Class 2 Device Recall: Sengstaken Tube and Sengstaken-Blakemore Tube

Date Posted: April 24, 2014
Recall Status: Open
Recall Number: Z-1508-2014
Recall Event ID: 0764P22
Premarket Notification 510(K) Numbers: K97389223, K98120324
Product Classification: Tubes. Gastrointestinal (And Accessories), Product Code KNT25
Product: Sengstaken Tube and Sengstaken-Blakemore Tube. Teleflex product codes 204820, 204821, and 2048203, a gastrointestinal tube and accessories, consisting of flexible or semi-rigid tubing used for instilling fluids into, withdrawing fluids from, splinting, or suppressing bleeding of the alimentary tract.
Code Information: Lots 10251, 10201, 10301, 10401, 10481, 10381, 11041, 11321, 12151, 12231, 1226, 11201, 12311, 123821, 12474, 13151, 13191, 13211, 13261, 13381
Recalling Firm/Manufacturer: Teleflex Medical
4024 Stirrup Creek Dr
Durham, North Carolina 27703-9000
For Additional Information Contact: Michael T. Taggart
919-433-4616
Manufacturer Reason for Recall: Stability of the product cannot be guaranteed.
Action: Letters were issued on 3/4/2014 to consignees asking them to immediately discontinue use and quarantine any products with the recalled catalog numbers. Distributors were also asked to conduct a sub-recall. The recall letters included a Recall Acknowledgment Form which was to be faxed back to Teleflex.
Quantity in Commerce: 117,601 ea.
Distribution: Worldwide Distribution—USA (nationwide) including the states of AL, AK, AR, GA, CO, FL, GA, ID, IL, IA, KY, LA, MD, MA, MI, MN, MS, MO, NE, NH, NJ, NM, NY, NC, OH, PA, SC, TN, TX, UT, VT, VA, WA, WV, and WI, and the countries of Algeria, Andorra, Armenia, Argentina, Austria, Australia, Azerbaijan, Belarus, Bermuda, Bahamas, Bolivia, Brazil, Canada, Chile, China, Costa Rica, Cyprus, Czechoslovakia, Denmark, Estonia, Egypt, Finland, France, Great Britain, Georgia, Guadeloupe, Greece, Guyana, Curacao, Hungary, Israel, India, Italy, Jordan, Japan, Kuwait, Kazakhstan, Luxembourg, Latvia, Libya, Madagascar, Macedonia, Martinique, Malta, Mauritius, Mexico, Nicaragua, Nigeria, Netherlands, Norway, Oman, Peru, French Polynesia, Poland, Portugal, San Marino, Singapore, Spain, Suriname, San Salvador, Thailand, Tunisia, Turkey, Uruguay, Uzbekistan, Wallis & Futuna Islands, Zambia.
Total Product Life Cycle: TPLC Device Report27

1 For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.5528

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=125902
5/5/2014