OSMA

ORTHOPEDIC INSTRUMENT ACCESSORIES

Classification Challenges

Multiple Classifications for Same Instrument

Most are Class I as per published classification

Have been "upclassified" by FDA (Class II and III) through premarket review due to association with implant system

Instruments considered Class I exempt for many years until FDA began to communicate policy that instruments were accessories to implant system- i.e., "parent device"- and, therefore, took on the classification of the higher class implant system

- No formal guidance on submission requirements
- Inconsistent reviewer direction
- Does not address legacy instruments of the same type introduced to market at an earlier time point
- Introduces complexity for manufacturers in tracking multiple classifications for same instrument through internal PLM systems

Post-market Impact

Classifications also drive post-market requirements, which do not reflect relative risk of instrument vs. implant

- Example- Changes to design, manufacturing process or site of manufacture of a Class III instrument (e.g., broach used with Class III hip system), will require a PMA supplement

MDR Reporting/Recalls

- Using implant product code can cause confusion as to what devices are the subject of recalls or MDR reports
    - Some manufacturers have received queries from FDA asking for clarification due to use of implant product codes

UDI

Using implant product code causes mismatch with GMDN codes and descriptions

- Issue will magnify as UDI requirements are adopted by other Health Authorities

Class I reusable devices are not required to be direct part marked before September 2020

- UDI direct part marking compliance dates are September 2016 for Class III and September 2018 for Class II

OSMA Request

- With these complexities in mind, and with new classification/reclassification mechanisms afforded by FDARA, as well as the risk-based approach mandated by the 21st Century Cures Act, we ask FDA to consider appropriate reclassification action for the types of orthopedic instruments described above. **As these "device-specific" instruments have never been formally defined by FDA either through Guidance or Regulation, we respectfully request that FDA revert to its previous longstanding practice and treat all manual surgical instruments provided with Class II or Class III orthopedic implant systems as Class I (510(k)/PMA exempt) devices, in accordance with the already established Class I classification designations- i.e., *manual surgical instrument for general use 21 CFR § 878.4800 or orthopedic manual surgical instrument 21 CFR § 888.4540*, or other established Class I product codes. Alternatively, we request that FDA publish new classifications (with associated product code description(s)) for those instruments which FDA believes carry a higher risk, and, therefore, should be classified as Class II or III.**

Potential Paths Forward

- **Communicate revised FDA policy that new and currently marketed instruments can follow the classifications already defined by currently published regulations**
  - If necessary, appropriate risk-based rationales that are documented by manufacturers and subject to FDA review during QMS inspections could be compiled
- **Update FDA Accessories guidance** to reflect the revised policy (i.e., retrospective reclassification based on supporting internal documentation) or **publish new guidance that is specific to orthopedic instrument accessories**
- **Provide submission format and requirements for manufacturers to submit instrument reclassification requests *(not ideal pathway due to resource requirements and inefficiencies for both manufacturers and FDA)***
- **Other regulatory mechanisms** to address realignment of instrument classifications with currently published regulations? Mass updates to the GUDID database to align updated product codes/classifications?