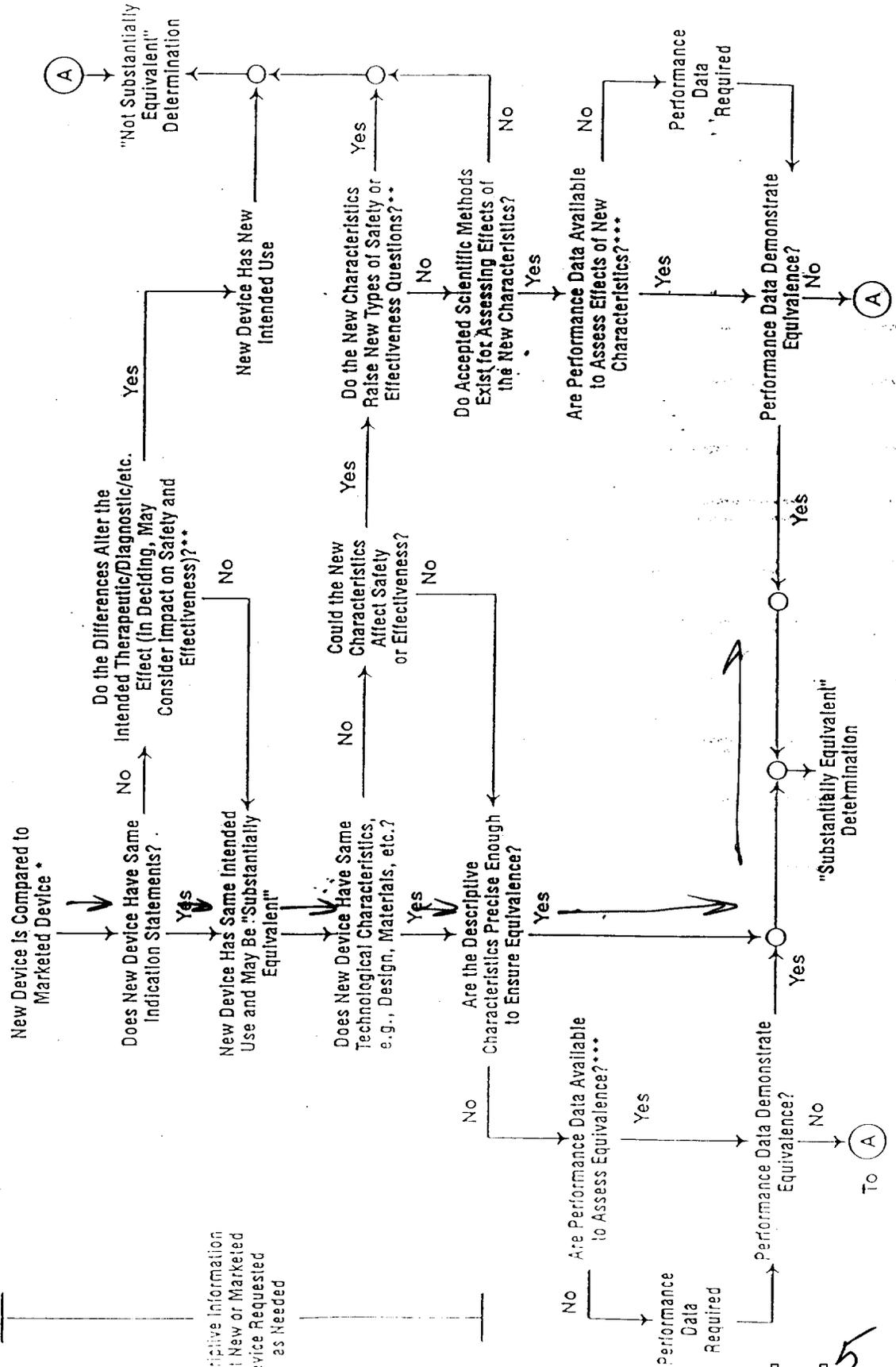
Review: [Signature]  
(Branch Chief)

9/2/01 (Branch Code) 11/30/01 (Date)

Final Review: [Signature]  
(Division Director)

12/4/01 (Date)

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



Descriptive Information about New or Marketed Device Requested as Needed

\* New Devices to Marketed Devices. FDA Requests Relationship Between Marketed and "Predicate" (Pre-Amendments) Devices Is Unclear.

