



Medmarc Risk Management Webinar Series

Webinar Summary

Medical Device v2.0: Safer but Riskier? Litigation and Compliance Implications for Medical Device Improvements

Presenter: Matthew (Matt) L. Marshall | Clark Hill PLC.

In this on-demand webinar, recorded live on June 25, 2025, Matt Marshall of Clark Hill focused his discussion on medical device improvements and their implications for safety, regulation, and litigation. Matt explored how continuous improvement in medical devices affects compliance with FDA regulations and international standards, while also examining the legal considerations around subsequent remedial measures and their admissibility in court cases. The conversation concluded with insights on the FDA's regulatory process for device changes, the importance of documentation and communication with the agency, and the balance between innovation and litigation concerns in the medical device industry.

Full On-demand Recording

On-demand Chapters:

- 00:00 – Introduction of the Presenter
- 02:16 – What is meant by “continuous improvement” in the medical device context and why is it important?
- 07:08 – How does device improvement potentially impact litigation?
- 18:53 – How does device improvement implicate regulatory concerns?
- 39:57 – What are some best practices when it comes to device improvements?
- 45:00 – Questions



Matthew (Matt) L. Marshall | Clark Hill PLC.

Matthew L. Marshall litigates product liability cases in the life science industry, in matters involving medical device, pharmaceutical, and dietary supplement claims.

Matt's medical device clients are diverse and include manufacturers of dozens of different types of Class III, II, and I devices.

Matt represents pharmaceutical manufacturers and distributors in product liability cases, and sponsors and contracts research and manufacturing organizations in clinical trials litigation. He also represents manufacturers, distributors, ingredient suppliers, and contract manufacturers of dietary supplements and other food products. Additionally, he represents testing labs in personal injury litigation.

In the commercial products industry, Matt represents manufacturers of bulk plastics, thermoplastic OTR tires, molds, pre-manufactured barns, toilet valves, appliance hoses, resurfacing coatings, and component parts.

In the consumer products industry, Matt represents manufacturers of utility vehicles, off-road protective gear, tires, exercise equipment, smartphones, tablets and chargers, and pet supplies.

Matt has successfully tried to verdict numerous claims involving death or serious injuries including stroke, neurological deficits & paralysis, respiratory failure, SJS, burns, organ damage & failure, amputation, RSD, blindness, and other catastrophic injuries.

Matt has also served as national and regional counsel in several coordinated mass tort litigation and class actions.