By Royal Charter

UKCA Certificate - Full Quality Assurance System

Part II of The Medical Devices Regulations 2002, Annex II excluding Section 4 [as modified by Part 2 of Schedule 2A to The Medical Devices Regulations 2002]

No. **UKCA 778529**

Issued To: **Pioneer Surgical Technology Inc**
375 River Park Circle
Marquette
Michigan
49855
USA

In respect of:

See certificate scope page.

On the basis of our examination of the quality assurance system under the requirements of Part II of the Medical Devices Regulations 2002, Annex II excluding Section 4 [as modified by Part II of Schedule 2A to The Medical Devices Regulations 2002]. The quality assurance system meets the requirements of the regulation. For the placing on the market of class III products an Annex II (modified as described above) Section 4 certificate is required.

For and on behalf of BSI, an Approved Body for the above Regulation (Approved Body Number 0086):

Graeme Tunbridge, Senior Vice President Medical Devices

First Issued: **2022-11-18** Date: **2022-11-18** Expiry Date: **2024-06-18**

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By Royal Charter

Certificate No: UKCA 778529

Certificate Scope:

The design and manufacture and final inspection of;
-sterile Porcine gelatin-based resorbable biological synthetic bone graft substitutes
-sterile Hip fixation implants,
-non-sterile Orthopaedic bone screw and washer implants
-sterile Orthopaedic fixation cerclage wire/cable implant
-sterile and non-sterile Spinal fixation cable implants
-sterile and non-sterile Sternal fixation cable/plate implants
-non-sterile non-cervical Intervertebral spinal fusion implants
-sterile Interbody fusion implants
-sterile Interspinous lumbar decompression spacer implant
-non-sterile instruments intended for connection to an active medical device
-non-sterile single-use instruments.

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Supplementary Information to UKCA 778529

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Number	Device Name	Intended purpose per IFU
Class III		
---	nanoOss Bioactive 3D Bone Void Filler	See UKCA 778539
Class IIb		
61325	Bone-screw internal spinal fixation system	Intervertebral spinal fixation implant system non-cervical indications
61531	Lumbar interspinous spacer	Interspinous Decompression spacer implant for lumbar indications
56642/61670	Orthopaedic bone screw and washer system	Orthopedic Bone Fixation Implant System
34017	Sternal Fixation System	Internal Sternal Fixation Implant
44797/61465	Spinal fixation cable system	Internal spinal cable fixation implant system
61690	Hex Button	Internal Orthopedic Fixation Cerclage wire/cable implant

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Class IIb		
34003	Hip internal fixation system (GTR-Greater Trochanteric reattachment)	Hip Fixation Implant
60847	3D printed PEKK interbody spinal fusion cages	Cervical Interbody Fusion, Lumbar Interbody Fusion, 1 or 2 contiguous levels for Spondylolisthensesis or degenerative disk disease
Class IIa		
MD 0106	Single-use Orthopaedic Instruments	Orthopaedic manual surgical instrument, single use
MD 0106	Reusable Instruments connected to an active device	Orthopaedic surgical instruments connected to active device, reusable, Invasive (transient use)

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UKCA Certificate - Full Quality Assurance System Certificate History

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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
Current	3757093	First Issue, Traceable to CE 52820

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