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ALERTS

FDA Updates Recognized Consensus Standards For Medical Devices

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The FDA recently released extensive updates to the consensus standards it recognizes for medical devices. Section 514 of the Food, Drug & Cosmetic Act allows FDA to recognize consensus standards developed by international and national organizations for use in satisfying portions of device premarket review (510(k)) submissions or other requirements. FDA periodically updates the list of such standards that it recognizes and keeps a searchable database available on its website.

The updates included both newly-recognized standards and changes, corrections and withdrawals of existing standards. Categories of devices affected by the changes include anesthesiology, cardiovascular, dental/ENT, general hospital and general plastic surgery, in vitro diagnostics, neurology, OB-GYN/gastroenterology/urology, ophthalmic, orthopedics, physical medicine, radiology, and software/informatics. Changes were also made in the areas of biocompatibility, materials, nanotechnology, and sterility.

The FDA-recognized new standards came in the categories of anesthesia, cardiovascular, general hospital and general plastic surgery, OB-GYN/gastroenterology/urology, ophthalmic, orthopedics, radiology, and software/informatics. New standards were also recognized in the areas of materials and sterility.

For more information, contact the Barnes & Thornburg attorney with whom you work or one of the following attorneys:

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