

FDA requires tracking codes on medical implants

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Federal health regulators will begin tracking millions of medical devices, from pacemakers to hip replacements, using a new electronic system designed to protect patients by catching problematic implants earlier.

The Food and Drug Administration published new rules Friday that require certain medical devices sold in the U.S. to carry a unique code, identifying its make, manufacturer and lot number. The codes will be stored in a publicly accessible database to help regulators, doctors and companies monitor safety issues with devices.

The tracking system has been promoted by doctors and public <u>safety</u> <u>advocates</u> for more than a decade. But industry groups favored voluntary tracking efforts by individual companies.

The FDA will begin phasing in the new system in the coming year, starting with high-risk devices like heart stents and defibrillators.

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