Medmarc Risk Management Webinar Series
Webinar Summary

Importing Medical Devices into the U.S. in Compliance with the U.S. FDA
Presenter: Jennifer (Jen) Diaz | President and Founder of Diaz Trade Law

In this on-demand webinar recorded live on October 17, 2023, Jennifer explained what a medical device is according to the FDA. She highlighted that a medical device is an instrument or apparatus intended to diagnose, cure, mitigate, treat, or prevent disease, and it must not achieve its primary intended purpose through a chemical action. Jennifer also emphasized the importance of correctly classifying a device for regulatory approval, with different classes requiring different levels of scrutiny. She discussed the role of customs brokers and the responsibility of importers to be aware of necessary regulations and classifications. Jennifer also outlined the regulations and responsibilities for the import and export of FDA-regulated items, and the consequences of not having an active registration with the FDA. She also clarified the process and costs associated with submitting a 510(k) for medical device approval and the importance of keeping up with regulatory changes. Finally, Jennifer discussed the reasons for product refusal into the US and the process of liquid data damages claim.

Full On-demand Recording

On-demand Chapters

Jennifer (Jen) Diaz is the President and Founder of Diaz Trade Law. Jen is a Chambers ranked, Board Certified International Attorney specializing in customs and international trade. For more than 17 years, Jen has provided legal advice and customized training on import and export compliance to industry, with a strong record of success in mitigating federal administrative enforcement actions. Jen has received many accolades from the legal community, including being recognized by "Super Lawyers" as a Top International Attorney, having an AV rating of "Superb," and serving as President of the Organization of Women in International Trade (OWIT International) as well as OWIT South Florida. A frequent media commentator, Jen has authored book chapters for The Florida Bar and the American Bar Association, numerous Bloomberg Law articles, and other leading publications. Jen is Editor of the Customs & International Trade Law blog recognized by the U.S. Library of Congress as being an important part of the legal historical record.