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✓ Facility

✓ Products Listing

Annual Registration Successful

Facility: Xtant Medical Holdings, Inc., Belgrade, Montana, UNITED STATES

You have successfully updated your registration and listing information for 2025.

Your registration will be valid through Dec 31, 2025.

Be sure to print this page for your records.

The next registration renewal period is October 1 - December 31, 2025.

Registering your facility and listing devices does not, in any way, constitute FDA approval of your facility or devices.

You may contact the FDA with any questions at reglist@cdrh.fda.gov.

The Owner/Operator Number for this Registration is: 10028385.

Facility Information

Registration Number:
3005031160

Initial Importer:
N

Facility Name:
Xtant Medical Holdings, Inc.

Legal Name:
Xtant Medical Holdings, Inc.

Address:
664 Cruiser Lane,
Belgrade, Montana, 59714, UNITED STATES

DUNS Number:

Foreign Trade Zone:
N

Facility URL:
www.xtantmedical.com

Other Business Trade Name(s):

1. Xtant Medical Inc.
2. Xtant Medical
3. X-spine Systems, Inc.
4. Bacterin International, Inc.

Establishment located on a campus:

Owner/Operator Information

Owner/Operator Number:
10028385

Contact Name:

Rebecca Lennemann

Company:
XTANT MEDICAL HOLDINGS, INC.

Address: 664 Cruiser Lane
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DUNS Number:

Official Correspondent Information

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DUNS Number:

Device Listings

Listing Number	Premarket Submission Number	Premarket Submission Type	Product Code(s)	Device Name(s)	Activities
D509306	P110008		NQO	Prosthesis, spinous process spacer/plate	Complaint File Establishment
D216699		510(k) exempt	HXE	FORK	Specification Developer Repackager/Relabeler
D514213	K172139		KWP	APPLIANCE, FIXATION, SPINAL INTERLAMINAL	Manufacturer
			NKG	Posterior cervical screw system	
D514212	K090222		KWQ	Appliance, fixation, spinal intervertebral body	Manufacturer
D216697		510(k) exempt	GAD	RETRACTOR	Specification Developer Repackager/Relabeler
D216698		510(k) exempt	HXP	INSTRUMENT, BENDING OR CONTOURING	Repackager/Relabeler Specification Developer

D216695		510(k) exempt	GFI	OSTEOTOME, MANUAL	Repackager/Relabeler Specification Developer
D216696		510(k) exempt	HTE	ELEVATOR	Repackager/Relabeler Specification Developer
D524826	K111528		KWQ	Appliance, fixation, spinal intervertebral body	Complaint File Establishment
D216693		510(k) exempt	HTQ	BROACH	Repackager/Relabeler Specification Developer
D524827	K130427		KWQ	Appliance, fixation, spinal intervertebral body	Complaint File Establishment
D216694		510(k) exempt	HWA	IMPACTOR	Specification Developer Repackager/Relabeler
D524824	K170830		OVE	Intervertebral fusion device with integrated fixation, cervical	Complaint File Establishment
D524825	K152793		OVE	Intervertebral fusion device with integrated fixation, cervical	Complaint File Establishment
D514211	K221403		NKB	Thoracolumbosacral pedicle screw system	Manufacturer
D514210	K213493		MAX	Intervertebral fusion device with bone graft, lumbar	Manufacturer
			ODP	Intervertebral fusion device with bone graft, cervical	
D524828	K112496		MAX	Intervertebral fusion device with bone graft, lumbar	Manufacturer
			ODP	Intervertebral fusion device with bone graft, cervical	
			MQP	Spinal vertebral body replacement device	
D544550	K241892		NKB	Thoracolumbosacral pedicle screw system	Complaint File Establishment Manufacturer
D524829	K133455		MAX	Intervertebral fusion device with bone graft, lumbar	Complaint File Establishment
			ODP	Intervertebral fusion device with bone graft, cervical	
			MQP	Spinal vertebral body replacement device	
D248732	K150834		KWQ	Appliance, fixation, spinal intervertebral body	Specification Developer

