List of Artificial Intelligence and Machine Learning (AI/ML)-enabled Devices Available on FDA's Website



The U.S. Food and Drug Administration (FDA) now provides a list of **Artificial Intelligence and Machine Learning (AI/ML)-Enabled Medical Devices** that are legally marketed in the United States. These include devices (1) cleared via 510(k) premarket notifications, (2) authorized pursuant to De Novo requests, and (3) approved via premarket approval applications, or PMAs. FDA explains that the list, developed by FDA's Digital Health Center of Excellence, while not exhaustive or comprehensive, is intended to increase transparency and access to information on these devices that span across medical disciplines.

Read the **client alert**.