Class 2 Device Recall Dermabond "Prineo" System

See Related Information[22]

Date Initiated by Firm	November 27, 2017
Create Date	March 21, 2018
Recall Status[1]	Open[3], Classified
Recall Number	Z-1147-2018
Recall Event ID	79355[23]
510(K)Number	K133864[24]
Product Classification	Prosthesis, hip, semi-constrained, polyurethane acetabular bearing surface, cemented or uncemented - **Product Code** OMO
Product	DERMABOND" PRINEO" Skin Closure System Product Usage: DERMABOND PRINEO System is intended for topical application only to hold closed easily approximated skin edges of wounds from surgical incisions, including punctures from minimally invasive surgery, and simple, thoroughly cleansed, trauma-induced lacerations. DERMABOND PRINEO System should be used in conjunction with, but not in place of, deep dermal stitches. Additionally, the adjunct wound closure device component maintains temporary skin edge alignment along the length of the wound durinQ application of the liquid adhesive
Code Information	LEJ230, LEJ246, LEJ259, LEJ368, LGP375, LGP605, LGP606, LGP675, LGP814, LGR689, LGR710, LGR756, LHH468, LHH469, LHH560, LHH608, LHH686, LHH784, LHP498, LHP599, LHP602, LHP868.
Recalling Firm/ Manufacturer	Ethicon, Inc. Us Highway 22 West Somerville NJ 08876
For Additional Information Contact	Tom Morris 908-218-0707
Manufacturer Reason for Recall	Ethicon discovered that specific lots of DERMABOND"PRINEO"System may not dry within the specified time after proper application, and thus may fall off.
FDA Determined Cause [2]	Component change control
Action	Ethicon sent an URGENT MEDICAL DEVICE RECALL REMOVAL letter dated November 2017 to customers titled: "DERMABONDTM PRINEOTM SKIN CLOSURE SYSTEM (22 CM)". The letter identified the affected product, problem and action to be taken. The letter instructed customers to do not use or distribute any product which is subject to recall. Customers are asked to examine inventory, quarantine products that are subject to recall and contact the firm for return of product. Also, post the recall letter in a visible location at facility. If you have additional questions regarding this recall (removal) or to report any customer complaints, please contact Ethicon Customer Support Center at 1-877-ETHICON (1-877-384-4266). The Customer Support Center is open Monday through Friday, 7:30 AM to 6:30 PM ET.
Quantity in Commerce	20,090 eaches (10,545 units)