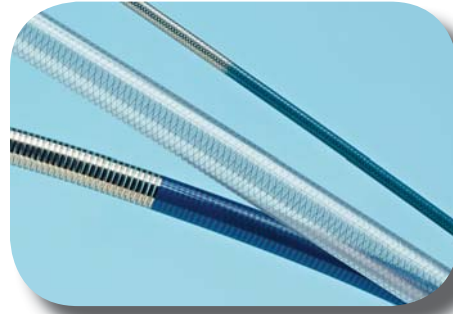




GLOBAL REGULATORY SERVICES

Strategy Development | Sustaining Product Support | Submission Preparation



TELEFLEX MEDICAL OEM CAN HELP YOU ACHIEVE SUCCESS IN TODAY'S CHALLENGING REGULATORY ENVIRONMENT

REGULATORY SERVICES TAILORED TO YOUR NEEDS

- Get the Teleflex Medical OEM advantage: our proven experience in the licensing and registration of medical products.
- Depending on the product, target market, and requirements profile, we can help bring your product to market.
- Our regulatory services are conducted according to international standards.

EXPERT TEAM OF REGULATORY SPECIALISTS

- Regulatory experts on staff monitor the constantly changing national and international regulatory environments.
- We can provide expertise in the overall planning and execution of regulatory compliance through all phases of the product life cycle.
- Teleflex Medical OEM has an extensive record of successful approvals with major regulatory agencies across the world.

COMPREHENSIVE REGULATORY STRATEGY DEVELOPMENT

- The development of a regulatory strategy will include the assessment of regulatory approval options, approaches, and risks based on specific assumptions regarding the product and regulatory environment. In addition, the strategy will provide detailed information about regulatory requirements, schedules, and fees.
- Our regulatory team will keep a watchful eye on maintaining full compliance with national and international regulations and standards.
- We can provide sustaining support and regulatory assessment for impact of a product change.

SUBMISSION SUPPORT AND APPROVALS

- We offer full-service regulatory support from submission to clearance and routine sustaining product support, which includes medical device registration, and certifications and/or approvals.
- Your choice: Teleflex Medical OEM can prepare sections or the complete application for traditional devices and systems.
- Our regulatory team can maintain regulatory coverage, as required, for product life cycle management.
- Teleflex Medical OEM's portfolio of services includes:
 - 510(k) submission for FDA clearance
 - STED – Summary Technical Document Preparation
 - EU Technical File for CE Marking Approval
 - Canada Medical Device License Approval and Registration
 - International Device Approvals, Licensing and Registration



DATA PREPARATION AND PRESENTATION

- As your regulatory partner, we will prepare and submit a review package that is well researched, focused and will present your product as clearly and effectively as possible to the regulatory agency.
- Teleflex Medical OEM can provide documentation to support:
 - Product master files
 - Declarations of Conformance to Standards
 - Safety sheets or certificates of analysis
 - Technical and regulatory information

DOCUMENTATION FOR LABELING AND PROMOTION CLAIMS

- Our regulatory team also provides labeling review and support for claims in collateral and literature.

WE ARE READY TO TAKE YOUR PROJECT FROM CONCEPT TO COMPLETION

Teleflex Medical OEM is a single source provider of the design, development, and production services you need to take your project from concept to completion. We offer you a unique, customer-focused combination of expertise, decades of experience, advanced facilities, in-house capabilities, and dedication to service. That is why Teleflex Medical OEM can take on challenges few other suppliers can. And why we should be your “go to” partner for your next project.

CONCEPT DEVELOPMENT AND DESIGN

Teleflex Medical OEM has designed and engineered hundreds of medical products ranging from surgical instruments to complex catheters. As a result, we have some of the industry’s most experienced medical product design and manufacturing engineers on staff. We will brainstorm multiple concepts, and then narrow them down. Our engineering team can even suggest novel approaches based on years of manufacturing medical products.

ENGINEERING SUPPORT

Our engineering staff knows the manufacturing of medical products inside and out. They will team with you to refine the design and material choice for cost-effective manufacturability and resolve any production issues that could arise.

PROTOTYPING

Efficient product realization depends on prototypes of outstanding quality. That is why Teleflex Medical OEM has well-equipped prototype development facilities. This capability allows us to effectively support your project, and trims time from the project’s development schedule.

MANUFACTURING, ASSEMBLY, AND PACKAGING

Are you ready to ramp up for production? We can do that too. Using advanced technology and processes, our highly-skilled and knowledgeable personnel will implement production of your project at one of our state-of-the-art facilities. Teleflex Medical OEM has the essential product development and production capabilities that translate into quality products and efficient turnaround.

REGULATORY SERVICES

Let us help with the details. Since your project will be backed up by a multi-disciplinary team of design engineers, production technicians, and regulatory specialists, we can offer assistance with your regulatory submissions and provide the necessary documentation.

Teleflex Medical OEM is a market leader in providing design, development, and production services to medical device manufacturers across the world. We set ourselves apart with deep expertise, decades of experience, and integrated, concept-to-completion capabilities, which include:

- Product concept and design specifications
- Regulatory affairs
- Materials selection
- Rapid prototyping
- Testing and validation
- Custom tooling
- Manufacturing
- Secondary processing
- Assembly and packaging

You can count on Teleflex Medical OEM to deliver industry-leading innovations and next-generation solutions for precision extrusions, high-performance interventional catheters, sutures, performance fibers, bioresorbable resins and yarns, and custom medical devices. For detailed information, see www.teleflexmedialoem.com

Teleflex Incorporated is a leading global provider of specialty medical devices used for diagnostic and therapeutic procedures in critical care and surgery. Our mission is to provide solutions that enable healthcare providers to improve outcomes and enhance patient and provider safety. We specialize in devices for general and regional anesthesia, cardiac care, respiratory care, urology, vascular access and surgery and we serve healthcare providers in more than 130 countries. For detailed information, see www.teleflex.com

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