\*\* This Decision Limited To: 510(k), Other 510(k)s, The Center's Classification Files, or the Literature.

\*\*\* Data May Be: 510(k), Other 510(k)s, The Center's Classification Files, or the Literature.

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

**To:** THE FILE

**RE:** DOCUMENT NUMBER K 013928

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**.  
*This change was for increasing the pump capacity from 100cc to 200cc, and increasing the maximum flow rate from 2ml per hour to 4ml per hour.*
4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics, and pump type, capacity, flow control, rate, applications, contraindications, and benefits
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)

11/30/01  
(Date)

**Comments:**

Breg has submitted this Special 510(k) to add the Breg Pain Care 3200 to their line of Pain Care Infusion Pumps. The 3200 has an increased capacity and increased maximum rate, but does not have an increased the maximum bolus size. The new maximum rate and capacity does not exceed those of similar pumps previously cleared for market. I recommend the Breg Pain Care 2000L be determined substantially equivalent to the predicate device, the Breg Pain Care 3000

PC 11/30/01

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

510(k) Number: K013928

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

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

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

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

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

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

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

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

	Present	Inadequate or Missing
For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type. (If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.)		
For a submission, which relies on a recognized standard, a declaration of conformity [For a listing of the required elements of a declaration of conformity, SEE <b>Required Elements for a Declaration of Conformity to a Recognized Standard</b> , which is posted with the 510(k) boilers on the H drive.]		
For a submission, which relies on a recognized standard without a declaration of conformity, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has <u>not</u> been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device and any additional information requested by the reviewer in order to determine substantial equivalence.		
Any additional information, which is not covered by the guidance document, special control, recognized standard and/or non-recognized standard, in order to determine substantial equivalence.		

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

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

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

*Items with checks in the "Present but Deficient" column require additional information from the sponsor. Items with checks in the "Missing" column must be submitted before substantive review of the document.*

Passed Screening  Yes  No

Reviewer: Suf

Concurrence by Review Branch: \_\_\_\_\_

Date: NOV 28

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

## 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.		✓

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.

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

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

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

**ATTACH ADDITIONAL SUPPORTING INFORMATION**

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 28, 2001

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

510(k) Number: K013928  
Received: 28-NOV-2001  
Product: PAIN CARE 3200

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

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

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

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

Sincerely yours,

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

K013928

**SPECIAL 510(k): Device Modification**

for the

**PAIN CARE™ 3200**

Made by

**BREG, INC.**

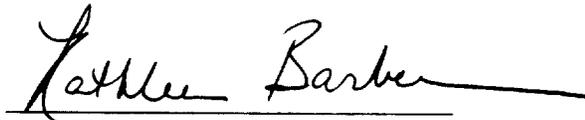
2611 Commerce Way

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.

NOV 26 10 25 AM '01  
FBI/DOJ/REGISTRATION

November 26, 2001

EFF 4 170  
class?

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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 (b)(4) whose FDA Registration Number is (b)(4)

RECEIVED

NOV 28 10 25 AM '01

FDA/CDRH/OCE/DMC

**2. DEVICE NAME**

The proprietary name of the product is **PAIN CARE 3200**. It is a modification to the BREG, Inc. product, **PAIN CARE 3000, K002073**.

**3. DEVICE DESCRIPTION**

BREG's **PAIN CARE™ 3200** consists of a dispensing device that is connected via a Luer LOK connector to a 16 gauge epidural catheter. Included is a 16 gauge intravenous (IV) catheter insertion needle to assist in insertion of the catheter into the operative site. A 60 cc syringe is supplied to fill the dispensing device with fluid (appropriate local anesthetic recommended by a licensed physician). Diagrams of the device are found in Diagram I.

The dispensing device consists of a 200 cc fluid reservoir, a flexible bulb, check valves, a glass flow restrictor, 16 GA catheter, luer fittings, plungers and springs. The device can be attached to the patient's clothing via the molded clip on the device. This device has twice the volume and twice the flow rate of the Pain Care 3000.

There is a one-way Luer LOK fill port connected to the fluid reservoir. This port permits injection of the fluid into the device via the 60 cc syringe. The fill port has a tethered removable cap. When the device is full, the springs are depressed and the fluid flows continuously at the rate of 4ccs per hour. The bulb serves as a reservoir of 4ccs.

