Greenleaf Health

Heather Rosecrans, F.R.A.P.S

Executive Vice President, Medical Devices & Combination Products

BACKGROUND	• 30-plus years with the FDA's Center for Devices and Radiological Health (CDRH) and over a decade as Executive Vice President for Medical Devices and Combination Products at Greenleaf Health
SPECIALTY	• FDA's 510(k) program, the 513(g) program, classification and reclassification, De Novo petitions, and other premarket regulatory requirements
EXPERIENCE	• Extensive experience in FDA premarket review processes for medical devices • Device regulation at multiple levels within the FDA and consulting for industry on medical device regulation in the U.S.

Heather Rosecrans has more than 45 years of public health and medical device experience. She continues her commitment to public health by providing strategic consulting services and working with Greenleaf clients to bring innovative devices to the U.S.

Before joining Greenleaf, Heather served as Director of the 510(k) Premarket Notification Staff at the FDA's Center for Devices and Radiological Health (CDRH). She was responsible for implementing administrative and regulatory policy for the 510(k) program, the 513(g) program, classification and reclassification, De Novo petitions, and other premarket regulatory requirements.

Heather started her FDA career as a biologist in the Bureau of Medical Devices. In 1980, she joined the newly organized CDRH Premarket Application (PMA) Staff. For the next seven years, she coordinated the administrative, scientific, and regulatory review of PMAs, as well as product development protocols, master files, and associated submissions.

In 1987, Heather joined the 510(k) Section of CDRH's Program Operations Staff. In this role, she served as a Consumer Safety Officer and was a key contact for CDRH and within the FDA on 510(k) matters. Heather held this position until 1992, when she became Director of the 510(k) Staff.

Heather's accomplishments include drafting guidance documents and regulations on the 510(k) program, training FDA staff and other stakeholders, as well as assisting in the implementation of the Medical Device User Fee Modernization Act, the Food and Drug Administration Modernization Act, and the Safe Medical Devices Act.

Heather's extensive experience at CDRH—specifically her pivotal role in developing the 510(k) program—has made her one of the nation's leading 510(k) experts. Since the program's inception in 1976, the FDA has reviewed more than 150,000 device 510(k)s for a determination regarding substantial equivalence.

Heather represented CDRH in multiple forums, including national conferences, FDA advisory committee meetings, and international symposiums. While at the FDA, she worked collaboratively with the Centers for Medicare and Medicaid Services and other regulatory agencies. Her published works include numerous guidance and regulatory documents. Heather continues to speak on matters related to FDA premarket regulation of medical devices.

Heather holds a B.S. in biology from Pfeiffer College in Misenheimer, N.C.