US demands data on older medical devices

Reuters

WASHINGTON, DC, USA: US regulators have ordered makers of 25 types of medical devices to supply safety and effectiveness data so the US government can decide whether the products must undergo the most stringent review process. The order addresses complaints that the Food and Drug Administration had allowed some devices that were sold before 1976 without agency approval to remain on sale without a thorough evaluation.

The devices include metal hip joints, dental implants and screws used for spinal surgery, an FDA notice said. The FDA oversees medical devices ranging from simple bandages and tongue depressors to the most complex products such as pacemakers and heart- valve replacements. Each is classified based on the level of risk to patients. The most dangerous are labeled “Class III” and subject to the most rigorous level of review.

Some Class III devices that were on the market before 1976 were allowed to go through a less stringent evaluation while the FDA developed regulations to address them or decided they were less risky.

In January, the Government Accountability Office criticized the FDA for failing to complete work on all of the pre-1976 Class III devices more than three decades later.

The GAO, a watchdog arm of Congress, urged the FDA to “expeditiously” deal with the remaining products. The order is the first step toward completing that process, FDA officials said.

“We are now committed to addressing this quickly,” Kate Cook, associate director of regulation and policy in the FDA’s device center, said in an interview.