Hogan Lovells

Premarket Review

Our premarket review practice focuses on providing strategic advice from the earliest stages in the product development cycle in order to optimize the regulatory pathway. Leveraging the technical background of our lawyers and regulatory science professionals, we provide comprehensive regulatory assistance during all phases of the Food and Drug Administration (FDA) clearance or approval process.

We also assist clients in preparing all types of premarket submissions, including investigational device exemptions (IDEs), pre-submissions, 510(k) notices, de novo submissions, premarket approvals (PMAs), and related submissions. We are involved in a substantial portion of all PMA applications filed annually with FDA, as well as dozens of pre-submissions and IDE submissions and hundreds of 510(k) notices each year.

Representative experience

Advocated FDA's reclassification of a novel imaging device, tissue culture media products for ex vivo growth of human cells, and in vitro diagnostic test systems, avoiding the need for a PMA approval.

Although a client had received two non-approvable letters prior to our involvement, we assisted in the preparation of necessary PMA amendments and secured a unanimous Advisory Panel recommendation for approval.

To assist a client in expediting a product to market, we

Contacts

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Practices

Medical Device and Technology Regulatory

obtained the FDA's designation of expedited review status for a novel orthopedic and women's health device and negotiated favorable review timetables.

Though the FDA previously told our client that a device for diagnosing tubo-peritoneal infertility would require a PMA approval, we drafted a 510(k) notice that the agency cleared.

When other FDA counsel had concluded a device would require PMA approval, we assisted a small start-up client in obtaining clearance of a 510(k) notice without clinical data for a cardiac bypass device.

After FDA determined that existing clinical data did not demonstrate substantial equivalence, we met with FDA to explain the data, addressed the issues, and helped our client obtain a 510(k) clearance.

Advised and assisted a client seeking FDA regulatory marketing approval of its Retinal Prosthesis System.

Assisted a client in preparing an abbreviated 510(k) notice for a surgical mesh that demonstrated the device's substantial equivalence. FDA cleared this within 60 days of its submission.

Assisted a foreign client in obtaining PMA approval for an extracorporeal device for removing cholesterol from the blood of certain types of patients with hypercholesterolemia.

Assisted companies on numerous cardiovascular device approvals, including left ventricular assist devices and artificial heart devices.

Managed the Advisory Panel process and helped secure a positive vote on the risk-benefit of the ResQCPR System, a CPR- assist device that increases likelihood of survival after cardiac arrest.

Latest thinking and events

Insights and Analysis

Life Science Law Update – Key developments for pharma and device companies in EU and EU Big Five

News

FDA authority to conduct bioresearch monitoring inspections expanded by appropriations legislation

News

U.S. Congress embraces FDA's approach to clinical trial diversity in new Omnibus legislation

News

Cell, tissue and gene therapies – Regulatory challenges and responses in Australia

News

FDA Breakthrough Devices Program guidance targets health inequality

News

Seeking harmony: FDA to align its human subject research regulations with Common Rule