A Luer LOK fitting to the bulb connects the device to the 16 gauge catheter or a tube extension set. Fluid that has accumulated within the bulb is injected through the catheter and into the operative site by depressing the bulb (see Diagram 1 for complete configuration). The patient is able to dispense local anesthetic into the operative site as needed for pain relief. All components are provided in a sterile package.

#### 4. MECHANICAL FUNCTION

- 200cc Fluid reservoir filled with fluid through the fill port.
- Fill port capped.
- Bulb is depressed to prime system.
- 4 cc bulb creates an aspirating vacuum within the system (the compressed bulb will try to expand to its natural state, drawing fluid into it).
- The one-way valve between the bulb and catheter prevents aspiration of fluids from the catheter back into the device.
- As determined by the user's pain relief need, the bulb is depressed.
- Fluid is injected through the one-way valve, through the catheter, and into the operative site.
- One-way valve prevents injection of fluid back into the fluid reservoir.
- Cycle repeats.
- Patient depresses bulb as needed for pain.
- PAIN CARE<sub>TM</sub> 3200 use is discontinued once fluid reservoir is empty. A sight tube located on the exterior of the device shows how much medication is left in the reservoir
- The PAIN CARE<sub>TM</sub> 3200 will last for approximately 2-3 days of use, depending upon the frequency of injections.
- Catheter is removed by day three.

#### 5. STERILITY ASSURANCE:

The type of sterilization is (b)(4) gamma radiation performed by (b)(4) (b)(4) to achieve a sterility assurance level of 10 to the -6. This process is equivalent to the Pain Care 3000 device

The sterility validation methodology used to initially establish our dose requirements and our ongoing quarterly audits complies with the following specifications: (1) USP Section 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.

## 6. SUMMARY OF DESIGN CONTROL ACTIVITIES

### **Risk Analysis**

Risk analysis is performed using FMEA to identify those areas which pose the greatest failure risk in the manufacture of the Pain Care 3200. Each issue is assigned a value and actions assigned to eliminate or reduce the risk to a level that has 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.

### **Validation/Verification**

Validation and verification are 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 are corrected.

Specific examples of validation include:

1. The material of the piston seal was changed to a class VI silicone. Testing shows that there was no change in leak characteristics. This material meets the biocompatibility requirements of AAMI, ISO and FDA guidance.
2. The sterilization process Pain Care 3200 is validated using AAMI, ISO and GLP standards.
3. The flow rate is tested with the glass restrictor to verify that the rate does not exceed 4ml/hour. These tests include values at nominal, maximum and minimum limits for full spectrum results.
4. The assembly process validation
5. Testing on units produced by the assembly process to determine if the testing equipment is valid to include both alpha and beta failure modes.

### **DECLARATION OF CONFORMITY**

1. As required by risk analysis, all verification and validation activities for the Pain Care 3200 were performed by the BREG, Inc. Engineering staff. The results demonstrate that the predetermined acceptance criteria are 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.



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**Kathleen Barber**  
Vice President, RA/QA

