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Companion Diagnostics Solutions [1]

Navigate BioPharma has broad experience in the development and support of companion diagnostics and submission for CE marking. Our flexible business models include partnering with pharmaceutical and in vitro diagnostic (IVD) manufacturers to provide customized analytical and clinical validation services for Premarket Approval (PMA) approvals. Additionally, we have in-house capability to support PMA submissions by Navigate BioPharma. Our team can support your regulatory needs by filing risk assessments and Investigational Device Exemption (IDE), PMA, Institutional Review Board (IRB) and CE marking submissions. Our unique capabilities across diverse platforms provide integrated solutions for technical comparisons across several technical platforms that suit the customized needs of our sponsors. At Navigate BioPharma, our quality systems are designed to ensure compliance with applicable regulatory requirements for drug and diagnostic approvals. Together with our expertise in clinical trial testing, we aim to be your partner of choice for integrated solutions from pre IDE to PMA submission and approval.

Source URL: https://www.navigatebp.com/our-services/companion-diagnostics-solutions

Links
[1] https://www.navigatebp.com/our-services/companion-diagnostics-solutions