Class 2 Device Recall da Vinci Si Surgical System IS3000, Disposable Accessory Kit

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Date Posted	April 06, 2015
Recall Status[1]	Open
Recall Number	Z-1393-2015
Recall Event ID	70777
Premarket Notification 510(K) Number	K050322
Product Classification	Drape, Surgical - **Product Code** KKX
Product	da Vinci Si Surgical System IS3000, Disposable Accessory Kit, 4 ARM, 5 Pack. Microtek Medical Equipment Drapes are to be used to cover a variety of surgical and non-surgical equipment in various settings throughout the clinical setting.
Code Information	Product number 420291-03; da Vinci Si Disposable Accessory Kit, 4 ARM, 5 Pack. Lot Numbers for Cloudy/Waxy issue: ALL lot numbers Lot Numbers for Tear issue: D142185, D142195, D142195A, D142205, D142215, D142255, D142255A, D142265, D142265A, D142325, D142325A, D142335, D142335A, D142345, D142395, D142405, D142405A, D142415, D142415A, D142445, D142445A, D142455, D142455A, D142535, D142545, D142545A, D142555, D142555A, D142585, D142585A, D142595, D142595A, D142675, D142675A, D142685, D142685A, D142695, D142695A, D142745, D142745A, D142755, D142765, D142805, D142805A, D142815, D142815A, D142825, D142865, D142865, D142865A, D142875, D142875A, D142885, D142915, D142935, D142935A, D142945, D142975, D142975A, D142985, D143005, D143075, D143075A, D143085, D143085A, D143095, D143115, D143115A, D143155, D143235, D143245, D143255, D143285, D143285A, D143295, D143335, D143355, D143355A, D143365, D143365A, D143405, D143425, D143425A, D143435, D143435A, D143465, D143495, D143495A, D143505, D143505A, D143515, D150065, D150065A, D150075, D150075A, D150135, D150135A, D150145, D150145A, D150205, D150215, D150285, D150285A, D150295, D150335, D150335A, D150345, D150405, D150405A, D150415, D150495, D150495A, D150505, D150505A, D150515, D150515A, D150555, D150565, D150565A, D150625, D150625A, D150635, D150695, DA142585, DA150335, DA150405

Recalling Firm/ Manufacturer	Intuitive Surgical, Inc. 1266 Kifer Rd Bldg 100 Sunnyvale, California 94086-5304
FDA Determined Cause [2]	PRODUCTION CONTROLS: Packaging Process Control
Action	Firm issued field safety notice to all customers on March 16, 2015. Field safety notice includes acknowledgement form to be returned to recalling firm.
Quantity in Commerce	442,475 total for all drape models
Distribution	Worldwide Distribution-Argentina, Australia, Austria, Belgium, Brazil, Bulgaria, Canada, Chile, China (including Hong Kong), Colombia, Cyprus, Czech Republic, Denmark, Dominican Republic, Ecuador, Egypt, Finland, France, France, Germany, Greece, Iceland, India, Indonesia, Ireland, Israel, Italy, Japan, Kuwait, Lebanon, Luxembourg, Malaysia, Mauritius, Mexico, Monaco, Netherlands, New Zealand, Norway, Pakistan, Panama, Philippines, Poland, Portugal, Puerto Rico, Qatar, Romania, Russia, Saudi Arabia, Singapore, Slovakia, Slovenia, South Africa, South Korea, Spain, Sweden, Switzerland, Switzerland, Taiwan, Thailand, Turkey, United Arab Emirates, United Kingdom, United States, Uruguay, Venezuela, Vietnam.
Total Product Life Cycle	TPLC Device Report

[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55

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

510(K) Database

510(K)s with Product Code = KKX and Original Applicant = MICROTEK MEDICAL, INC.

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U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Email FDA