## **STATEMENT OF INDICATIONS FOR USE**

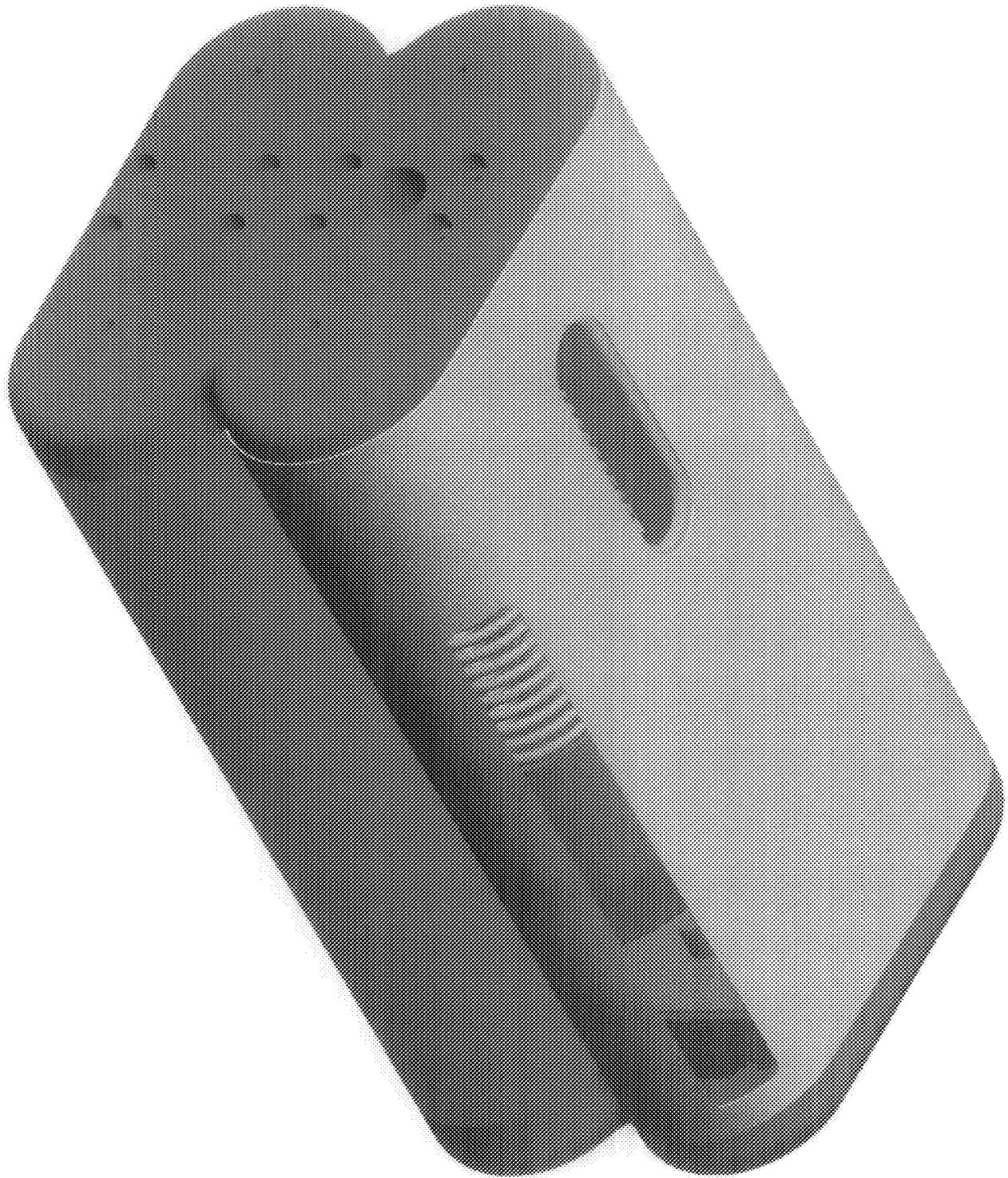
### **Intended Use**

BREG's Pain Care 3200 has the same intended use as BREG's Pain Care 3000. Both units are intended to provide continuous infusion of a local anesthetic into an intra-operative site for the post-operative management of pain.

The purpose of BREG's Pain Care 3000 and 3200 is to provide a delivery mechanism of local anesthetic maintenance doses in order to sustain pain relief that is initially established by the bolus of local anesthetic that is injected intra-operatively (loading dose).

**Comparison of Features Pain Care 3200 v. Pain Care 3000**

<b>Device Name</b>	<b>Pain Care 3200</b>	<b>Pain Care 3000</b>
<b>Manufacturer</b>	BREG, Inc.	BREG, Inc.
<b>Type</b>	Continous flow pain infusion device spring operated. The bulb serves as a reservoir of 4ccs.	Continous flow pain infusion device spring operated. The bulb serves as a reservoir of 4ccs.
<b>Capacity</b>	200 cc	100 cc
<b>Rate</b>	4 cc per hour w/4cc bolus administered by patient	2cc per hour w/4cc bolus administered by patient
<b>Flow control</b>	Flow restrictor controls flow to 4cc/hr. The bulb serves as a reservoir for 4ccs	Flow restrictor controls flow to 2cc/hr. The bulb serves as a reservoir for 4ccs
<b>Duration</b>	2-3 Days	2-3 Days
<b>Applications</b>	Procedures requiring local analgesic non-narcotic pain relief.	Procedures requiring local analgesic non-narcotic pain relief.
<b>Contraindications</b>	Not designed for epidural, subcutaneous or vascular drug delivery. Not for blood, blood products or TPN use.	Not designed for epidural, subcutaneous or vascular drug delivery. Not for blood, blood products or TPN use.
<b>Benefits</b>	Direct pain relief w/o side effects of narcotics, decreased breakthrough pain, reduced hospital stay, earlier ambulation and greater range of motion.	Direct pain relief w/o side effects of narcotics, decreased breakthrough pain, reduced hospital stay, earlier ambulation and greater range of motion.





