

Teleflex is a global company specializing in products and services for vascular access, respiratory, general and regional anesthesia, cardiac care, urology, and surgery.

Teleflex Medical OEM provides product development, outsourcing, and regulatory services to original equipment manufacturers across the world. The business has extensive, in-house capabilities which include the design, engineering, prototyping, manufacturing, assembly, and packaging of extrusion, catheters, performance fibers, sutures, surgical instruments, and other specialty products.

The Teleflex Medical OEM family of brands includes BEERE MEDICAL®, KMEDIC®, SMD®, DEKNATEL®, and TFX OEM®.

Teleflex Incorporated (NYSE:TFX) has annual revenues of approximately \$1.9 billion and serves healthcare providers in 140 countries.

For detailed information, see www.teleflex.com

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IMAGINE IT. ACHIEVE IT.®

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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.

LET'S GET STARTED

- To discuss how Teleflex Medical OEM can help you achieve your regulatory objectives, contact your sales representative today.

WE ARE YOUR SINGLE SOURCE SOLUTION FOR PRODUCT DEVELOPMENT AND OUTSOURCING SERVICES

Teleflex Medical OEM transforms ideas into market-ready products. We design and deliver specialized instruments and devices that touch nearly every organ and system in the human body. As your product development partner, we will use our extensive in-house capabilities and years of experience to take your latest innovation from concept to completion.

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.

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