Peeling the 510(k) Onion: From Fundamentals to Latest Trends
Saturday, 9 September 2017

8:00 am	**Registration and Continental Breakfast**
9:00 am	**Introductions: Faculty and Meeting Participants** **Agenda Review** **Introduction to 510(k)** • What is a 510(k)? • The complexities and challenges of 510(k)s • Workshop objectives **Heather Rosecrans, FRAPS,** executive vice president, medical devices and combination products Greenleaf Health LLC and vice president, regulatory affairs , MDMA **Donna-Bea Tillman, FRAPS**, Medical device team leader, Biologics Consulting
9:45 am	**510(k) Regulatory Framework** • Meaning of substantial equivalence • Intended use vs indications for use • Different types of questions • Procodes **Heather Rosecrans, FRAPS,** executive vice president, medical devices and combination products Greenleaf Health LLC and vice president, regulatory affairs , MDMA
10:30 am	**Refreshment Break**
10:55 am	**Developing a regulatory strategy** • Short-term versus long-term • Is my device suitable for a 510(k)? - 513(g) - RFDs - De novos • Picking a predicate • Presubmission meetings • Software **Donna-Bea Tillman, FRAPS**, Medical device team leader, Biologics Consulting
11:40 am	**Preparing your documents** • How to write a test report - Mechanical testing - Biocompatibility - Sterilization **Hollace Saas Rhodes,** senior director, Orthopedic regulatory affairs, Musculoskeletal

	Clinical Regulatory Advisers, LLC
12:15 pm	**Different Devices, Submissions and Studies** • Clinical data considerations **Dan Schultz, MD,** principal, medical devices and combination products, Greenleaf Health
12:30 pm	**Lunch**
1:30 pm	**How to Prepare a 510(k)** • Best practices for 510(k)s preparation • The components of a robust and defensible 510(k) • How to write a product description for consistent company and 510(k) use • How to write the indication statement • How to make a case for substantial equivalence • How to prepare a "Refuse-to-Accept" (RTA) checklist **Calley Herzog,** senior consultant, Biologics Consulting Group
2:45 pm	**Promotions and Advertising** **Maura Norden, JD,** senior vice president, medical devices and combination products, Greenleaf Health Inc.
3:15 pm	**Refreshment Break**
3:45 pm	**Final Steps Prior to Submission** • Checklist for final preparations prior to submission • UDI • MDUFA goals and how they impact 510(k) submission, review and clearance **Melissa Kann,** senior manager regulatory affairs, Stryker Instruments
4:30 pm	**FDA Perspectives** **Marjorie Shulman, MBA,** chief of premarket notification 510(k) section, ODE, CDRH, FDA
5:00 pm	**Adjourn**

Sunday, 10 September 2017

7:00 am	**Registration and Continental Breakfast**
8:00 am	**The Origin and Evolution of 510(k)** • The legislative purpose of 510(k)s, and the 510(k) framework • The legislative history and evolution of 510(k)s **Steve Terman,** principal, Olson Frank Weeda Terman Matz PC
8:30 am	**The Review Process** • What happens if the 510(k)s is not accepted (RTA) • How to interact with FDA representatives • Managing responses to additional information • The basis for and how to effectively push back • The appeal process • Future steps in case of NSE **Mike Santalucia,** vice president regulatory affairs, Terumo BCT
9:30 am	**Refreshment Break**
10:00 am	**Reviewer's Smart Template** **Patrick Axtell, PhD,** program operations staff, ODE, CDRH, FDA
10:30 am	**IVD Perspectives** • Special considerations for IVD 510(k)s • The importance of CLIA • The impact of CLIA on 510(k)s **April Veoukas,** director of regulatory affairs, Abbott Quality & Regulatory
11:15 pm	**Modifications** • Managing device modifications • Is my 510(k) Special? **Melissa Kann,** senior manager regulatory affairs, Stryker Instruments **April Veoukas,** director of regulatory affairs, Abbott Quality & Regulatory
12:00 pm	**Lunch**
1:00 pm	**MDUFA IV/21st Century Cures Update** **Heather Rosecrans, FRAPS,** executive vice president, medical devices and combination products Greenleaf Health LLC and vice president, regulatory affairs , MDMA
1:30 pm	**Additional Topics for Discussion** • Symbols • Cybersecurity • Clinical data in 510(k)s • 510(k), limitations on exemptions • Audience input on other hot topics **Panel of Industry Presenters: All**

2:30 pm	**Refreshment Break**
3:00 pm	**FDA Perspectives** • First-hand accounts from FDA representatives about 510(k) • Q&A **Panel of Presenters:** **Patrick Axtell, PhD,** program operations staff, ODE, CDRH, FDA **Fatemeh Razjouyan**, 510(k) program lead/policy analyst, OIR, CDRH, FDA **Marjorie Shulman, MBA,** chief of premarket notification 510(k) section, ODE, CDRH, FDA
4:00 pm	**Adjourn**