**BREG, Inc. Pain Care 3200**

ITEM	DESCRIPTION	MATERIAL	VENDOR	PART NUMBER
1	Cap, Male Luer W/Strap	(b)(4)		
2	Check Valve (Fill Port)			
3	Manifold Body & Top			
4	End Cap, Top			
5	AEF Filter, 1.2 micron			
6	Body, (Medication Storage Chambers, 200cc total)			
7	Flow Restrictor			
8	Piston Seals			
9	Piston Seal Coating			
10	Silicone Lubrication			
11	Pistons			
12	Drip Chamber			
13	Compression Springs			
14	End Cap, Bottom			
15	Male Luer Fitting			
16	Low Pressure Check Valve (Outlet)			
17	Smallbore-Female Luer Lock Adapter			
18	Smallbore Tubing			
19	Slide Clamp			
20	Bolus Squeeze Bulb			
21	Luer Adapter			
22	Low Pressure Check Valve (Bulb)			
23	Catheter Connector			
24	Multi-Port Catheter			
25	Catheter Markings			

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

**PART NO. 11030**  
CONTENTS / INHALT /  
CONTENUTO / CONTENIDO: **1**

# PAIN CARE™ 3200

4 ml/Hour Continuous Flow Infusion Device

200 ml Volume • 4 ml Bolus Dose



For Single Patient Use Only



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

**CONTENTS:**  
1 each - 200 ml Vol., Infusion Device  
1 each - Bolus Assembly  
1 each - Catheter Introducer Needle  
1 each - 16 GA Catheter Set  
1 each - 60 cc Latex Free Syringe

Contents of Unopened, Undamaged Package are:

**STERILE R**

E/U Authorized Representative

MD/SS  
Burckhardtstrasse 1  
D-30163 Hannover  
Germany



**PATENTS PENDING**  
P/N 1.09520 Rev. A 12/01

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

# PAIN CARE™ 3200



VISTA, CA 92083 U.S.A.  
1-800-321-0607

**PART #:** 11030  
**CONTENTS**  
1 - 200 ml Vol., 4 ml/hr  
Infusion Device  
1 - Bolus Assembly  
1 - Catheter Introducer  
1 - Needle  
1 - 16 GA Catheter Set  
1 - 60 cc Latex Free Syringe

**Peel & Affix to Patient Record**

Pn1.09520 ReVA.cdr

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# Pain Care™ 3200

## Patient Instructions

- ◆ The *Pain Care™ 3200* automatically delivers numbing medication at an average rate of 4 cc's per hour (0.14 fluid ounces per hour) continuously through the catheter tube and into the surgical site.
- ◆ To start the *Pain Care™ 3200*, or to ensure that it is ON, make sure the white clip is not pinching off the hose.
- ◆ To check and see if the *Pain Care™ 3200* is flowing properly, simply look through the Flow Indicator while holding the unit upright. The unit is working properly when a drop of medication forms on the tip of the yellow glass tube every half minute or so. You may have to tap the unit slightly to clearly view the drops forming.
- ◆ If your doctor has chosen to incorporate the optional injection bulb with the *Pain Care™ 3200*, additional medication may be injected through the catheter to sustain pain relief. By simply squeezing the injection bulb attached to the *Pain Care™ 3200*, an additional dose of numbing medicine can be injected into the surgical site. To do this, firmly squeeze the bulb between your thumb and index finger until it has collapsed. Over the next 1 – 2 hours, the bulb will gradually refill. After squeezing the injection bulb, the medicine will take effect in approximately 10 - 15 minutes.
- ◆ Once the injection bulb has refilled, squeeze the injection bulb as needed for pain relief.
- ◆ Your *Pain Care™ 3200* therapy is finished once the fluid reservoir is empty, as can be seen through the windows in the front of the case.
- ◆ Once the *Pain Care™ 3200* fluid reservoir is empty or if directed by your doctor, the catheter must be removed. Your doctor will provide instructions regarding catheter removal. If you do not have catheter removal directions, contact your doctor's office once your therapy is completed
- ◆ Discontinue if any part of the *Pain Care™ 3200* becomes disconnected. **Do Not Reconnect!** Call your doctor's office immediately.
- ◆ For further instructions and information, consult the complete patient instructions attached to the *Pain Care™ 3200*.
- ◆ Any other questions call your doctor's office.



