FDA releases 180-day PMA memos

Mass Device

The FDA's Center for Devices & Radiological Health releases a smattering of summary review memos of 180-day design changes to medical devices that have already won a green light from the federal watchdog agency.

The FDA's Center for Devices & Radiological Health released a selection of summary review memos detailing applications to make substantial changes to already-approved medical devices.

The federal watchdog agency's med-tech oversight arm said it began releasing the documents as part of the CDRH's transparency initiative.

The 180-day supplements seek to make "a significant change in components, materials, design, specification, software, color additive, and labeling to an approved premarket application or premarket report," according to the agency.