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The FDA this week published a new proposed rule looking to establish procedures and criteria for its De Novo certification pathway.

If the rule is finalized, it would establish classifications for new types of medical devices and provide guidelines for the de novo classification process.

The proposed rule would also establish requirements for the formatting and content of de novo requests, according to the FDA release, and would clarify the agency's criteria for approval, declining and withdrawing such requests.

The pathway, originally created through the Food and Drug Administration Modernization Act allows new, low to moderate risk devices without a predicate devices to be cleared as a Class I or Class II device and avoid the pre-market approval pathway and Class III designation.

The FDA said it has opened the proposed rule to public comments.

The proposed rule comes only a week after the agency released plans for updating its 510(k) clearance pathway, including a push to move away from using predicate devices over 10 years old and the creation of a new alternative 510(k) pathway that will allow approval based on objective safety and performance criteria.

The post FDA floats changes to De Novo pathway appeared first on MassDevice.