K023445

IV. 510(k) Summary

This summary of safety and effectiveness is being submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 CFR §807.92.

A. Date Prepared

October 11, 2002

MAR 11 2003

B. General Information

Manufacturer: Parallax Medical, Inc.
940 Disc Drive
Scotts Valley, CA 95066-4544

Contact: Linda Bradley
Manager, Regulatory and Clinical Affairs
(831) 439-0130, ext 251 (phone)
(831) 439-1725 (fax)

C. Device Information

Trade Name:	TRACERS Bone Cement Opacifier
Common Name:	Barium Sulfate
Device Classification:	II
Classification Name:	Accessory, Barium Sulfate, Methyl Methacrylate for Cranioplasty
Product Code(s):	MYU

D. Predicate Device Identification

The subject device is substantially equivalent to TRACERS Bone Cement Opacifier (K991893).

E. Intended Use

TRACERS Bone Cement Opacifier is intended for use as an additive to Secour Acrylic Resin or Codman Cranioplastic™ (Type I – Slow Set) to provide radiopacity for imaging purposes.

F. Product Description

TRACERS Bone Cement Opacifier is an additive to be used with Codman Cranioplastic (K8736989) or Secour Acrylic Resin (K994022) to provide radiopacity to the resin and assist in placement and visualization of material. The TRACERS Bone Cement Opacifier is added to the Cranioplastic or Secour monomer (powder) prior to mixing with the Cranioplastic or Secour polymer (liquid). The end product (Cranioplastic or Secour and Tracer particles) is substantially equivalent to Cranioplastic and Secour alone.

G. Substantial Equivalence

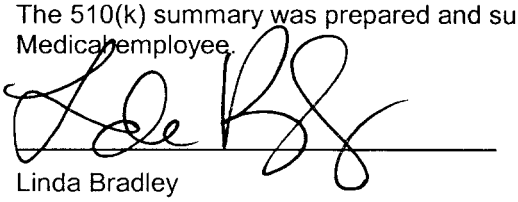
The subject device is equivalent in intended use, design, and technological characteristics to TRACERS Bone Cement Opacifier (K991893).

H. Summary

Based on the information provided in this notification, the subject device is substantially equivalent to the predicate devices in intended use, technological characteristics, and design.

I. Signature of Preparer

The 510(k) summary was prepared and submitted by the following Parallax Medical employee.



Linda Bradley
Manager, Regulatory and Clinical Affairs

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 11 2003

Ms. Linda Bradley
Manager, Regulatory and Clinical Affairs
Parallax Medical, Inc.
940 Disc Drive
Scotts Valley, CA 95066

Re: K023445
Trade/Device Name: Tracers Bone Cement Opacifier
Regulation Number: 21 CFR 882.5300
Regulation Name: Methyl methacrylate for cranioplasty
Regulatory Class: II
Product Code: MYU
Dated: February 13, 2003
Received: February 14, 2003

Dear Ms. Bradley:

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

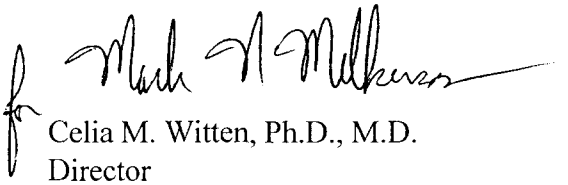
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



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

III. Statement of Indications for Use

Indications for Use

510(k) Number (if known): K023445

Device Name: TRACERS Bone Cement Opacifier

Indications for Use:

TRACERS® Bone Cement Opacifier is intended for use as an additive to Secour™ Acrylic Resin or Codman Cranioplastic™ (Type I – Slow Set) to provide radiopacity for imaging purposes.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K023445

Prescription Use _____ OR Over-The Counter Use _____

(Per 21 CFR 801.109) (Optional Format 1-2-96)