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510(k) Summary

Submitter: Integrated Surgical Systems, Inc.
829 W. Stadium Lane
Sacramento, CA 95834
(916) 646-3487

Trade name: ORTHODOCR Model 500 Preoperative Planning Software

Common name: Templating System

Classification name: Template for clinical use (21 CFR 888.4800)

Indications for use: The ORTHODOC Preoperative Planner is a software device indicated for the planning of primary total hip arthroplasties on a personal computer. The software is intended to import computed tomography data, provide a constructed image of the data, and use computerized files, representing implant patterns of femoral components, to overlay the constructed image to aid surgeons in their selection and positioning of the femoral components.

Legally marketed predicate: All femoral component templates supplied by femoral component manufacturers. For example, Depuy AML templates and Howmedica Osteolock HA templates.

Device description: This software is designed to run on a PentiumR-based personal computer. The device is a software-only product and is not intended to operate any other medical device or act directly on a patient. The application stores scaled graphic images of femoral stem components and provides a means for surgeons to superimpose these patterns on a CT image of the patient's femur. The implant patterns can be moved over the femur images to select what in the surgeon's judgement is the best stem size, position, neck length, and head diameter to achieve the physician's surgical goal.

The library of implant patterns, called surface model files, is developed from computer-aided-design (CAD) geometric data supplied by the implant's manufacturer. The implant surface model file used by ORTHODOC contains implant identification information as well as geometric data which defines the shape and dimensions of the implant surface.

Technological charactistics:	The implant patterns of the predicates are scaled computer-generated images that are plotted, photographed, and contact printed to maintain accurate scale. These are held over the x-ray and moved by hand to position them to assist the surgeon in planning the stem's placement. The ORTHODOC software contains a library of computer-generated femoral component images which can be called-up and superimposed over a CT image of the patients femur. The images are moved by hand, employing a mouse pointer, to position them to assist the surgeon in planning the stem's placement.
Performance data:	There has been no pre-clinical or clinical performance data generated upon which to make a decision of substantial equivalence.