MEDCER

spineserv GmbH & Co. KG

Consultancy for U.S. Legal Requirements

www.medcer.com.tr | info@medcer.com.tr

www.spineserv.com | experts@spineserv.de

Who We Are?

MEDCER

MEDCER is founded in 2015 by Mehmet Fatih Örmeci. MEDCER is accredited on ISO 13485 as a certification body from 2016 to 2020. MEDCER continues to activities on ISO 13485:2016 certification as 3rd party certification body together with partners. In addition to this, MEDCER provide supplier audits and internal audits according to ISO 13486, 2017/MDR and 21 CFR 820 for their clients.

MEDCER also provides consultancy services to clients for technical documentation on legal requirements and quality management systems. These covers design dossier and technical file preparation for EU legal requirements and 510(k) submission file preparation for US legal requirements.

MEDCER also supporting medical device industry for post market surveillance activities and clinical evaluation consultancy.

spineserv GmbH & Co. KG

SpineServ is a spin-off company of the research group of Prof. Dr. Hans-Joachim Wilke (Institute of Orthopaedic Research, University of Ulm, www.biomechanics.de). It was founded in 2007 and is specialized in providing a broad variety of mechanical testing services for medical devices.For this purpose SpineServ is accredited according to DIN EN ISO/IEC 17025:2018.

Spinal implants, osteosynthesis implants, endoprostheses and dental implants, surgical instruments, implant materials and biomaterials undergo static testing, dynamic fatigue testing, wear testing or corrosion testing either according to standards (ASTM, ISO) or following custom testing procedures.

Due to our expertise in biomechancis, medicine and biology we also offer our know-how to answer questions regarding the mechanical safety and effectiviness of medical devices through scientific consulting, expert opinion and literature reviews.

Contact - Our Location in Turkey and Germany

Turkey

MEDCER ULUSLARARASI MEDİKAL BELGELENDİRME A.Ş.

M. Fatih Örmeci

Phone : +90 312 436 08 44

info@medcer.com.tr / www.medcer.com.tr

Germany

SpineServ GmbH & Co. KG

Phone: +49 (0)731 1756788

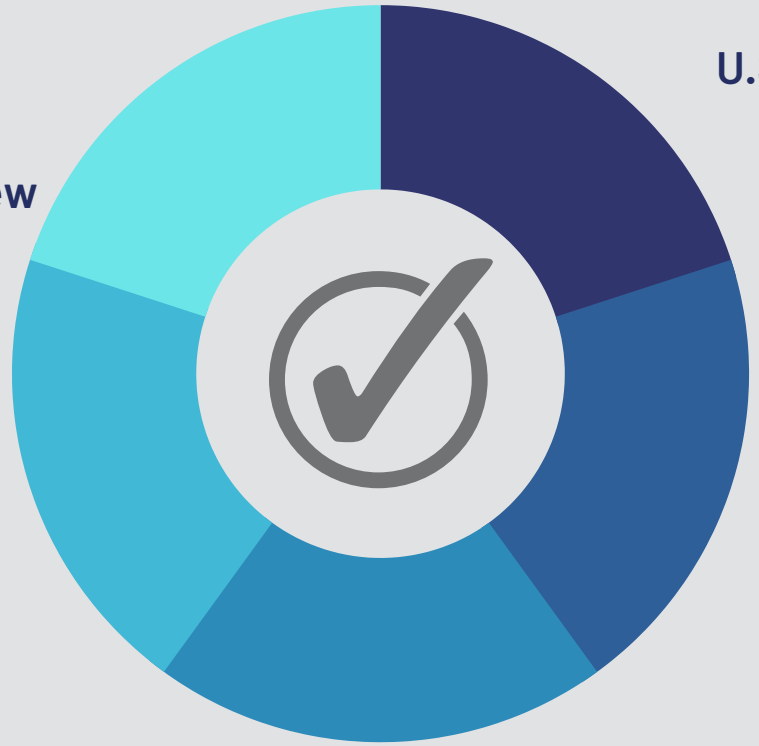
experts@spineserv.de / www.spineserv.com

MEDCER

U.S. Regulation
Our Services

GAP Analysis
–
510k Submission File Review

U.S. Agent Service



On-Site Mock-Up Audit

Product Registration
and Device Listing

510(k) Submission
File Preparation

FDA registrations are required for medical devices to be sold to the US market. The FDA classifies medical devices as class I, class II, and class III. This classification has sub-categories within itself.

Direct registration can be performed for Class I (exempt) products without any conformity assessment.

Products that are not class I exempt are subject to a conformity assessment program called class II products and some class III 510 (k). For this, 510 (k) file is prepared to be submitted to the FDA.

510 (K) processes are performed according to the schedule below. Companies approved for 510 (k) compliance continue with the FDA registration process and after the completion of the FDA registration process, product sales to the USA become possible.

