TELOS PARTNERS

Q1 2021

REGULATORY SPOTLIGHT

FDA'S SAFER TECHNOLOGY PROGRAM

FDA released final guidance on a new, voluntary review process for devices designed to treat non-life-threatening diseases and make available treatments safer.

The STeP Program is modeled after the Breakthrough Devices Program in expediting the development, assessment, and review of devices that are deemed eligible by the Agency.

"Consistent with the agency's statutory mission to protect and promote public health, FDA believes that this 'Safer Technologies Program' or 'STeP' will help patients have more timely access to these medical devices and device-led combination products by expediting their development, assessment, and review while preserving the statutory standards for premarket approval, De Novo marketing authorization, and 510(k) clearance," the agency said in a news release.

Devices eligible for STeP should improve on existing treatments' safety by reducing adverse events, device failures, use-related hazards, or user errors, or by improving the safety of other devices or interventions.

If you are interested in whether your new product is eligible, let's start the conversation to see if it can benefit from this program!

DID YOU KNOW?

During the pandemic, FDA has received more than 5,000 EUA device requests, but just over 600 have been authorized.

Despite resource reallocation, performance metrics showed CDRH's Office of Orthopedic Devices hit their 90-day performance goal for 510(k) decision on 100% of applications Accepted in 2020 (qty 636) and 2021 so far (qty 118). Pretty impressive!

LOOKING AHEAD

MAY 26, 2021

The long-awaited European Medical Device Regulation (EU MDR 2017/745) will apply.

MAY 31, 2021

FDA's enforcement discretion policy for HCT/Ps will expire, opening up life sciences companies involved in manufacturing, selling, or using these products to increased regulatory scrutiny.

MAY 31, 2021

FDA's highly anticipated and much delayed Quality System Regulation (QSR) is set to be harmonized with ISO 13485 and proposed/draft regulations are planned to be issued for comment.

Recent Publications, Standards Revisions:

The FDA's CDRH recently published the report,"Examples of Real-World Evidence (RWE) Used in Medical Device Regulatory Decisions," summarizing 90 examples of real-world data used to support regulatory decision making.

Congratulations to our clients OrthoPediatrics and Vilex LLC for winning approvals using RWE and being featured in this recent FDA publication.