Class 2 Recall
Ascension Orthopedics PyroSphere
CMC & PyroSphere TMT

Date Posted
December 16, 2014

Recall Status
Open

Recall Number
Z-0813-2015

Recall Event ID
69719

Premarket Notification
510(K) Number
K060569

Product Classification
Prosthesis, Toe, Hemi, Phalangeal - Product Code KWD

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
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

1 For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55
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.

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