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Government Accountability Office Urges Tough Review of Medical Devices

Last week, the General Accountability Office said in a report the FDA had cleared more than 200 high-risk devices, known as "class III," to go through a less stringent review process that was intended for simpler products.

The FDA should "expeditiously" issue regulations that would require the toughest level of review for all products deemed high-risk, the report said.

FDA spokeswoman Karen Riley said "we're considering the legal and procedural options to accomplish the objective."

View the full article [here](#).

Free White Paper: Standard Work for Problem Solving

When problems occur, are they addressed in a planned, consistent, predictable way? Does your problem solving team have a consistent expectation of roles & responsibilities? Are your investigations and the resulting documentation providing the objective evidence needed to demonstrate compliance?

In this complementary white paper, industry expert Chris Tsai discusses how a well planned execution of Standard Work can improve the overall performance of the quality system.

View the paper [here](#).

New FDA Guidance Recommends CAPA System to Monitor Imports

This month, the FDA issued a draft guidance outlining four critical quality control practices for importers. The guidance is aimed at increasing the overall quality of goods imported to the US and concentrates on the reduction of contamination and counterfeiting.

Read the draft guidance [here](#).

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