D207732	K131951		OVE	Intervertebral fusion device with integrated fixation, cervical	Specification Developer Repackager/Relabeler
D207733	K123932		MRW	SYSTEM, FACET SCREW SPINAL DEVICE	Repackager/Relabeler Specification Developer
D308311	K170224		KWQ	Appliance, fixation, spinal intervertebral body	Repackager/Relabeler Specification Developer
D207738		510(k) exempt	LXH	Orthopedic manual surgical instrument	Repackager/Relabeler Specification Developer
D308310	K120832		MNH	Orthosis, spondylolisthesis spinal fixation	Specification Developer Repackager/Relabeler
			MNI	Orthosis, spinal pedicle fixation	
D216688		510(k) exempt	GDI	DISSECTOR, SURGICAL, GENERAL & PLASTIC SURGERY	Repackager/Relabeler Specification Developer
D216689		510(k) exempt	HWT	TEMPLATE	Repackager/Relabeler Specification Developer
D216686		510(k) exempt	HTR	RASP	Repackager/Relabeler Specification Developer
D216687		510(k) exempt	HWN	INSTRUMENT, COMPRESSION	Specification Developer Repackager/Relabeler
D216684		510(k) exempt	HXL	MALLET	Specification Developer Repackager/Relabeler
D216685		510(k) exempt	HXC	WRENCH	Repackager/Relabeler Specification Developer
D216683		510(k) exempt	HXB	PROBE	Repackager/Relabeler Specification Developer
D262370	K160114		NQW	ORTHOSIS, SPINE, PLATE, LAMINOPLASTY, METAL	Specification Developer
D216680		510(k) exempt	EMF	KNIFE, SURGICAL	Specification Developer Repackager/Relabeler
D114449	K100154		MRW	SYSTEM, FACET SCREW SPINAL DEVICE	Specification Developer Repackager/Relabeler
D216681		510(k) exempt	HTC	PLIERS, SURGICAL	Repackager/Relabeler Specification Developer

D509310	K201704		PEK	Spinous process plate	Complaint File Establishment
D216679		510(k) exempt	FZX	Guide, surgical, instrument	Specification Developer Repackager/Relabeler
D514236	K211408		KWQ	Appliance, fixation, spinal intervertebral body	Manufacturer
D216677		510(k) exempt	HTF	CURETTE	Specification Developer Repackager/Relabeler
D216678		510(k) exempt	HTJ	GAUGE, DEPTH	Repackager/Relabeler Specification Developer
D216675		510(k) exempt	GFC	DRIVER, SURGICAL, PIN	Repackager/Relabeler Specification Developer
D216676		510(k) exempt	HXG	TAMP	Specification Developer Repackager/Relabeler
D216673		510(k) exempt	LRP	TRAY, SURGICAL	Repackager/Relabeler Specification Developer
D216674		510(k) exempt	KTZ	CALIPER	Specification Developer Repackager/Relabeler
D216671		510(k) exempt	HWB	EXTRACTOR	Specification Developer Repackager/Relabeler
D216672		510(k) exempt	HXW	BENDER	Specification Developer Repackager/Relabeler
D216670		510(k) exempt	HXY	BRACE, DRILL	Repackager/Relabeler Specification Developer
D524840	K082821		KWQ	Appliance, fixation, spinal intervertebral body	Complaint File Establishment
D324119	K170530		KWQ	Appliance, fixation, spinal intervertebral body	Specification Developer Repackager/Relabeler
D216668		510(k) exempt	HWX	TAP, BONE	Specification Developer Repackager/Relabeler
D216669		510(k) exempt	HTW	BIT, DRILL	Specification Developer Repackager/Relabeler

D163629	K122163		KWP	APPLIANCE, FIXATION, SPINAL INTERLAMINAL	Specification Developer Repackager/Relabeler
			MNI	Orthosis, spinal pedicle fixation	
D216666		510(k) exempt	HXX	SCREWDRIVER	Specification Developer Repackager/Relabeler
D216667		510(k) exempt	HWJ	AWL	Specification Developer Repackager/Relabeler
D216664		510(k) exempt	HXD	CLAMP	Specification Developer Repackager/Relabeler
D216665		510(k) exempt	GDF	GUIDE, NEEDLE, SURGICAL	Repackager/Relabeler Specification Developer
D324120	K171567		OVD	Intervertebral fusion device with integrated fixation, lumbar	Specification Developer Repackager/Relabeler
D324121	K140079		OUR	Sacroiliac joint fixation	Specification Developer Repackager/Relabeler
D524837	K101790		NKB	Thoracolumbosacral pedicle screw system	Complaint File Establishment
			KWQ	Appliance, fixation, spinal intervertebral body	
			KWP	APPLIANCE, FIXATION, SPINAL INTERLAMINAL	
			MNH	Orthosis, spondylolisthesis spinal fixation	
			MNI	Orthosis, spinal pedicle fixation	
D324122	K152132		MNH	Orthosis, spondylolisthesis spinal fixation	Repackager/Relabeler Specification Developer
			MNI	Orthosis, spinal pedicle fixation	
D524838	K072703		KWQ	Appliance, fixation, spinal intervertebral body	Complaint File Establishment
D324123	K173832		ODP	Intervertebral fusion device with bone graft, cervical	Specification Developer
D248749		510(k) exempt	HTD	FORCEPS	Repackager/Relabeler Specification Developer