2611 Commerce Way  
Vista, CA 92083  
800-321-0607

# Pain Care™ 3200

Patient Instructions

**WARNING: READ COMPLETELY BEFORE OPERATION**

Patents Pending



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MDSS  
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Germany

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(760) 599-3000  
Telefax (760) 598-6193

P/N 1.09530 Rev. A 08/01

## WARNING

## WARNING

1. THE *PAIN CARE™ 3200* IS TO BE APPLIED BY A LICENSED HEALTH CARE PROVIDER.
2. ALL MEDICATION USED IN THE *PAIN CARE™ 3200* IS TO BE PRESCRIBED BY A LICENSED HEALTH CARE PROVIDER.
3. PATIENT EDUCATION REGARDING PROPER USE MUST BE INITIATED BY A LICENSED HEALTH CARE PROVIDER. IF YOU HAVE ANY QUESTIONS REGARDING THE OPERATION OF THE *PAIN CARE™ 3200* AFTER READING THESE INSTRUCTIONS CONTACT YOUR PHYSICIAN.
4. THE *PAIN CARE 3200™* IS DISPOSABLE AND INTENDED FOR SINGLE PATIENT USE ONLY.
5. DISCARD/DESTROY THE *PAIN CARE™ 3200* AFTER USE.
6. THE *PAIN CARE™ 3200* MUST BE FILLED BY A LICENSED PHYSICIAN OR LICENSED HEALTH CARE PROVIDER.
7. MEDICATIONS BEING USED WITH THE *PAIN CARE™ 3200* MUST BE USED IN ACCORDANCE WITH THE INSTRUCTIONS PROVIDED FROM THE DRUG MANUFACTURER.
8. PATIENTS WITH KNOWN ALLERGIES OR COMPLICATIONS ARISING FROM THE MEDICATION USED IN THE *PAIN CARE™ 3200* SHOULD NOT USE THE *PAIN CARE™ 3200*. CONTACT YOUR PHYSICIAN IMMEDIATELY IF ANY ADVERSE REACTIONS OCCUR SUCH AS BREATHING DIFFICULTY. HEART RATE FLUCTUATIONS, RASH, HIVES, EXCESSIVE SWEATING OR NAUSEA.
9. IF ANY OF THE *PAIN CARE™ 3200* BECOMES DISCONNECTED OR IF THE CATHETER TUBE BECOMES DETACHED AFTER THE SURGICAL PROCEDURE IS COMPLETED, INFECTION COULD RESULT. DO NOT RECONNECT IT. CONTACT YOUR DOCTOR IMMEDIATELY FOR INSTRUCTIONS.
10. AVOID DROPPING THE *PAIN CARE™ 3200*. IF THE *PAIN CARE™ 3200* SHOULD FALL AND BREAK, CONTACT YOUR PHYSICIAN.
11. THE *PAIN CARE™ 3200* SHOULD ONLY BE REMOVED PER THE PHYSICIAN'S INSTRUCTIONS.

## DIRECTIONS FOR PATIENT USE

BREG's *Pain Care™ 3200* is a portable, infusion pump designed to deliver pain relieving medicine directly to the surgical site. The medicine is continuously delivered (average 4cc's per hour) through a tiny tube called a catheter which is placed inside the

wound by your doctor during surgery. Your doctor has filled the *Pain Care™ 3200* with a numbing medicine and has attached it to the catheter tube. This procedure is similar to the way a dentist numbs your mouth to fill a cavity or pull a tooth. Other pain control therapies such as pain pills and narcotics taken by mouth go throughout the entire body and often cause side effect such as drowsiness, disorientation, nausea, constipation, and vomiting.

If more medicine is needed to decrease pain, simply squeeze the Bolus Bulb on the *Pain Care™ 3200* one time and an additional 4-6 cc's (0.14 - 0.21 fluid ounces) of numbing medicine will be injected directly into your wound site through the catheter.

The *Pain Care™ 3200* has a capacity of 200 cc's (7.0 fluid ounces). This device is designed to provide approximately 48 hours of continuous treatment. How often you decide to squeeze the Bolus Bulb for an increase in the delivery of your pain medication will vary depending upon a number of factors: the frequency you may decide to squeeze the Bolus Bulb to inject the medication, the surgery performed, your individual pain tolerances, the effectiveness of the pain medicine prescribed by your doctor, and how much pain medicine you take orally.

