

WHAT RESEARCH & CLINICAL EVIDENCE MEANS TO APPAREL

Bill Schultz, President & Founder of AlignMed

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AlignMed, Inc (www.alignmed.com) believes that people deserve an apparel product that does what it says. Born of medical science, fabric technology and clinical validation, AlignMed applies medically accepted research techniques to validate clothing that can improve a variety of human functions.

It is common that health and performance claims are made by sports and performance apparel manufacturers that blur the lines between the claims and the authentication to back them. This article defines how the medical academic community, institutional review boards and regulatory bodies, such as the FDA, define what scientific research and clinical validation is and what it is not. It establishes guidelines for manufacturers who must exercise responsibility and support claims with sound science.

AlignMed uses a technology of controlled resistance panels to activate muscles, trademarked this as NeuroBands™. NeuroBands™ have shown to improve posture, joint alignment, strength, balance and to reduce pain. This technology and the research behind it is growing in medical and consumer acceptance, and presents a challenge to big brand manufacturers of sports performance apparel.

FDA REGISTRATION

Clinical research and medical validity are generally required to register a product with the FDA as a medical device. Furthermore, medical claims by manufacturers are not allowed in the marketing of products if they have not been registered by the FDA. AlignMed submits its products to the rigors of clinical testing and FDA for registration. The FDA has registered the products as Class 1 Medical Devices having the potential of minimal or non-existent side effects.

The screenshot shows the FDA's public database for Establishment Registration & Device Listing. The page header includes the FDA logo and the text "U.S. Food and Drug Administration Protecting and Promoting Your Health". A search bar is visible in the top right corner. The main content area displays details for a specific device listing:

Proprietary Name:	Align, AlignMed, MyLign, MyLign2, MyLign3, Posture Shirt, S3, Spine, Spineula Stabilization Brace
Classification Name:	ORTHOSIS, LIMB BRACE
Product Code:	021
Device Class:	1
Regulation Number:	000,2473
Medical Specialty:	Physical Medicine
Registered Establishment Name:	ALIGNMED, INC.
Registered Establishment Number:	3000137579
Owner/Operator:	AlignMed, Inc.
Owner/Operator Number:	10044246
Establishment Operations:	Manufacturer, Specification Developer

At the bottom of the listing, it states "Page Last Updated: 08/09/2013" and "Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players." The footer of the page includes the FDA logo and links for Accessibility, Contact FDA, Careers, FDA Basics, FDA, No Fear Act, Site Map, Transparency, and Website Policies.

MEDICAL RESEARCH REQUIREMENT

Any promising drug or device is subjected to studies where different aspects of the test product, including its safety, toxicity and efficacy are studied. Medical Research is a branch of medical science that determines the safety and effectiveness of medications, devices, diagnostic products and treatment regimens intended for human use. Most often an Institutional Review Board (IRB) oversees the clinical research ethics of any given clinical trial. The IRB understands and acts according to local and national law.

An IRB is a stringent parameter required for the conduct of clinical trials and the implementation of good clinical practice when performing such trials. Clinical research guidelines are an integral component of AlignMed products, yet they are rarely, if ever, followed by apparel manufacturers for three main reasons:

- 1) Medical or clinical research is not required unless you choose or attempt to make a medical claim.
- 2) A clinical trial may invalidate or discredit your current product lines.
- 3) Medical and clinical research is expensive to perform.

CLINICAL VALIDATION

Only when a product has relevant data and scientific results, can the information be clinically valid with this and used to market or reference a claim. Anything that is not clinically validated is considered irrelevant, unreliable or anecdotal. We cannot find sports performance apparel outside of AlignMed that has been independently tested and validated to improve a function.

MEDICAL PRESCRIPTION CONSIDERATIONS

Medical prescriptions are highly regulated by law and a subject of medical ethics because of potential risks. There are a stringent amount of research parameters and requirements to determine a products potential upside and downside to human health and whether or not it would require a licensed physician to prescribe its use. Two of AlignMed's products, the SpinalQ™ and the Jox Shorts™ have received prescription approval. We know of no sports performance apparel that has received prescription status.

INSURANCE REIMBURSEMENT AND CODING

Medical procedures, pharmaceuticals and durable medical equipment (DME) products are assigned Medical Reimbursement Codes by Medicare through a coding verification process. The assigned codes are the billing parameters for these particular products. With incredible effort, AlignMed has received Medicare reimbursement Codes for the SpinalQ™ and the Jox™ Shorts.

Our other products, such as the S3®, MyLign™, AlignMe™ Active Bra or Posture Shirt® are not prescription approved by Medicare but can be reimbursed by a private health insurance if a physician should deem that writing a prescription for the these products is appropriate for the patient's condition. This does not guarantee that the health insurance carrier will reimburse for it, but we are working hard for prescription coding approval for these products.

SCIENTIFIC LITERATURE

This comprises references to scientific publications that report original, empirical and theoretical work in the natural and medical sciences. Referencing published literature is common and expected in scientific publications. AlignMed research and marketing efforts will often quote published Scientific Literature for purposes of clinical reference and evidential conviction related to the effectiveness of AlignMed's Apparel.

ACADEMIC AND SCIENTIFIC PUBLISHING

This refers to the process of placing the results of one's research into the literature. In most cases the research data must be reviewed and approved by a scientific peer review group in order to be considered relevant. It is not a simple matter to be published in a medical 'Peer Review' journal, it is time consuming, expensive and involves scientific scrutiny that is demanding. It is a primary reason that producers of Sports Apparel and Compression Garments choose to remove themselves from the inspection of this process. AlignMed research is always submitted for peer review publication.

SUMMARY

Ten years ago AlignMed began accredited research with medical doctors and accredited scientists with thousands of hours of training in orthopedics, sports medicine, injury prevention and injury rehabilitation. The goal was to design dynamic garments to retrain muscle, improve posture and joint alignment; and to verify it. We can find no other company in the apparel industry that follows medical research guidelines when designing or testing their products. AlignMed has performed 6 IRB studies with 2 in progress and many more being considered. Additionally, there is feedback from over 90,000 customers and 1400 clinicians who use the products. It is not a stretch to predict that AlignMed apparel inserted into injury prevention models could improve an athlete's longevity. As important, is the potential for posture improvement in a wide demographic that could save billions in health care. AlignMed and the technology behind NeuroBands may forever change the face of what today's consumer will expect from performance based apparel.

