

Recently-Approved Devices

The products listed here include some of the newest medical technology available. For each product, you can find information about what the device is, how it works, when it can be used, and when it should not be used.

Approvals

- [2022 Device Approvals \(/medical-devices/recently-approved-devices/2022-device-approvals\)](/medical-devices/recently-approved-devices/2022-device-approvals)
- [2021 Device Approvals \(/medical-devices/recently-approved-devices/2021-device-approvals\)](/medical-devices/recently-approved-devices/2021-device-approvals)
- [2020 Device Approvals \(/medical-devices/recently-approved-devices/2020-device-approvals\)](/medical-devices/recently-approved-devices/2020-device-approvals)
- [2019 Device Approvals \(Archived\) \(https://public4.pagefreezer.com/browse/FDA/28-01-2022T11:16/https://www.fda.gov/medical-devices/recently-approved-devices/2019-device-approvals\)](https://public4.pagefreezer.com/browse/FDA/28-01-2022T11:16/https://www.fda.gov/medical-devices/recently-approved-devices/2019-device-approvals) [↗ \(http://www.fda.gov/about-fda/website-policies/website-disclaimer\)](http://www.fda.gov/about-fda/website-policies/website-disclaimer)
- [2018 Device Approvals \(Archived\) \(https://wayback.archive-it.org/7993/20201220103902/https://www.fda.gov/medical-devices/recently-approved-devices/2018-device-approvals\)](https://wayback.archive-it.org/7993/20201220103902/https://www.fda.gov/medical-devices/recently-approved-devices/2018-device-approvals) [↗ \(http://www.fda.gov/about-fda/website-policies/website-disclaimer\)](http://www.fda.gov/about-fda/website-policies/website-disclaimer)
- [2017 Device Approvals \(Archived\) \(https://wayback.archive-it.org/7993/20201220103911/https://www.fda.gov/medical-devices/recently-approved-devices/2017-device-approvals\)](https://wayback.archive-it.org/7993/20201220103911/https://www.fda.gov/medical-devices/recently-approved-devices/2017-device-approvals) [↗ \(http://www.fda.gov/about-fda/website-policies/website-disclaimer\)](http://www.fda.gov/about-fda/website-policies/website-disclaimer)
- [2016 Device Approvals \(Archived\) \(http://wayback.archive-it.org/7993/2017114011507/https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm494389.htm\)](http://wayback.archive-it.org/7993/2017114011507/https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm494389.htm) [↗ \(http://www.fda.gov/about-fda/website-policies/website-disclaimer\)](http://www.fda.gov/about-fda/website-policies/website-disclaimer)
- [2015 Device Approvals \(Archived\) \(http://wayback.archive-it.org/7993/20170111000324/http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm430692.htm\)](http://wayback.archive-it.org/7993/20170111000324/http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm430692.htm) [↗ \(http://www.fda.gov/about-fda/website-policies/website-disclaimer\)](http://www.fda.gov/about-fda/website-policies/website-disclaimer)
- [2014 Device Approvals \(Archived\) \(http://wayback.archive-it.org/7993/20170111091458/http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm381097.htm\)](http://wayback.archive-it.org/7993/20170111091458/http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm381097.htm) [↗ \(http://www.fda.gov/about-fda/website-policies/website-disclaimer\)](http://www.fda.gov/about-fda/website-policies/website-disclaimer)
- [2013 Device Approvals \(Archived\) \(http://wayback.archive-it.org/7993/20170111091459/http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm335803.htm\)](http://wayback.archive-it.org/7993/20170111091459/http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm335803.htm) [↗ \(http://www.fda.gov/about-fda/website-policies/website-disclaimer\)](http://www.fda.gov/about-fda/website-policies/website-disclaimer)
- [2012 Device Approvals \(Archived\) \(http://wayback.archive-it.org/7993/20170111091500/http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm286493.htm\)](http://wayback.archive-it.org/7993/20170111091500/http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm286493.htm) [↗ \(http://www.fda.gov/about-fda/website-policies/website-disclaimer\)](http://www.fda.gov/about-fda/website-policies/website-disclaimer)
- [2011 Device Approvals \(Archived\) \(http://wayback.archive-it.org/7993/20170111091501/http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm241143.htm\)](http://wayback.archive-it.org/7993/20170111091501/http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm241143.htm) [↗ \(http://www.fda.gov/about-fda/website-policies/website-disclaimer\)](http://www.fda.gov/about-fda/website-policies/website-disclaimer)
- [2010 Device Approvals \(Archived\) \(http://wayback.archive-it.org/7993/20170111091503/http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm199026.htm\)](http://wayback.archive-it.org/7993/20170111091503/http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm199026.htm) [↗ \(http://www.fda.gov/about-fda/website-policies/website-disclaimer\)](http://www.fda.gov/about-fda/website-policies/website-disclaimer)

Please note: The lists in this section do not include every new medical device that has been cleared or approved for sale in the US. You can find additional information at the links below:

- [PMA Approvals \(/medical-devices/device-approvals-denials-and-clearances/pma-approvals\)](/medical-devices/device-approvals-denials-and-clearances/pma-approvals): Monthly listings of all new or high-risk medical devices that were approved via the premarket approval (PMA) pathway. These devices require a more rigorous premarket review than the 510(k) pathway.
- [510\(k\) Clearances \(/medical-devices/device-approvals-denials-and-clearances/510k-clearances\)](/medical-devices/device-approvals-denials-and-clearances/510k-clearances): Monthly listings of new devices that have been shown to be "substantially equivalent" to devices that are already marketed legally for the same use.
- [Humanitarian Device Exemptions \(HDE\) \(/medical-devices/device-approvals-denials-and-clearances/hde-approvals\)](/medical-devices/device-approvals-denials-and-clearances/hde-approvals): Listing of devices that have been approved to treat or diagnose a disease or condition that affects fewer than 4,000 individuals in the United States per year.
- [De novo Classification Orders \(/about-fda/cdrh-transparency/evaluation-automatic-class-iii-designation-de-novo-summaries\)](/about-fda/cdrh-transparency/evaluation-automatic-class-iii-designation-de-novo-summaries): Listings of new devices for which a de novo has been granted.