D524835	K093692		NKB	Thoracolumbosacral pedicle screw system	Complaint File Establishment
			KWQ	Appliance, fixation, spinal intervertebral body	
			MNH	Orthosis, spondylolisthesis spinal fixation	
			MNI	Orthosis, spinal pedicle fixation	
D524836	K093771		MNH	Orthosis, spondylolisthesis spinal fixation	Complaint File Establishment
			MNI	Orthosis, spinal pedicle fixation	
D524839	K081132		KWQ	Appliance, fixation, spinal intervertebral body	Complaint File Establishment
D524830	K131724		MQP	Spinal vertebral body replacement device	Complaint File Establishment
D524833	K070973		NKB	Thoracolumbosacral pedicle screw system	Complaint File Establishment
			KWQ	Appliance, fixation, spinal intervertebral body	
			KWP	APPLIANCE, FIXATION, SPINAL INTERLAMINAL	
			MNH	Orthosis, spondylolisthesis spinal fixation	
			MNI	Orthosis, spinal pedicle fixation	
D524834	K080518		KWQ	Appliance, fixation, spinal intervertebral body	Complaint File Establishment
			NKB	Thoracolumbosacral pedicle screw system	
			KWP	APPLIANCE, FIXATION, SPINAL INTERLAMINAL	
			MNH	Orthosis, spondylolisthesis spinal fixation	
			MNI	Orthosis, spinal pedicle fixation	
D524831	K041167		NKB	Thoracolumbosacral pedicle screw system	Complaint File Establishment
			KWP	APPLIANCE, FIXATION, SPINAL INTERLAMINAL	
			MNH	Orthosis, spondylolisthesis spinal fixation	
			MNI	Orthosis, spinal pedicle fixation	

D524832	K070551		NKB	Thoracolumbosacral pedicle screw system	Complaint File Establishment
			KWP	APPLIANCE, FIXATION, SPINAL INTERLAMINAL	
			MNH	Orthosis, spondylolisthesis spinal fixation	
			MNI	Orthosis, spinal pedicle fixation	
D191540	K123702		OUR	Sacroiliac joint fixation	Specification Developer Repackager/Relabeler
D235751		510(k) exempt	HTZ	INSTRUMENT, CUTTING, ORTHOPEDIC	Repackager/Relabeler Specification Developer
D247863		510(k) exempt	MJG	Device, percutaneous, biopsy	Repackager/Relabeler Specification Developer
D514209	K071849		MQV	FILLER, BONE VOID, CALCIUM COMPOUND	Repackager/Relabeler
			MBP	Filler, bone void, osteoinduction (w/o human growth factor)	
D248021		510(k) exempt	HTX	RONGEUR	Repackager/Relabeler Specification Developer
D248023		510(k) exempt	GDZ	HANDLE, SCALPEL	Repackager/Relabeler Specification Developer
D088335	K090224		MNH	Orthosis, spondylolisthesis spinal fixation	Specification Developer Repackager/Relabeler
			MNI	Orthosis, spinal pedicle fixation	
D088336	K083637		ODP	Intervertebral fusion device with bone graft, cervical	Specification Developer Repackager/Relabeler
			MQP	Spinal vertebral body replacement device	
D070116	K072943		KWQ	Appliance, fixation, spinal intervertebral body	Repackager/Relabeler Specification Developer
D070115	K052292		KWQ	Appliance, fixation, spinal intervertebral body	Specification Developer Repackager/Relabeler
D239745	K133947		OVD	Intervertebral fusion device with integrated fixation, lumbar	Repackager/Relabeler Specification Developer

