Class 2 Recall Ascension Orthopedics PyroSphere CMC & PyroSphere TMT

See Related Information[22]

Date Posted	December 16, 2014
Recall Status[1]	Open
Recall Number	Z-0813-2015
Recall Event ID	69719[23]
Premarket Notification 510(K) Number	K060560[24]
Product Classification	Prosthesis, Toe, Hemi-, Phalangeal[25] - **Product Code** KWD[26]
Product	Ascension Orthopedics PyroSphere CMC & PyroSphere TMT, intended to replace the joint between the first metacarpal and the trapezium and 4th/5th tarsometatarsal where degenerative of post-traumatic arthritis presents. Size 10; Catalogue No. PCS-430-10-WW
Code Information	Lot numbers: 140098T and 140929T
Recalling Firm/ Manufacturer	Integra LifeSciences Corp. 311 Enterprise Dr Plainsboro, New Jersey 08536-3344
For Additional Information Contact	David E. Gronostajski 609-936-6822
Manufacturer Reason for Recall	Integra LifeSciences has determined that a portion of some specific lots of size 10 PyroSphere CMC and PyroSphere TMT devices are non-radiopaque.
FDA Determined Cause [2]	COMPONENT CONTROLS (GMP - GOOD MANUFACTURING PRACTICE): Nonconforming Material/Component
Action	The firm sent out written notification of the recall on 11/6/14. The letter instructed the consignees to quarantine and return any affected product.
Quantity in Commerce	19 units
Distribution	WA, Australia, and France
Total Product Life Cycle	TPLC Device Report[27]

[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[28]
[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

510(K) Database	510(K)s with Product Code = KWD and Original Applicant = ASCENSION ORTHOPEDICS, INC.[29]

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