Why FDA registration is important?

MEDCER

FDA Registration Process

By Day 1:

FDA receives 510(k) application

By Day 7

FDA sends Acknowledgement Letter
Or
FDA sends Hold Letter if unresolved issues with User Fee and/or eCopy

By Day 15

FDA conducts Acceptance Review
FDA informs applicant if 510(k) is accepted for Substantive Review
Or
Placed on RTA Hold

By Day 60

FDA conducts Substantive Review (usually by day 60)
FDA communicates Substantive Interaction with applicant that İndicates FDA will proceed with Interactive Review or ask for Additional Information.

By Day 90

FDA sends final MDUFA Decision on 510(k) (usually by day 90)

By Day 100

If MDUFA Decision is not reached by Day 100 provides Missed MDUFA Decision Communication that identifies outstanding review issues.

GAP Analysis – 510(k) Submission File Review

Are you unable to identify your deficiencies in your 510(k) Submission File?

- We are reviewing your 510(k) application file.
- In order for you to succeed in the RTA stage we identify the shortcomings in your file.

MEDCER

On-Site Mock-Up Audit

Being a new company that has yet to be audited, operating under new or revised regulations/standards, having an upcoming certification audit, or expecting an FDA or other regulatory inspections are some of the reasons auditees look to perform mock audits.

Our auditors bring their experiences in these types of audits to role-play or simulate that experience for you and your team. We will work with you to plan a mock audit which may be announced or unannounced to your staff and will focus on your particular areas of concern.

MEDCER

MEDCER

We can prepare your 510(k) Submission File With Our Expert Team

File compilation and FDA 510(k) submission
When all required documents and information have been received, we will prepare your final 510(k) submission.

We will:

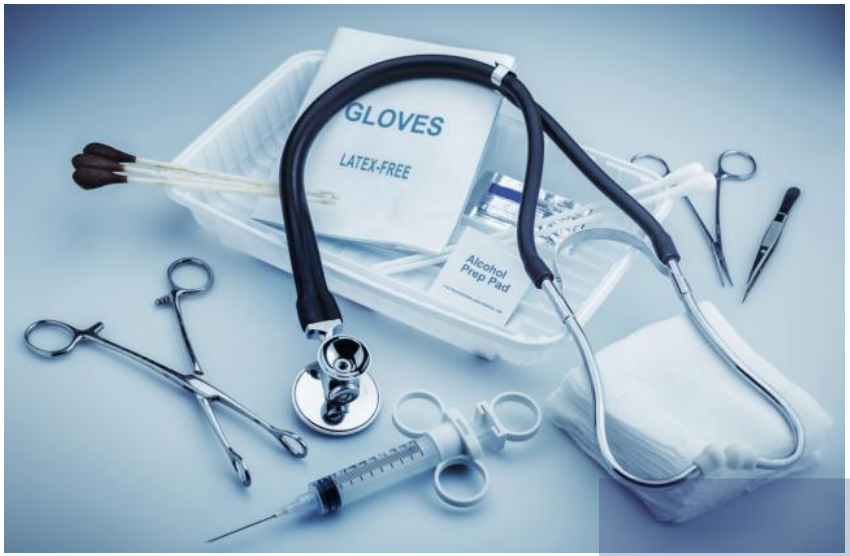
- Prepare a technical comparison of your medical device to the predicate device(s).
- Prepare all 21 sections of the FDA 510(k) application.
- Submit the hard copy and eCopy of the 510(k) to the CDRH division within the FDA and be the correspondent for further communications with the FDA.
- Coordinate payment of FDA 510(k) submission fees on your behalf.
- Immediately communicate with you regarding all information received from the FDA following the 510(k) submission, and assist in addressing their requests for additional information, if applicable.

Learn more about what happens after 510(k) regulatory clearance.

We want you to be successful introducing your device to the US market. As an FDA consulting firm for medical devices, we have successfully prepared and submitted FDA 510(k) submissions for medical device companies seeking to sell in the United States.

Contact Us

www.medcer.com.tr | info@medcer.com.tr



Product Registration and Device Listing

For assistance with registration and listing, contact one of our experienced consultants today.

Establishments engaged in the manufacturing or other activities of medical devices to be marketed in the US need to register the facility, list the devices and name an agent for communication purposes. Most establishments that are required to register with the FDA are also required to list the devices that are made there and the activities that are performed on those devices.

MEDCER

Contact Us

www.medcer.com.tr | info@medcer.com.tr

U.S. Agent Service

Do you know that to be able to enjoy the privileges of marketing and distributing regulated products in U.S., every foreign establishment must designate a U.S. Agent?

We designate your U.S Agent for you.

MEDCER

Contact Us

www.medcer.com.tr | info@medcer.com.tr