

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485: 2003

This is to certify that:

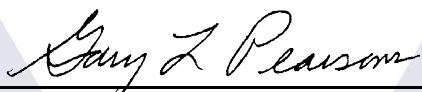
DePuy Orthopaedics, Inc.
PO Box 988
700 Orthopaedics Drive
Warsaw
Indiana
46581
USA

Holds Certificate No: **FM 70858**

and operates a Quality Management System which complies with the requirements of ISO 13485: 2003 for the following scope:

Design, manufacture, packaging and distribution of introducers, guide wires, adaptors, irrigation/drainages sets, surgical cases and trays, surgical sponges, resorbable material implants of both biological and non-biological origin, orthopaedic implants and instruments, bone prostheses, surgically invasive and implantable orthopaedic fixation devices for both internal and external stabilization, surgical ancillary aids, disposable surgical instruments, computer assisted surgical systems and software, and products intended to provide protection from contamination in the surgical environment in orthopaedics.

For and on behalf of BSI:



President, BSI Management Systems America, Inc.

Originally Registered: **11/11/2002**

Effective Date: **06/03/2008**

Expiry Date: **05/31/2011**



CMDCAS
Recognized
Registrar

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This certificate remains the property of BSI and shall be returned immediately upon request. An electronic certificate can be authenticated [online](#). Printed copies can be validated at www.bsigroup.com/ClientDirectory To be read in conjunction with the scope above or the attached appendix.

Americas Headquarters: 12110 Sunset Hills Road, Suite 200, Reston, VA 20190, USA.

Certificate No: **FM 70858**

Location

Registered Activities

DePuy Orthopaedics, Inc.
PO Box 988
700 Orthopaedics Drive
Warsaw
Indiana
46581
USA

Design, manufacture, packaging and distribution of surgically invasive and implantable orthopaedic fixation devices, medical devices and instrumentation and biologics.

DePuy Orthopaedics, Inc.
325 Paramount Drive
Raynham
Massachusetts
02767
USA

The manufacture, packaging and distribution of orthopaedic implants and instrumentation.

This appendix supersedes certificate FM 76807 dated July 7, 2003.

DePuy Orthopaedics, Inc.
50 Scotland Park Drive
Bridgewater
Massachusetts
02324
USA

The Distribution of Orthopaedic Implants and Instruments.

This appendix supersedes certificate FM 76807 dated July 7, 2003.

Hand Innovations, LLC
6303 Blue Lagoon Drive
Suite 100
Miami
Florida
33126
USA

The design and development of implantable orthopaedic fixation devices and instruments such as plates, nail plates, pegs, screws, intramedullary nails, sutures, nail caps and the following surgical instruments: drill bits, K-wire, drill guides, drill guide extensions, peg drivers, depth gauge, drill sleeves, obturator, curved bone awl, hex driver, square driver, contact handle, connect handle, forceps, needle nose pliers, periosteal elevator, nail handle, jig assembly (jig foot, handle, set screws and thumb screws), sterilization tray, shoulder caddy assembly, trochars for area of orthopaedic device usage category.

This appendix supersedes certificate FM 531941 dated November 26, 2007.

Originally Registered: **11/11/2002**

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