In 2015, Biomet and Australian health authorities issued a safety alert for the company’s metal-on-metal M2a hip implants. The company issued subsequent alerts for these devices in the United Kingdom, Ireland, Denmark, Germany and Italy. Why haven’t these devices been subjected a recall in the United States?

The FDA did not recall this device because it had taken action years before the 2015 Biomet/Australia alert to address safety concerns and strengthen regulatory requirements for these products. In addition, as of May 2016 there are no FDA-approved metal-on-metal (MoM) total hip implants being marketed in the United States.

It is not always possible to compare devices marketed in different countries by specifying a model or tradename because of differences in manufacturing requirements across the globe. That said, in 2011, four years before the Australian Department of Health issued its 2015 hazard alert on certain Biomet MoM total hip implants, the FDA issued a Safety Communication summarizing safety issues related to all manufacturers’ MoM total hip implants marketed in the US, including those made by Biomet. The FDA then convened a 2012 meeting of the Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee for an open public dialogue among manufacturers, physicians, researchers, and patients to review the clinical performance and adverse events associated with MoM total hip implants. The goal was to better characterize the benefits and risks of these devices, and make recommendations for clinicians and patients based on the most current information available.

The following year, the FDA updated its Safety Communication with more detailed recommendations for patients and health care professionals. And on January 18, 2013 the FDA issued a proposed order to strengthen the regulatory oversight of all MoM total hip implants to require premarket approval (PMA), the most stringent regulatory category of the FDA’s oversight for medical devices. In the order, the FDA cited reports published by the Medicines and Healthcare Products Regulatory Agency (2010), the Australian Orthopaedic Association National Joint Replacement Registry (2010) and the American Academy of Orthopedic Surgeons (2011). The FDA cited these reports, along with recalls of MoM total hip implants in the US as indicative of risks associated MoM total hip implants, distinct from other types of bearing surfaces, as well as the potential for an increased risk of premature device revision. This historical information appears in detail on the FDA’s MoM hip implants webpage.

The final order requiring PMA approval for total MoM hip implants was published February 18, 2016 and went into effect in May 2016. This means that as of that date, all manufacturers of MoM total hip implants were required to cease marketing their devices in the U.S. and submit PMA applications that must be approved before the devices could be marketed in the U.S. In addition, FDA requested in the order that manufacturers take action to prevent the further use of MoM hips for which no PMA has been filed. After the effective date of the order, the FDA is not aware of any recalls in the U.S. for MoM bearing issues. There are currently no FDA-approved PMAs for MoM total hip implants.

REFERENCES

