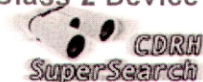




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Class 2 Device Recall Poly Component Trial, CR

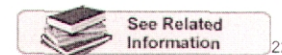


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Class 2 Device Recall Poly Component Trial, CR



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	<u>Prosthesis, knee, patellofemorotibial, semi-constrained, cemented, polymer/metal/polymer</u> ²⁵ - Product Code JWH ²⁶
Product	<p>Poly Component Trial, CR, packaged in the following sizes and configurations:</p> <ul style="list-style-type: none"> 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 <p>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</p>
Code Information	<p>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.</p>
Recalling Firm/Manufacturer	<p>Medtronic Sofamor Danek USA Inc 1800 Pyramid Pl Memphis TN 38132-1703</p>
For Additional Information Contact	<p>Eric Epperson 901-344-1435</p>
Manufacturer Reason for Recall	<p><i>The dovetails of poly trials, Beta 2.0, were observed as either cracked or broken.</i></p>
FDA Determined Cause ²	<p>Under Investigation by firm</p>
Action	<p>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</p>