

AUG 10 1998

K981855

**SUMMARY OF THE SAFETY AND EFFECTIVENESS  
INFORMATION IN THE PREMARKET NOTIFICATION FOR THE  
PRINCE MEDICAL CEMENT PLUG**

Prince Medical, Inc.

**Design Parameters**

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The Prince Medical Cement Plug consists of various sizes and is made from Medical Grade Ultra High Molecular Weight Polyethylene (UHMWPE). The component is produced in two outside diameters and is introduced into the medullary canal using a stainless steel inserting tool. Design drawings are typical for such components that are used in the industry. Under this premarket notification, the device is available in 18.5 and 25.0mm outside diameter.

**Material Specifications**

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The Prince Medical Cement Plug is manufactured from Medical Grade Ultra High Molecular Weight Polyethylene corresponding with ASTM F648

**Biocompatibility**

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Ultra High Molecular Weight Polyethylene has a long history of use in orthopaedic applications. Its biological response has been well characterized by a history of clinical and laboratory studies (Turner, J., Lawrence, W., and Autian, J., "Subacute Toxicity Testing of Biomaterials Using Histopathologic Evaluation of Rabbit Muscle Tissue", *Journal of Biomed. Mater. Research*, Vol. 7, 1973; Laing, P., "Compatibility of Biomaterials", *Orthopedic Clinics of North America*, Vol 4, No. 2, April 1973; and Escalas, F., Galante, J., and Rostoker, W., "Biocompatibility of Materials for Total Joint Replacement", *Journal of Biomed. Mater. Research*, Vol 10, No. 2, 1976). These tests include data on human and animal performance and show that the tissue exhibits excellent biocompatibility.

## **Sterilization**

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The Prince Medical Cement Plug is supplied double packaged in sealed, Tyvek pouches. The device is sterilized by Gamma Irradiation sterilization. The sterility assurance level is (SAL)  $10^{-6}$ . To substantiate this (SAL) sterility, testing will be performed on the actual device. The validation is based on the AAMI protocol.

## **Utilization and Implantation**

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Selection of the Prince Medical Cement Plug depends on the judgement of the surgeon in relationship to the requirements of the patient. The surgeon should become thoroughly familiar with the technique of implantation by the appropriate reading of the literature, and training in the operative skills and techniques required for the total hip arthroplasty surgery.

The femoral canal is prepared according to the surgeon's typical methodology for cemented hip arthroplasty. The proper size Prince Medical Cement Plug is chosen based on the size of the femoral canal as estimated by the surgeon.

The bone plug will be positioned in the intramedullary canal 2-3mm below the distal tip of the implant. The selected femoral component should be measured using the Cement Plug Inserter, allowing the length of the femoral component, plus the height of the bone plug, plus 2-3mm.

To insert the Prince Medical Cement Plug, it is screwed onto the Cement Plug Inserter and inserted into the prepared femoral canal to the pre-established depth. Once correctly placed, the cement plug inserter is unscrewed from the plug by turning the inserter counter-clockwise, leaving the Prince Medical Cement Plug in position.

## **Indications**

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The Prince Medical Cement Plug is indicated for use with cemented total hip or endoprosthetic femoral components to:

1. Prevent the bone cement from distal migration during insertion.

2. **Increase the pressure of the cement during cement and femoral component insertion to facilitate bone penetration and distribution of the cement**

### **Contraindications and Adverse Effects**

**The Prince Medical Cement Plug should not be used in non-cemented total hip procedures or for applications other than those which are indicated.**

**The Indications, contraindications, and adverse effects of the bone cement and the femoral component being used should be reviewed prior to using the Prince Medical Cement Plug. Patient Conditions and / or predispositions noted in these inserts should be avoided.**

**It is possible that some patients, although infrequently, may be allergic to implant materials. These allergies should be ruled out preoperatively.**



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

AUG 10 1998

Mr. Mike Prince  
President  
Prince Medical, Inc.  
126 S.W. 140<sup>th</sup> Terrace  
Newberry, Florida 32669

Re: K981855  
Trade Name: Prince Medical Cement Plug  
Regulatory Class: II  
Product Code: JDI  
Dated: May 22, 1998  
Received: May 26, 1998

Dear Mr. Prince:

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 devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

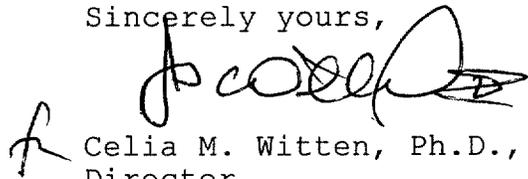
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

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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) 594-4659. 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" (21 CFR 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/dsmamain.html>".

Sincerely yours,

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

Enclosure

510(k) Number (if known): K981855

Device Name: PRINCE MEDICAL CEMENT Plug.

Indications For Use:

The Prince Medical Cement Plug is indicated for use with cemented total hip or endoprosthetic femoral components to :

1. Prevent the bone cement from distal migration during its insertion.
2. Increase the pressure of the cement during cement and femoral component insertion to facilitate bone penetration and distribution of the cement.

(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 Devices**  
**510(k) Number** K981855

Prescription Use X  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use     

(Optional Format 1-2-96)