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for the Medical Device industry

FDA Accredited Persons Third-Party 510(k) Review Program

TÜV SÜD America, an EU Notified Body subsidiary, has participated in the FDA's 510(k) Third-Party Review Program since its inception in 1996. Under this program TÜV SÜD America is permitted to review 510(k) applications on behalf of FDA for all eligible class I and class II devices.

The term 510(k) originates from section 510(k) of the Federal Food, Drug, and Cosmetic Act. Also known as a premarket notification, a 510(k) submission allows the U.S. Food and Drug Administration (FDA) to determine whether a device is "substantially equivalent" to a device already legally marketed in the United States. Medical Device manufacturers are required to submit a 510(k) if they intend to introduce a device into commercial distribution in the U.S., or if they reintroduce a device that has been substantially changed or modified.

At present, the eligible devices under the FDA 510(k) Accredited Persons Program account for more than 60% of all 510(k) submissions.

Submitters may only request information from the FDA on the status of their 510(k) review 90 days after its initial date of submission to the FDA. The Accredited Persons Program requires the FDA to respond to third-party reviewed files within 30 days.

TÜV SÜD America's staff of reviewers will stay in contact with both manufacturers and the FDA throughout the review process. This can often accelerate the review process and improve your product's time to market.

If your device is eligible for the Accredited Persons Third-Party 510(k) Review Program, and your organization is seeking rapid market entry, then you should consider the knowledge and experience of TÜV SÜD America.

For a list of eligible devices, links to guidance documents, and information about the 510(k) process, visit our website at: **www.tuvamerica.com/FDA**

Additional medical services

Auditing

- ISO 13485
- MDD (Annex II, V and VI)
- AIMD (Annex 2, 5 and 6)
- IVDD (Annex IV and X)
- CMDCAS (Health Canada)
- JPAL (JGMP)
- Taiwan GMP

Testing

- CB Scheme (EC 60601, EC 61010)
- NRTL (UL 60601)
- SCC (CSA C22.2.601)
- EMC testing according to EU standards and for FDA, FCC, IEC 60601-1-2
- CE marking
- MDD (Annex III)
- AIMD (Annex 3)
- IVD (Annex IV and X)
- GOST-R certification

File review

- Clinical assessment of Medical Devices or of safety and efficiency/usability
- MDD (Annex II.4), and Design Dossier reviews
- FDA 510(k)
- Technical file review
- AUS-EC MRA certification

Your contact partner at TÜV SÜD Product Service can provide further information.

Georg Bauer
Phone: +49 89 5008-4143
Email: Georg.Bauer@tuev-sued.de

Dawn Tibodeau
Phone: +1 651 638-0288
Email: dtibodeau@tuvam.com