

# A&M BioMedical

## CAPABILITY GUIDE

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Your Trusted Medical Device  
Manufacturing Partner

ISO 13485 Certified • FDA Registered • 30+ Years Experience

Laguna Hills, California

# About A&M BioMedical

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A&M BioMedical is a women-owned contract medical device manufacturer with over 30 years of experience in precision manual and electro-mechanical assembly. Based in Orange County's established medical device manufacturing hub, we partner with companies from prototype through full-scale production — maintaining the quality standards your products demand.

Our core philosophy is simple: **do it right the first time**. We treat every device as if our name is on it, because in a real sense, it is. Our clients trust us to manufacture products that improve and save lives, and we take that responsibility seriously.

**30+**

Years in  
Business

**>98%**

First-Pass  
Yield Rate

**0**

FDA 483/Major Audit  
Findings

## Manufacturing Capabilities

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### Manufacturing & Assembly

- Precision manual assembly for complex medical devices
- Electro-mechanical assembly and integration
- Cleanroom assembly (Class 7 / ISO 14644 Class 10,000)
- Non-cleanroom assembly environments
- Process development, validation, and documentation

### Production Services

- Prototype and R&D builds
- Pilot production runs
- High-volume manufacturing (150 to 150,000+ units/month)
- Scalable production lines that grow with your needs
- Inventory management
- Packaging, labeling, and kitting

## Supply Chain & Logistics

- Supplier qualification and monitoring
- Component receiving and incoming inspection
- Inventory management and tracking
- Transportation to/from sterilization facilities
- Sterilization release coordination
- Distribution and fulfillment

## Device Categories

Our team has successfully manufactured devices across a wide range of medical specialties:

Cardiovascular	Respiratory	Ophthalmic
Surgical / Lumbar	Brachytherapy	Dental
Biological Indicators	Electromechanical	Incontinence

# Quality & Compliance

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Quality isn't a department at A&M BioMedical — it's the foundation of everything we do. Our quality management system is built into every process, every inspection, and every decision we make. With ISO 13485 certification and zero FDA warning letters, our track record speaks for itself.

## Certifications & Registrations

Certification	Details
ISO 13485	Medical Device Quality Management Systems — valid through September 2027
FDA Registered	Manufacturing facility registered with the U.S. Food & Drug Administration
Cleanroom	Class 7 / ISO 14644 (Class 10,000) controlled environment

## Quality Management System

- Anticipatory inspection workflows at every production stage
- Document control and change management
- Process validation protocols (IQ/OQ/PQ)
- Supplier qualification and ongoing auditing
- Corrective and preventive action (CAPA) programs
- Regular internal and external audits
- Continuous employee training and competency verification

# Why A&M BioMedical

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### ■ Precision + Complexity

We specialize in both detailed manual assembly and electro-mechanical integration — one partner that can handle your full device, no matter how complex.

### ■ **Scale With Confidence**

From 150 units per month to 150,000+, we've helped companies grow from startup through acquisition without missing a beat. Our production lines are built to scale with you.

### ■ **Responsive Partnership**

As a smaller, focused organization, you get direct access to engineering leadership and fast decision-making. When you call, you talk to the people building your product.

### ■ **Compliance as Foundation**

FDA and ISO compliance aren't afterthoughts — they're embedded in every process. ISO 13485 certification and zero FDA warnings reflect our operational discipline.

### ■ **Proven Stability**

Based in Orange County's medical device hub for over three decades. Our clients stay with us through acquisitions and growth because we deliver consistent results.

### ■ **Full-Service Solutions**

From receiving and inventory through assembly, packaging, sterilization coordination, and fulfillment — we manage the full production cycle so you can focus on your market.

# Client Success Stories

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## Vertos Medical → Stryker

### 11-Year Partnership: From Startup to Acquisition

In 2015, Vertos Medical selected A&M BioMedical to manufacture their minimally invasive lumbar surgical kit. Starting at 150 units per month, A&M scaled production to over 3,000+ units per month — doubling output every two months in a planned scaling program aligned with growing clinical adoption. A&M performed full IQ/OQ/PQ process validation, built in-house manufacturing lines, and managed the V1 to V2 product transition in 2024, producing both versions during a one-year overlap period.

When Stryker acquired Vertos in September 2024, they audited A&M's facility before continuing the partnership — and chose to keep production in place. The relationship remains active today, spanning 2015 to present.

*Results: >98% first-pass yield · Zero quality escapes · 100% on-time delivery*

*"A&M has consistently exceeded my expectations in many ways. Vertos has found A&M to be extremely compliant with FDA and ISO standards. A&M has reliably delivered on their promises — timing, cost, and quality. A&M has treated us like a partner, allowing full access, promptly notifying us of any issues, and being fully committed to our success — all of these things even when we were a small volume customer!"*

*— David Lalor, VP of Operations, Regulatory Affairs and Quality Assurance*

## Cianna Medical → Merit Medical

### Quality That Survives Transitions

Our partnership with Cianna Medical continued seamlessly after their acquisition by Merit Medical. Given our years of manufacturing experience and in-depth product knowledge, Merit Medical decided to keep production at A&M — over four years after the acquisition.

*Services: Assembly process refinement, electro-mechanical expertise, quality management*

## ASP (Johnson & Johnson)

### Manual Precision Outperforms Automation

When ASP needed to ramp inventory for biological indicators, their automated equipment couldn't keep up. A&M's manual assembly process achieved a greater than 98% yield rate — outperforming the automated alternative. This enabled ASP to avoid backorders and troubleshoot their equipment without production downtime.

*"A&M's attention to detail and commitment to quality control allowed ASP to ramp up inventory while maintaining the highest standards."*

## Indian Wells Medical

### Complex Device Transfer & Production

A&M BioMedical successfully managed the manufacturing transfer of the Steerable Transeptal Needle (STSN) used in catheterized cardiac procedures. Our team refined the assembly process and established comprehensive QMS compliance for this high-precision device.

*Services: Manufacturing transfer, process refinement, QMS compliance support*

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## Ready to Get Started?

Whether you're launching a new device or looking for a more reliable manufacturing partner, we'd welcome the conversation. Our team is ready to discuss your specific needs and show you how A&M BioMedical can support your success.

<b>Website</b>	ambiomedical.com
<b>Location</b>	Laguna Hills, California
<b>Designation</b>	Women-Owned Small Business