



Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that: Pioneer Surgical Technology Inc.

375 River Park Circle

Marquette Michigan 49855 USA

Holds Certificate No:

FM 703393

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

The design, development, manufacture and servicing of sterile and non-sterile, biological, non-resorbable and resorbable orthopedic and spinal implants and instruments that include such product families as spinal fusion, spinal arthroplasty, orthopedic retention, fracture fixation and sternal cable systems, including product category Greater Trochanteric Reattachment Device (GTR).

The design, development and manufacture of bone graft substitute utilizing synthetic powders and animal tissue.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

jany C Stade

Original Registration Date: 2003-02-13 Effective Date: 2020-09-22 Latest Revision Date: 2020-09-22 Expiry Date: 2023-09-21

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bsi.



...making excellence a habit."

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Location Registered Activities

Pioneer Surgical Technology Inc. 375 River Park Circle Marquette Michigan 49855 USA The design, development, manufacture and servicing of sterile and non-sterile, biological, non-resorbable and resorbable orthopedic and spinal implants and instuments that include such product families as spinal fusion, spinal arthroplasty, orthopedic retention, fracture fixation and sternal cable systems, including product category Greater Trochanteric Reattachment Device (GTR).

Pioneer Surgical Technology Inc. 1800 A North Greene St. Greenville North Carolina 27834 USA The design, development and manufacture of resorbable spinal and orthopedic bone graft substitutes utilizing synthetic powders and animal tissue materials and of non-resorbable spinal implants containing synthetic powders. The design and development of ancillary instrumentation.



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