No part of the *Pain Care™ 3200* should be disconnected, and the system should remain intact for the entire duration of your therapy. This is important: if any part of the unit becomes disconnected, infection could result.

Your therapy is complete when the medication reservoir is empty or when it is no longer needed for pain control. The total medication remaining can be viewed through the windows in the front of the *Pain Care™ 3200*.

1. The *Pain Care™ 3200* system consists of the continuous infusion pump ❶, a bolus assembly ❷, and a catheter ❸.
2. Do NOT disconnect ANY of the caps or connections of the *Pain Care™ 3200* as infection could result. If any part of the device becomes disconnected, call your doctor as soon as possible.
3. Take care to completely attach the *Pain Care™ 3200* to your belt, clothing, brace, or sling with the clip on the back of the device. The device may be damaged if dropped.
4. To check for proper flow of medication, grasp the *Pain Care™ 3200* and hold it upright (Bolus Assembly pointing downward). View the flow indicator. Proper flow is confirmed when drops of medication drip off the glass tube inside the flow indicator.
5. If you start to feel an increase of aching and discomfort at the surgery site, simply squeeze the bulb of the Bolus Assembly. This will inject an additional 4 cc's of numbing medicine into the surgery site. This additional dose should start to decrease your discomfort in 15 minutes.
  - ◆ Squeeze the Bolus Bulb slowly and firmly. Additional pressure is NOT needed to increase the rate of administration. Once the bulb is completely squeezed, release it. The bulb will gradually refill on its own.
6. Your therapy is completed when the medication reservoir is empty (as can be seen through the windows in the front of the case.)
  - ◆ The *Pain Care™ 3200* is designed to provide approximately 48 hours of continuous flow of pain medication into your surgical site.
  - ◆ The continuous flow of pain relieving medication should control your pain.

- ◆ If you experience any problems with the *Pain Care*<sup>™</sup> 3200 unit such as leakage, the device becoming disconnected, or the tube pulling out of the wound site, contact your physician immediately. Do NOT attempt to reattach any part of the unit as infection could result.
- ◆ If you should drop the *Pain Care*<sup>™</sup> 3200 and it cracks, breaks, or stops working, contact your physician immediately.
- ◆ Once the *Pain Care*<sup>™</sup> 3200 is empty, the catheter tube must be removed. Contact your physician for his/her instructions regarding catheter removal.

# **Pain Care™ 3200**

Clinical Instructions

Patents Pending



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2611 Commerce Way  
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Telephone (800) 321-0607  
(760) 599-3000  
Telefax (760) 598-6193

P/N 1.09540 Rev. A 08/01

**CAUTION: federal (U. S. A.) law restricts this device to be sold by the order of a health care professional.**

## **INTENDED USE**

BREG's *Pain Care™ 3200* is intended to provide continuous flow and patient controlled infusion of a local anesthetic into an operative site for the post-operative management of pain for approximately forty-eight (48) hours.

## **USE ASEPTIC TECHNIQUE AT ALL TIMES**

### **PLACING THE CATHETER**

1. Place the Catheter Using Visual Control.
2. Insert the 16 gauge introducer needle/insertion catheter through the skin (approximately 3-5 cm away from the wound site). Next, push the introducer needle into the surgical site.
3. Remove the introducer needle from the insertion catheter.
4. Insert the marked end (multiple markings) of the 16 gauge Multi-port Catheter through the hub of the insertion catheter and into the wound site. Ensure the last port (as indicated by the last catheter marking) is well beneath the surface of the skin and into the wound site.
5. Remove the insertion catheter while holding the 16 gauge Multi-port Catheter tightly in place.
6. Secure catheter placement in the wound site with any appropriate tape or dressing.
7. Attach the catheter connector to the free end of the catheter. (Tighten the connector by twisting until the catheter cannot be removed from the catheter connector).

### **OPTIONAL "Y" ADAPTER (For infusion of two sites)**

1. Place the additional catheter provided in the "Y" Accessory Kit in the second wound site as described above.
2. Connect the Catheter Connectors of each catheter to the male ends of the "Y" adapter by twisting firmly until secure.

