

SECTION IV - REGULATORY HISTORY OF THE DEVICE

FDA issued a Proposed Rule classifying 77 orthopedic devices on July 2, 1982 (47 FR 29052), and the Final Rule on September 4, 1987 (52 FR 33686). The Final Rule established twelve separate categories of implantable knee prostheses (21 CFR 888.3480 through 888.3590). Each of the twelve types of knee prostheses described were assigned to either Class II or Class III depending on system attributes such as fixation method, level of constraint, and degree of resurfacing (e.g., patellofemorotibial versus femoral). None of the categories, however, describes the type of total knee replacement system that has come to be known as the mobile bearing knee.

DePuy Orthopaedics, Inc. (Warsaw, IN), was the first manufacturer to introduce a mobile bearing knee to the U.S. market. Finding no pre-amendment mobile bearing knee system and no existing Class II knee system to form the basis for a Substantial Equivalence determination, the mobile bearing knee was automatically classified as a Class III device requiring a Pre-Market Approval Application (PMA). DePuy submitted a PMA (P830055) for their LCS Total Knee System and obtained marketing approval for the system in April of 1985. The mobile bearing components to the LCS Total Knee System obtained initial marketing approvals as follows:

- Rotating Platform LCS Knee: PMA approved 4/1985.
- Bicruciate Retaining Meniscal Bearing Knee: PMA Supplement approved 4/1985.
- Posterior Cruciate Retaining Meniscal Bearing Knee: PMA Supplement approved 11/1985.
- Uncemented Posterior Cruciate Retaining Knee: PMA Supplement approved 9/1990.
- Uncemented Rotating Platform LCS Knee: PMA Supplement approved 2/1994.
- Posterior Stabilized Rotating Platform Tibial Trays and Bearing Components: PMA Supplement approved 5/1998.

DePuy also submitted a PMA (P910016) for the uncemented Unicompartmental Device Configuration of the LCS Total Knee System and received marketing approval for that configuration in 1992.

No manufacturer other than DePuy has received Pre-Market Approval for a mobile bearing knee system. DePuy's mobile bearing knee, therefore, is the only mobile bearing knee system in commercial distribution in the United States. There are, however, numerous other mobile bearing knee systems that have been in the international orthopedic marketplace for many years. A listing of these knee systems and their basic description may be found in Section XI of this document, "Devices Currently/Previously Available".