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TruO2 OTC FAQ

Why is the FDA clearance process important?

The FDA clearance process is critical for several reasons, primarily centered on ensuring public health and safety. Overall, the FDA clearance process is essential for maintaining high standards in the medical device industry, ensuring that devices are safe and effective for public use.

- **Public Safety:** The FDA regulates medical devices to allow the public to benefit from access to safe and effective medical devices. This includes evaluating the potential risks and benefits of the device.
- **Effectiveness:** The FDA requires that medical devices perform as intended and provide the claimed benefits. This helps prevent ineffective, misleading, or harmful devices from reaching the market.
- **Rigorous Testing:** The clearance process involves thorough scientific and clinical evaluations, including clinical evidence, bench testing, and biocompatibility testing, to verify the safety and efficacy of the device.
- **Trust:** FDA clearance instills confidence in consumers, healthcare providers, and insurers that the risks and benefits of the device have been evaluated for the public benefit.
- **Regulatory Compliance:** Manufacturers must adhere to legal and regulatory requirements, ensuring that devices are marketed responsibly and ethically.
- **Preventing Harm:** The FDA provides oversight to prevent harmful or fraudulent devices from entering the market, protecting public health and reducing the incidence of device-related injuries or deaths.
- **International Recognition:** FDA clearance often serves as a benchmark for other regulatory agencies across the globe. This facilitates international trade and the global distribution of medical devices.

What is required for a med device to obtain OTC clearance?

- Obtaining U.S. over-the-counter (OTC) clearance for a medical device involves several steps and requirements set by the US FDA.
- Some of the steps include the following: device classification, pre-submission and regulatory pathway, product development, testing and validation, labeling and instructions for use, quality management system, 510(k) submission, FDA review and clearance, post-market surveillance, marketing and distribution.

How are Health & Wellness medical devices different than a device that has OTC clearance by the FDA?

- Health & wellness devices are not regulated by the FDA. They focus on general well-being only. OTC medical devices undergo a rigorous FDA clearance process to demonstrate that they are safe and effective for specific medical uses. This difference impacts how these devices are marketed, sold, and monitored in the market.

What is the difference between OTC and prescription?

- The difference between OTC (Over-The-Counter) and prescription medical devices primarily revolves around accessibility, regulatory requirements, and the level of medical supervision needed for their use.

- OTC devices can be directly purchased by consumers without a prescription from a healthcare provider. They are available at pharmacies, grocery stores, online retailers, and other general retail outlets.

- Prescription devices can only be obtained with a prescription from a licensed healthcare provider. They are usually dispensed by a pharmacy or a medical supply company and may require professional fitting or setup.

Additional resources regarding the FDA clearance process can be found in the links below.

· Medical Device Safety and the 510(k) Clearance Process | FDA

· General Wellness: Policy for Low Risk Devices - Guidance for Industry and Food and Drug Administration Staff (fda.gov)

· Why is FDA clearance important?

· FDA's Role in Regulating Medical Devices

· Factors to Consider Regarding Benefit-Risk in Medical Device Product Availability, Compliance, and Enforcement Decisions - Guidance for Industry and Food and Drug Administration Staff (fda.gov)

· Learn if a Medical Device Has Been Cleared by FDA for Marketing | FDA

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