K011736

JAN 2 9 2002

**Premarket Notification**
**510(k) Summary of Safety and Effectiveness**
**DRG QuickMix**

## Company Information

Doctors Research Group, Inc.
50 Altair Ave.
Plymouth, CT 06782
Phone: 800-371-2535
Fax: 860-283-1589

Contact: Richard Deslauriers, MD

Registration Number: 1226001

## Summary Preparation Date

May 31, 2001

## Device Information

| | |
|---|---|
| Trade Name: | QuickMix Mixing System for BoneSource® Hydroxyapatite Cement (HAC) |
| Common Name: | Hydroxyapatite Cement (HAC) |
| Classification Name: | Methyl Methacrylate for Cranioplasty |
| Device Classification Panel: | Neurology |
| Regulation Number: | 21CFR Part 882.5300 |
| Class: | II |
| Product Code: | GXP |

**Predicate Device**

The DRG QuickMix mixing system is substantially equivalent to the BoneSource® Hydroxyapatite Cement (HAC) Expanded Kit distributed by Stryker Leibinger (K991398), which contains BoneSource® Hydroxyapatite Cement powder, one (or two based on the size of the kit) prefilled syringe containing sodium phosphate solution and a mixing spatula. Kits are provided in sizes ranging form 2.5g to 50g.

**Device Description**

The DRG QuickMix mixing system consists of a syringe containing a 0.25 M sodium phosphate solution and a mixing syringes containing BoneSource® Hydroxyapatite Cement. The mixing syringe also contains a filter which allows liquid, but not the cement mixture, to pass through it.

The sodium phosphate and cement mixing syringes are first connected tip to tip. The sodium phosphate solution is then injected into the mixing syringes and the cement mixture is shaken to thoroughly blend it. Excess liquid is then pulled from the mixing chamber through the filter assembly by retracting the solution plunger. The two syringes are then disconnected. The filter cap is then removed from the mixing syringe and the mixture is ejected.

Kits are being provided in five sizes:

| Mixing Syringe, cc | BoneSource, g | .25 M Sodium Phosphate, mL |
|---|---|---|
| 5 | 2.5 | 2.25 |
| 10 | 5.0 | 4.5 |
| 20 | 10.0 | 9.0 |
| 50 | 25.0 | 22.5 |
| 100 | 50.0 | 45.0 |

**Indications for Use**

QuickMix is indicated for use in mixing BoneSource® Hydroxyapatite Cement and sodium phosphate solution. The cement is indicated for use in the repair of neurosurgical burr holes, contiguous craniotomy cuts and other cranial defects with a surface area no larger than 25 $cm^2$ per defect, and for augmentation or restoration of bony contours in the craniofacial skeleton including the fronto-orbital maler and mental areas.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 3 0 2002

Richard Deslauriers, M.D.
President
Docfors Research Group, Inc.
143 Wolcott Road
Wolcott, Connecticut 06716

Re: K011736
Trade/Device Name: QuickMix Mixing System for BoneSource®
Regulation Number: 21 CFR 882.5300 and 878.3550
Regulation Name: methyl methacrylate for cranioplasty; prosthesis, chin, internal; and implant, malar
Regulatory Class: II
Product Code: GXP, FWP and LZK
Dated: November 28, 2001
Received: November 28, 2001

Dear Dr. Deslauriers:

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) 594-4659. 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/dsmamain.html

Sincerely yours,

for Mark N Melkerson

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

Enclosure

**Doctors Research Group, Inc.**
**143 Wolcott Road**
**Wolcott, CT 06716**
**(203) 879-9422**

K011736

## Statement of Indications For Use

510(k) Number (if Known):

Device Name: QuickMix Mixing System for BoneSource® Hydroxyapatite Cement (HAC)

Indications for use:

QuickMix is indicated for use in mixing BoneSource® Hydroxyapatite Cement and sodium phosphate solution. BoneSource is indicated for use in the repair of neurosurgical burr holes, contiguous craniotomy cuts and other cranial defects with a surface area no larger than 25 $cm^2$ per defect, and for augmentation or restoration of bony contour in the craniofacial skeleton including the fronto-orbital maler and mental areas.

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

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

for Mark N Milhauser

(Division Sign-Off)
Division of General, R[illegible]orative
and Neurological Devices

510(k) Number K011736

**Prescription Use** ✓ **OR** **Over-The-Counter Use**
**(Per 21 CFR 801.109)**