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✓ Facility

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Annual Registration Successful

Facility: ORTHO MEDICAL GMBH IMPLANTS, DUERBHEIM, Baden-Wurttemberg, GERMANY

You have successfully updated your registration and listing information for 2024.

Your registration will be valid through Dec 31, 2024.

Be sure to print this page for your records.

The next registration renewal period is October 1 - December 31, 2024.

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: 9041960.

Facility Information

Registration Number:

9617257

Initial Importer:

N

Facility Name:

ORTHO MEDICAL GMBH IMPLANTS

Legal Name:**Address:**HAUPTSTR.5,
DUERBHEIM, Baden-Wurttemberg, 78589, GERMANY**DUNS Number:****Foreign Trade Zone:**

N

Facility URL:**Other Business Trade Name(s):****Establishment located on a campus:**

Owner/Operator Information

Owner/Operator Number:

9041960

Contact Name:

MONIKA - KAPP

Company:

ORTHO MEDICAL GMBH IMPLANTS

Address:HAUPTSTR.5, --
DUERBHEIM, 78589, GERMANY**Telephone:**

074 - 24 - 940340

Fax:

-

E-mail:

MONIKA@KAPP-GERMANY.DE

DUNS Number:

Official Correspondent Information

Contact Name:
MONIKA - KAPP

Company:
ORTHO MEDICAL GMBH IMPLANTS

Address: **HAUPTSTR.5, --
 DUERBHEIM, 78589, GERMANY**

Telephone:
074 - 24 - 940340

Fax:
 -

E-mail: **MONIKA@KAPP-GERMANY.DE**

DUNS Number:

United States Agent Information

Contact First Name
Franz

Contact Last Name
Menean

Contact Title:
Mr

Business Name:
MEDAGENT, Inc.

Address: **264 Lafayette Road, Suite 7
 Portsmouth, New Hampshire, 03801, UNITED STATES**

Phone:
603 - 5702039

Fax:
603 -5702055

DUNS Number:

E-mail: **mail@medagent-usa.com**

Device Listings

Listing Number	Premarket Submission Number	Premarket Submission Type	Product Code(s)	Device Name(s)	Activities	Importers
D299701		510(k) exempt	HWT	TEMPLATE	Contract Manufacturer	GSOURCE, LLC.
D269490		510(k) exempt	HXK	HOLDER, NEEDLE; ORTHOPEDIC	Contract Manufacturer	GSOURCE, LLC.
D269491		510(k) exempt	HXL	MALLET	Contract Manufacturer	GSOURCE, LLC.
D264673		510(k) exempt	HNF	SCISSORS, OPHTHALMIC	Contract Manufacturer	GSOURCE, LLC.
D264674		510(k) exempt	HTD	FORCEPS	Contract Manufacturer	GSOURCE, LLC.
D264666		510(k) exempt	FFQ	SPECULUM, RECTAL	Contract Manufacturer	GSOURCE, LLC.
D264669		510(k) exempt	KBD	SCISSORS, NASAL	Contract Manufacturer	GSOURCE, LLC.

D263871	510(k) exempt	FFO	RETRACTOR, SELF- RETAINING	Contract Manufacturer	GSOURCE, LLC.
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D290196	510(k) exempt	HWA	IMPACTOR	Contract Manufacturer	GSOURCE, LLC.
D267149	510(k) exempt	EMJ	ELEVATOR, SURGICAL, DENTAL	Contract Manufacturer	GSOURCE, LLC.
D267148	510(k) exempt	EIG	RETRACTOR, ALL TYPES	Contract Manufacturer	GSOURCE, LLC.
D267150	510(k) exempt	EMK	CURETTE, SURGICAL, DENTAL	Contract Manufacturer	GSOURCE, LLC.
D402995	510(k) exempt	GEA	CANNULA, SURGICAL, GENERAL & PLASTIC SURGERY	Contract Manufacturer	GSOURCE, LLC.
D267159	510(k) exempt	JYL	HOOK, MICROSURGICAL EAR	Contract Manufacturer	GSOURCE, LLC.
D267156	510(k) exempt	GFJ	MALLET, SURGICAL, GENERAL & PLASTIC SURGERY	Contract Manufacturer	GSOURCE, LLC.
D267155	510(k) exempt	GFI	OSTEOTOME, MANUAL	Contract Manufacturer	GSOURCE, LLC.
D267158	510(k) exempt	JEX	PLIER, ORTHODONTIC	Contract Manufacturer	GSOURCE, LLC.
D267157	510(k) exempt	HTF	CURETTE	Contract Manufacturer	GSOURCE, LLC.
D267152	510(k) exempt	GDG	HOOK, SURGICAL, GENERAL & PLASTIC SURGERY	Contract Manufacturer	GSOURCE, LLC.
D267151	510(k) exempt	EMM	CHISEL, OSTEOTOME, SURGICAL	Contract Manufacturer	GSOURCE, LLC.
D267154	510(k) exempt	GDO	Applier, surgical, clip	Contract Manufacturer	GSOURCE, LLC.
D267153	510(k) exempt	GDH	GOUGE, SURGICAL, GENERAL & PLASTIC SURGERY	Contract Manufacturer	GSOURCE, LLC.
D267160	510(k) exempt	MDM	INSTRUMENT, MANUAL, SURGICAL, GENERAL USE	Contract Manufacturer	GSOURCE, LLC.
B118787	510(k) exempt	HTW	BIT, DRILL	Contract Manufacturer	GSOURCE, LLC.
B118788	510(k) exempt	LXH	Orthopedic manual surgical instrument	Contract Manufacturer	GSOURCE, LLC.
B118786	510(k) exempt	HTJ	GAUGE, DEPTH	Contract Manufacturer	GSOURCE, LLC.
B118793	510(k) exempt	FSM	TRAY, SURGICAL, INSTRUMENT	Contract Manufacturer	GSOURCE, LLC.
B118791	510(k) exempt	KBB	RONGEUR, NASAL	Contract Manufacturer	GSOURCE, LLC.
B118774	510(k) exempt	LRW	SCISSORS, GENERAL, SURGICAL	Contract Manufacturer	GSOURCE, LLC.
B118775	510(k) exempt	HXZ	CUTTER, WIRE	Contract Manufacturer	GSOURCE, LLC.

B118783	510(k) exempt	GEG	ELEVATOR, SURGICAL, GENERAL & PLASTIC SURGERY	Contract Manufacturer	GSOURCE, LLC.
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B118781		510(k) exempt	HXX	SCREWDRIVER	Contract Manufacturer	GSOURCE, LLC.
B118782		510(k) exempt	HTX	RONGEUR	Contract Manufacturer	GSOURCE, LLC.
B118769		510(k) exempt	GDJ	CLAMP, SURGICAL, GENERAL & PLASTIC SURGERY	Contract Manufacturer	GSOURCE, LLC.
B118768		510(k) exempt	GEN	FORCEPS, GENERAL & PLASTIC SURGERY	Contract Manufacturer	GSOURCE, LLC.
B118772		510(k) exempt	FHQ	HOLDER, NEEDLE, GASTROENTEROLOGIC	Contract Manufacturer	GSOURCE, LLC.
B118770		510(k) exempt	GAF	SPATULA, SURGICAL, GENERAL & PLASTIC SURGERY	Contract Manufacturer	GSOURCE, LLC.
B118771		510(k) exempt	GAD	RETRACTOR	Contract Manufacturer	GSOURCE, LLC.

Date of Initial Registration: 2000-06-22 15:49:57.0