### **PRIMING THE CATHETER AND ADDING THE LOADING DOSE OF LOCAL ANESTHETIC**

1. Close all wounds.
2. Fill the 60 cc syringe with an appropriate Loading Dose of local anesthetic (e.g. 20-50 cc's of 0.25% bupivacaine).
3. Attach 60 cc syringe to the Luer fitting on the tube end of the Bolus Assembly.
4. Hold the Bolus Bulb upright (●) and inject the local anesthetic until the Bulb is full and fluid begins to escape.
5. Attach the catheter connector (single catheter) or "Y" adapter (two catheters) to the Bolus Bulb and inject the remaining amount of local anesthetic through the catheter and into the wound site.
6. Clamp off the Bolus Tube by sliding the clamp shut and remove the 60 cc syringe from the Bolus Assembly.

### **FILLING THE PAIN CARE™ 3200**

1. Fill 60 cc syringe with 50 cc's of local anesthetic (e.g. 0.25% bupivacaine).
2. Remove protective cap from FILL PORT.
3. Attach 60 cc syringe to the FILL PORT.
4. Inject 50 cc's of the local anesthetic (as prescribed by the patient's physician) into the fluid reservoir through the FILL PORT. Hold the syringe in one hand and push the plunger with the other (●). DO NOT hold the *Pain Care*™ 3200 while filling.
5. Remove the syringe from the *Pain Care*™ 3200 and again fill the 60 cc syringe with 50 more cc's of local anesthetic.
6. Repeat steps 3 and 4 a total of 3 times (200 cc's total). (Do Not Overfill).
7. Re-apply the protective cap to the FILL PORT.

### **CONNECTING AND TURNING ON THE PAIN CARE™ 3200**

1. Attach the free end of the Bolus Tube to the port labeled CATHETER, twisting until secure.
2. Release the clamp on the Bolus Tube to start the delivery of medication.
3. Hold the *Pain Care*™ 3200 right side up (Bolus Assembly pointing downward) to view the Flow Indicator. The *Pain Care*™ 3200 is flowing properly when drops of medication drip within the Flow Indicator.
4. The *Pain Care*™ 3200 will continuously drip medication (Average Rate: 4 cc's per hour) for approximately 48 hours.
5. If additional pain relief is indicated, the Bolus Bulb may be squeezed to inject a 4 cc bolus of local anesthetic medication. The Bolus Bulb will refill in approximately one hour.

### **DISCONTINUING THE USE OF THE PAIN CARE™ 3200**

1. Infusion is complete when the *Pain Care*™ 3200 is empty as viewed through the windows.
2. The catheter should be removed at this time.
3. For catheter removal, consult a licensed health care provider.

### **WARNINGS**

1. The *Pain Care*™ 3200 is designed to be applied by a licensed health care provider.
2. All medication used in the *Pain Care*™ 3200 is to be prescribed by a licensed physician.
3. The prescribing health care provider must ensure that the patient understands the contraindications for the medication prescribed, related symptoms, and the risk of the infection should the device or its installation become compromised.

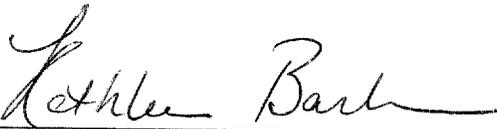
4. Use sterile technique at all times during implantation of catheter, while completing all connections to the *Pain Care*™ 3200 while filling the fluid reservoir of the *Pain Care*™ 3200 with the local analgesic, and upon removal of the catheter from the insertion site upon completion. If sterile technique is violated, a risk of infection exists.
5. Disposable – Single patient use only.
6. Discard/destroy after use.
7. Only refill the device per physician's instructions.
8. Do not re-sterilize the device.
9. Do not overfill fluid reservoir chamber.
10. Medications being used with the *Pain Care*™ 3200 should be used in accordance with instructions provided from the drug manufacturer.
11. If any of the Luer LOK catheter connections becomes disconnected from the *Pain Care*™ 3200 or if the catheter becomes disconnected from the Luer LOK catheter connector after the surgical procedure is completed, do not reconnect it. Infection could result if reattached. A licensed health care provider must be contacted to discontinue the use of the *Pain Care*™ 3200 and for catheter removal.
12. Avoid dropping the *Pain Care*™ 3200, if it should fall and break, contact the physician.

**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.



**Signature of Signer**

**Kathleen Barber**

**11/26/2001**

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**510(k)**

**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 all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.**



\_\_\_\_\_  
Signature

Kathleen Barber  
11/26/2001

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