SEP 2 4 1999

Modular Cutting Systems

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K990816

ALLEN P. SCHLEIN M.D. **February 28, 1999**

510 (K) Summary

AvCore System

The AvCore System comprises of a series of trephines and purchased canulated drill bits of matched size, used to obtain a appropriate sized and contoured bone graft in the treatment of avascular necrosis of the femoral head.. The device is classified under the nomenclature of drills, burs, Trephines & accessories (compound, powered). The product code is 84HBF and regulation number 882.4305 and is a Class II device.

Trephines of various types were originally utilized for performing burr holes into the skull since the days of the cave man. Modern trephines of stainless steel are still utilized in orthopedic and neurosurgery for obtaining cylindrical bone grafts and for removal of broken hardware. All of these devices including many made prior to 1976 are essentially equivalent to the cores described in this application as they are all hollow cylinders of hard stainless steel with teeth machined into their front end and shanks at the rear to be placed in a drill chuck. They are turned in a rotary fashion to obtain the circular grafts and all are sterilized by use of the steam autoclave.

In treating Avascular Necrosis of the femoral head, Ponseti reported on the use of trephines to remove the lesion for biopsy in The Journal of Bone and Joint Surgery **31-A 1949** and a similar report was written by Bonfiglio and Bardenstein in The Journal of Bone and Joint Surgery **52-A:322 1970**.

The trephines used by these authors are essentially the same as those in the AvCore System. The only difference in technique is that these authors used the trephines to remove the avascular area and then used a fibular or tibial bone graft in the formed channel. In the AvCore system the bone grafts are obtained from the base of the trochanter with the trephines and the matched drills used to remove the avascular area. The shaft of the AvCoreTrephines can be unlocked and be moved forward to act as an ejector for the graft material.

Substantial equivalance is claimed to the trephines manufactured by Gambale & Merrill in the performance of cranial flaps. The trephines in the Cloward System for obtaining bone grafts for cervical fusion and the Codman Anterior Cervical Fusion Kit are also similar to those used in the

AvCore System. A trephine was also part of the instrumentation utilized to insert the stem of the St. George- Buchholz knee. The above devices, I believe were marketed in the U.S.A. prior to 1976.

Trephines have been manufactured by DePuy Corporation, Warsaw, Indiana as screw removal instruments. The CORB Biopsy System manufactured by Zimmer Inc., Warsaw Indiana utilized powered trephines used for removal of avascular segments of the femoral head.

Trephines are presently marketed by Arthrex Inc., Naples Florida and Smith & Nephew, Andover, Massachusetts for obtaining and implantation of articular osteochondral grafts of the knee. Trephines are also used for the harvesting of knee ligament grafts and in obtaining grafts for wrist fusion by Roberts Medical, Inc. Boyertown, Pennsylvania.

Catalogue pages or advertisements are supplied for the items we feel are of substantial equivilance.

The Surgical Technique for the use of the instruments supplied as the AvCore System is also supplied in a separate section of this 510 (K) application.

Please note that all Avcore instruments are manufactured by a contract manufacturer, FDT Precision, Taunton, Massachusetts utilizing acceptable manufacturing principles and techniques. No instrument is supplied as sterile and all instruments can be steam sterilized.

No claims are to be made for the efficacy of the technique of core biopsy which has been discussed substantially in the orthopedic literature. The instruments in the AvCore system merely facilitate the manner in which the procedure is performed, as a secondary bone graft site is not required.

Based on the documentation that trephine instrumentation both existed and was used in the treatment of avascular necrosis of the hip and other areas prior to 1976, it is my feeling that the instruments should be considered exempt or at least substantially equivalent to trephines being manufactured and sold at the present time.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 24 1999

Allen P. Schlein, M.D.
President
Modular Cutting Systems, Inc.
650 Clinton Avenue
Bridgeport, Connecticut 06605

Re: K990816
Trade Name: AvCore System
Regulatory Class: I
Product Code: HWE
Dated: July 2, 1999
Received: July 8, 1999

Dear Dr. Schlein:

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.

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) 594-4595. 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

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510(k) Number (if known): K990816

Device Name: AV Core System

Indications For Use:

The AV Core System is a system of cannulated trephines and drills used to obtain and insert a tailored bone graft into a matched hole in the femoral head. The use of the system is indicated for patients suffering from Avascular Necrosis, but in which the head does not radiologically show signs of gross collapse or degerative changes.

(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 K990816

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

(Optional Format 1-2-96)