

FDA Issues Updated Final Guidance on the Breakthrough Devices Program

- On September 14, 2023, the Food and Drug Administration (FDA) issued updated Breakthrough Devices Program – Guidance for Industry and Food and Drug Administration Staff (Guidance).
- The Guidance clarifies:
 - How the Breakthrough Devices Program (Program) may apply to certain medical devices that promote health equity.
 - Considerations in designating devices, including eligible devices that may support innovation of new and existing technologies addressing health inequities.
 - That the Program may be available for certain non-addictive medical products to treat pain or addiction.
 - How the FDA discloses the Breakthrough status of designated devices once they receive marketing authorization.

More on This Topic:

- [Guidance](#)
- Upcoming FDA webinar on the Guidance – Nov. 14 at 1pm.

For questions, please reach out to [Vicky Jucelin](#).

[Manage Preferences](#)

