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Medical Devices

Reclassification

As experience and knowledge about a device increase, the original classification can be adjusted via the process of **reclassification**. Changes in classification are based on FDA's receipt of new information about a device. FDA may, on its own, or in response to an outside petition, change a device's classification by regulation. A manufacturer who wishes to have a device **reclassified** to a lower class must convince FDA that the less stringent class requirements will be sufficient to provide reasonable assurance of safety and effectiveness.

FDA notifies petitioners of determinations made on petitions for reclassification by a **reclassification letter**. If a determination is made to reclassify a device, FDA publishes a proposed rule to reclassify in the Federal Register which includes the scientific justification for reclassification and which affords a period for comment. Subsequently a final rule is published in the Federal Register which changes the reclassification.

Related Resources

- [515 Program Initiative](#)¹

Links on this page:

1. [/AboutFDA/CentersOffices/CDRH/CDRHTransparency/ucm240310.htm](#)