

510(k) Summary

R 960524

Proprietary Name: Alta® CFX IM Rod System

Common Name: Intramedullary Fixation Rod

Classification Name and Reference: 21 CFR 888.3020  
Intramedullary Fixation Rod

MAR 22 1995

Proposed Regulatory Class: Class II  
Device Product Code: OR(87) HSB

For Information Contact: Frank Maas  
Manager, Regulatory Affairs  
Howmedica, Inc.  
359 Veterans Boulevard  
Rutherford, N.J. 07070  
Telephone: (201) 507-7875  
Fax: (201) 507-6870  
Date Summary Prepared: 1-31-95

The Alta® CFX IM Rod System is a series of intramedullary rods in diameters of 11mm, 13mm, and 15mm with lengths of 300mm to 480mm.

These devices are intended to be used for the fixation of subtrochanteric, intertrochanteric, ipsilateral neck/shaft, and comminuted proximal femoral shaft fractures, as well as for temporary stabilization of fractures of the femoral shaft ranging from the femoral neck to the supracondylar regions of the femur.

Locking screws are available for both reconstructive and interlocking indications.

The substantial equivalence of these rods and screws is based on an equivalence in intended use, materials, design, operational principles, and relative indications and contraindications to Howmedica's Alta® CFX IM Rod System and Alta® Femoral IM Rod System (K926232 & K850441), Howmedica's Grosse & Kempf Locking Nail (K813371A), Ace Medical's AIM Femoral System, and Zimmer's ZMS Recon Nail System.