D210970	K130438		PEK	Spinous process plate	Repackager/Relabeler Specification Developer
D529512	K183060		KWQ	Appliance, fixation, spinal intervertebral body	Manufacturer
D139093	K112592		KWP	APPLIANCE, FIXATION, SPINAL INTERLAMINAL	Repackager/Relabeler Specification Developer
D139094	K112036		ODP	Intervertebral fusion device with bone graft, cervical	Repackager/Relabeler Specification Developer
			MQP	Spinal vertebral body replacement device	
D529517	K161498		KWP	APPLIANCE, FIXATION, SPINAL INTERLAMINAL	Manufacturer
			NKG	Posterior cervical screw system	
D529513	K130286		NKB	Thoracolumbosacral pedicle screw system	Manufacturer
			MNH	Orthosis, spondylolisthesis spinal fixation	
			MNI	Orthosis, spinal pedicle fixation	
D529514	K192396		NKB	Thoracolumbosacral pedicle screw system	Manufacturer
D529515	K133374		KWP	APPLIANCE, FIXATION, SPINAL INTERLAMINAL	Manufacturer
D529516	K150254		KWP	APPLIANCE, FIXATION, SPINAL INTERLAMINAL	Manufacturer
D207808		510(k) exempt	HWE	INSTRUMENT, SURGICAL, ORTHOPEDIC, AC-POWERED MOTOR AND ACCESSORY/ATTACHMENT	Specification Developer Repackager/Relabeler
D308308	K133094		KWP	APPLIANCE, FIXATION, SPINAL INTERLAMINAL	Specification Developer Repackager/Relabeler
D308309	K160428		KWP	APPLIANCE, FIXATION, SPINAL INTERLAMINAL	Specification Developer Repackager/Relabeler
			NKG	Posterior cervical screw system	
D308304	K171075		ODP	Intervertebral fusion device with bone graft, cervical	Specification Developer Repackager/Relabeler
D308303	K131350		MAX	Intervertebral fusion device with bone graft, lumbar	Repackager/Relabeler Specification Developer

D308305	K170119		MAX	Intervertebral fusion device with bone graft, lumbar	Repackager/Relabeler Specification Developer
D114450	K101471		KWP	APPLIANCE, FIXATION, SPINAL INTERLAMINAL	Repackager/Relabeler Specification Developer
D339015	K150621		MQV	FILLER, BONE VOID, CALCIUM COMPOUND	Manufacturer
			MBP	Filler, bone void, osteoinduction (w/o human growth factor)	
D339016	K130498		MQV	FILLER, BONE VOID, CALCIUM COMPOUND	Manufacturer
			MBP	Filler, bone void, osteoinduction (w/o human growth factor)	
D529521	K073177		MAX	Intervertebral fusion device with bone graft, lumbar	Complaint File Establishment
			ODP	Intervertebral fusion device with bone graft, cervical	
D339017	K091321		MQV	FILLER, BONE VOID, CALCIUM COMPOUND	Manufacturer
			MBP	Filler, bone void, osteoinduction (w/o human growth factor)	
D529522	K150521		MAX	Intervertebral fusion device with bone graft, lumbar	Complaint File Establishment
			ODP	Intervertebral fusion device with bone graft, cervical	
			MQP	Spinal vertebral body replacement device	
D529523	K170643		MAX	Intervertebral fusion device with bone graft, lumbar	Complaint File Establishment
			ODP	Intervertebral fusion device with bone graft, cervical	
			MQP	Spinal vertebral body replacement device	
D308411	K162944		OVE	Intervertebral fusion device with integrated fixation, cervical	Repackager/Relabeler Specification Developer
D529528	K133623		MAX	Intervertebral fusion device with bone graft, lumbar	Complaint File Establishment
			ODP	Intervertebral fusion device with bone graft, cervical	
			MQP	Spinal vertebral body replacement device	

D529524	K120724		KWQ	Appliance, fixation, spinal intervertebral body	Complaint File Establishment
D529525	K043066		KWQ	Appliance, fixation, spinal intervertebral body	Complaint File Establishment
D529526	K053053		KWQ	Appliance, fixation, spinal intervertebral body	Complaint File Establishment
D529527	K083663		KWQ	Appliance, fixation, spinal intervertebral body	Complaint File Establishment

Date of Initial Registration: 2009-01-26 12:53:10.0
