

Stuart Portnoy, MD, is Senior Consultant with Biologics Consulting Group. He is an expert at guiding new medical devices through the regulatory and clinical process and negotiating with the FDA. Eight years of experience regulating medical devices at the FDA: reviewed or supervised review of hundreds of cardiac device applications along multiple pathways - IDEs, PMAs, and 510(k)s. Evaluated clinical risks and benefits of new high-risk technologies, many high visibility. Pioneered inter-center combination drug/device product review process including drug-eluting stents. Negotiated FDA jurisdictional designation for combination products.

He previously worked at the FDA for 8 years, most recently as Branch Chief of the Interventional Cardiology Devices Group and Acting Deputy Director of the Division of Cardiovascular Devices in the Center for Devices and Radiological Health. At the FDA, Dr. Portnoy helped develop the FDA's approach to reviewing drug-eluting stents and other drug/device combination products. Prior to his experience as a manager, Dr. Portnoy specialized in the clinical review of cardiac electrophysiology devices including pacemakers, defibrillators, and EP catheters. Dr. Portnoy is a graduate of George Washington University School of Medicine and also has an MS in Bioengineering from the University of Pennsylvania.