FDA

Class 2 Device Recall Poly Component Trial, CR

See Related Information [22]

Date Initiated by Firm	February 20, 2017
Create Date	March 21, 2017
Recall Status[1]	Open[3], Classified
Recall Number	Z-1515-2017
Recall Event ID	76694[23]
510(K)Number	K150496[24]
Product Classification	Prosthesis, knee, patellofemorotibial, semi-constrained, cemented, polymer/metal/polymer[25] - **Product Code** JWH[26]
Product	Poly Component Trial, CR, packaged in the following sizes and configurations: a) Poly Component Trial - CR 3x10, REF 90-SRK-160310 b) Poly Component Trial - CR 3x12, REF 90-SRK-160312 c) Poly Component Trial - CR 3x14, REF 90-SRK-160314 d) Poly Component Trial - CR 4x10, REF 90-SRK-160410 e) Poly Component Trial - CR 4x12, REF 90-SRK-160412 f) Poly Component Trial - CR 4x14, REF 90-SRK-160414 g) Poly Component Trial - CR 5x10,REF 90-SRK-160510 h) Poly Component Trial - CR 5x12, REF 90-SRK-160512 i) Poly Component Trial - CR 5x14, REF 90-SRK-160514 j) Poly Component Trial - CR 6x10, REF 90-SRK-160610 k) Poly Component Trial - CR 6x12, REF 90-SRK-160612 l) Poly Component Trial - CR 6x14, REF 90-SRK-160614 The Responsive Orthopedics (RO) Total Knee Arthroplasty (TKA) System is intended to restore alignment, stability, range of motion, and alleviate pain by replacing the articulating surfaces of the knee joint
Code Information	Lot Numbers:, a) REF 90-SRK-160310, TU53730-01, b) REF 90-SRK-160312, TU53731-01, c) REF 90-SRK-160314, TU53732-01, d) REF 90-SRK-160410, TU53730-02, e) REF 90-SRK-160412, TU53731-02, f) REF 90-SRK-160414, TU53732-02, g) REF 90-SRK-160510, TU53730-03, h) REF 90-SRK-160512, TU53731-03, i) REF 90-SRK-160514, TU53732-03, j) REF 90-SRK-160610, TU53730-04, k) REF 90-SRK-160612, TU53731-04, l) REF 90-SRK-160614, TU53732-04.
Recalling Firm/ Manufacturer	Medtronic Sofamor Danek USA Inc *1800 Pyramid Pl* Memphis TN 38132-1703
For Additional Information Contact	Eric Epperson 901-344-1435
***Manufacturer Reason* for Recall**	*The dovetails of poly trials, Beta 2.0, were observed as either cracked or broken.*
FDA Determined Cause [2]	Under Investigation by firm
Action	Medtronic initiated their recall on 20 February 2017, by letter delivered by Fed Ex . The letter was addressed to the Risk/Materials Manager and stated that a Medtronic Clinical