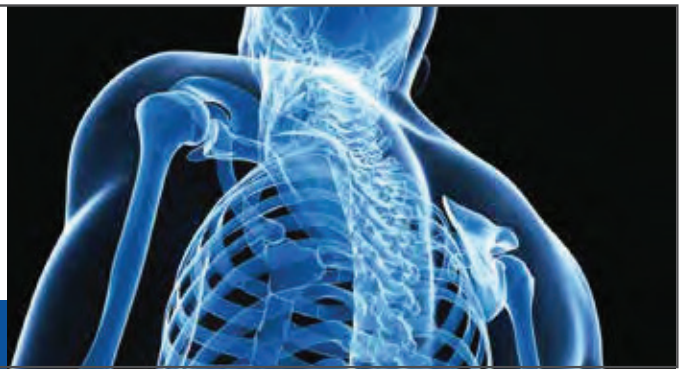
# orthopedic device



Medpace is dedicated to helping our medical device clients bring products to market safely, effectively and efficiently. Our experience spans:

- Pre-market, post-approval and post-market studies
- National, regional and global device trials
- Single-center, first-in-human, and feasibility trials to multi-center, full-service pivotal trials as well as large-scale, post-market outcomes studies

## Global Advantage

- Device offices in U.S. and Europe
- European authorized representative services
- Geographically diverse and multilingual employees understand local cultural environment and regulatory pathway

For more information about our medical device experience and services, visit our website at www.medpace.com/device, email us at info.mmd@medpace.com or contact us at one of our medical device offices below.

**Medpace Medical Device (Global HQ)**
3787 95th Avenue NE, Suite 100
Minneapolis, Minnesota 55014 USA
Tel: +1 612 234 8500
Fax: +1 612 234 8501

**Medpace Medical Device B.V.**
Il Fiore building B, 3rd Floor
Avenue Ceramique 227
6221 KX Maastricht, The Netherlands
Tel: +31 43 306 3320

## Experienced Orthopedic Device Development

Medpace has significant experience managing global studies for orthopedic device development, particularly early stage devices. Our orthopedic studies range from one site with 10 subjects to 20 sites involving 500 subjects.

Our orthopedic experience includes various devices to treat:

- Degenerative disc disease
- Spinal Stenosis
- Fracture fixation/bone stabilization
- Joint/back pain
- Rotator cuff repair
- Wrist arthroplasty

### Integrated Services to Maximize Efficiencies

To ensure seamless logistics, review and testing, Medpace provides global, integrated imaging and central laboratory services.

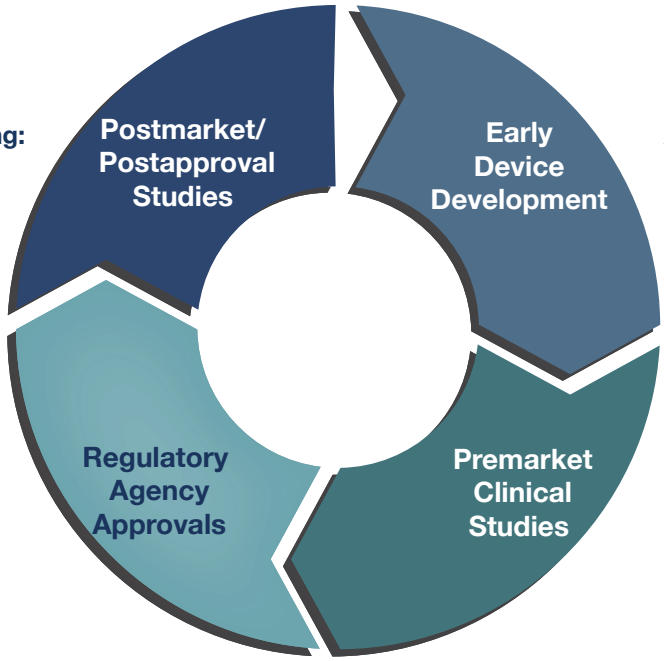
MEDPACE

## Medical Device Services

Medpace provides pre-market, post-approval and post-market device trial management, including regulatory development, planning and submission support.

**Full Service Clinical Trial offering:**

- Clinical Operations
- Study Start-up
- Regulatory Submissions
- Data Management
- Biostatistics
- Safety/CEC/DSMB
- Medical Writing & Regulatory Affairs
- Quality Assurance




**Additional services offered:**

- Regulatory Strategy including:
  - Device classification
  - Notified body discussions
  - Pre-submission FDA meetings
- Clinical evaluation reports, Clinical literature review (EU)
- Technical files & design dossiers
- EU authorized representative services

## Comprehensive Clinical Services

Clinical strategy development

Trial design including:

- Protocol
- Patient Consent
- Patient Information
- Investigator Brochure
- CRF
- Statistical

Trial management

- Clinical team management
- IRB/Ethics Committee submission
- Competent authority submission/notification
- Metrics and reporting
- CEC/DSMB management
- Episode adjudication

Site selection and qualification

Monitoring

- Site initiation
- Close out services

Data management

- Database development
- Data review and query management

Safety and risk management

- Safety and vigilance reporting
- Event management

Study report preparation

- Medical writing
- Data analysis

Device distribution services