Class 2 Device Recall ETHIBOND EXCEL ETHIBOND Polvester Suture

See Related Information[22]

Class 2 Device Recall ETHIBOND EXCEL ETHIBOND Polvester Suture

Date Initiated by Firm	April 19, 2019
Create Date	June 19, 2019
Recall Status[1]	Open[3], Classified
Recall Number	Z-1842-2019
Recall Event ID	82909[23]
510(K)Number	K946173[24]
Product Classification	Suture, nonabsorbable, steel, monofilament and multifilament, sterile[25] - **Product Code** GAQ[26]
Product	ETHIBOND EXCEL ETHIBOND Polvester Suture-Green 75cm USP1 Single Armed CTX Product Code: X865W Product Usage: ETHIBOND EXCEL Suture is intended for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic and neurological procedures
Code Information	Lot Code:PBQ797
Recalling Firm/ Manufacturer	Ethicon, Inc. Us Highway 22 West Somerville NJ 08876
For Additional	SAME

Information Contact	908-218-0707
Manufacturer Reason for Recall	Possibility that a suture raw material containing high endotoxin levels was used in the manufacturing of this lot
FDA Determined Cause [2]	Material/Component Contamination
Action	Ethicon notified primary and secondary US consignees by telephone on 4/19/19 and follow-up letter dated April 24, 2019 stating reason for recall, health risk and action to take: examine inventory, remove product for return. Complete the Business Reply Form (BRF) to Stericycle at 1-844-721-3045 or ethicon5905@stericycle.com. Questions regarding this action or to report any customer complaints, please contact your Ethicon sales representative or contact Ethicon Customer Support Center at 1-877-ETHICON (1-877-384-4266). The Customer Support Center is open Monday through Friday, 8:00 AM to 6:00 PM ET.
Quantity in Commerce	36 eaches
Distribution	Worldwide - US Nationwide Distribution - IA, NJ, RI, TX, WV Foreign: Canada
Total Product Life Cycle	TPLC Device Report[27]

[1] A record in this database is created when a firm initiates a correction or removal action. The record is updated if the FDA identifies a violation and classifies the action as a recall, and it is updated for a final time when the recall is terminated. Learn more about medical device recalls[28].

[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

[3] The manufacturer has initiated the recall and not all products have been corrected or removed. This record will be updated as the status changes.

510(K) Database	510(K)s with Product Code = GAQ and Original Applicant = ETHICON, INC.[29]

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22. http://www.fda.gov/safety/recalls/enforcementreports/default.htm
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27. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm?id=GAQ
28. http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm329946.htm
29. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm?start_search=1&productcode=GAQ&knumber=&applicant=ETHICON%2C%20INC%2E

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21. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm
22. http://www.fda.gov/safety/recalls/enforcementreports/default.htm
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