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# FDA Breakthrough Device Program Nears 800 Designations

by Elizabeth Orr

Almost 800 devices have been granted priority status through the US FDA's breakthrough devices program, the agency announced this week. But device clearance numbers continue to lag, with only 67 granted as of 31 March.

New *data* from the US Food and Drug Administration shows the growth of its breakthrough devices program, but may raise questions as to how effective the program is in getting innovative devices to market.

The breakthrough devices program, which launched as the expedited access pathway in 2015, grants regulatory advantages to some innovative devices that treat serious conditions. Products accepted to the pathway may benefit from "sprint discussions" with the FDA about the device development process and prioritized review of future regulatory submissions, among other perks. (Also see "*'Breakthrough' Blueprint: US FDA Draft Guideline Outlines Revised Expedited Development Program*" - Medtech Insight, 24 Oct, 2017.)

The most recent set of statistics, which was published on 12 July and includes data through 31 March, shows that 794 products have been awarded breakthrough status since 2015. Of these, 786 came from the FDA's device center, while eight came from the Center for Biologics Evaluation and Research.

According to the FDA, the number of breakthrough statuses granted each year rose steadily from 11 in 2015 to a peak of 206 in 2021 before dropping back to 166 in 2022. Sixty-four devices got the nod in the first three months of 2023 alone. For full data, see the table below.

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The FDA also released information on which types of devices are most likely to be labeled as breakthroughs. The three largest categories were cardiovascular, neurology and orthopedic, with gastroenterology and urology at a distant fourth. For a full breakdown, see the table below.

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## Approval Numbers Tick Up

The FDA's new data also shows that 19 breakthrough devices were cleared or approved in 2022, a step up from 15 the year before. An additional five devices were cleared in the first three months of 2023.

This means that 67 of the 794 devices have reached market, or about 8.4% – a rate that has led some to question whether the program is helping novel technology reach patients more quickly.

"The prevailing view is a lot of [breakthrough] products just struggle through the program, where the same products, not through the program, could sail through the FDA [approval] process," attorney Bradley Merrill Thompson of Epstein Becker Green told *Medtech Insight* last year. "It's definitely a scary thing." (Also see "*Medtech Monthly, Ep. 3: Breakthrough Device Analysis with Bradley Merrill Thompson*" - Medtech Insight, 9 Sep, 2022.)

The cause of the bottleneck is unclear, but Thompson and others have speculated that it may be funding issues, poor device performance in clinical trials, or the FDA imposing a higher evidentiary standard for breakthrough products.

For a full graph of when the authorizations were issued, see the table below.

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