The Food and Drug Administration should replace its 35-year-old 510(k) process for medical devices, the Institute of Medicine (IOM) urges in a new report. The IOM finds the process is flawed as a means to screen devices for safety and efficacy before they enter the market and can’t be adequately transformed.

The IOM encourages the FDA to develop a new regulatory framework that does a better job of screening devices before they are offered for sale and monitoring their performance afterward.

The 510(k) process, first set up in 1976, expedites the FDA’s evaluation of moderate-risk devices. Under the process, a new device can be cleared for marketing if it is “substantially equivalent,” or similar, to a previously cleared device or any device on the market prior to the law’s enactment in 1976. The FDA generally doesn’t require evidence of safety and effectiveness for a 510(k) clearance. That’s in contrast to the FDA’s premarket approval (PMA) for high-risk devices, which does require evidence of safety and efficacy.

Relying on “substantial equivalence” doesn’t ensure devices coming on the market are safe and effective, the IOM says. In most cases, the devices to which new devices are compared were never reviewed for safety and effectiveness themselves.

That doesn’t mean devices cleared through the 510(k) process are unsafe or ineffective, the IOM notes. Many have been used for years without evidence of problems.

Still, it isn’t clear that the 510(k) process is serving the needs of either industry or patients, and simply modifying it won’t help, said the report’s committee chair, David Challoner, MD, of the University of Florida, Gainesville.

Keys to a new process

The IOM committee wasn’t charged with detailing what a new framework should entail. But the report says the process should be clear, fair, predictable, and use regulation to ensure a device is safe and effective throughout its use.

Patients and the device industry both want a streamlined process. It would be impractical to require a PMA for every device. Thus, the IOM says it’s also essential to have a robust process for surveillance of new products after they enter the market. The IOM found the current oversight process is weak and heard from the FDA that it has limited authority to address problems with devices once they are on the market. If necessary, the IOM says, Congress should pass legislation to remove barriers to the FDA’s ability to collect, analyze, and act on information about devices’ performance after they are cleared.

The IOM says a new regulatory framework would benefit everyone—patients, providers, the device industry, and the FDA.

Reference