FDA

Class 1 Device Recall Roche CoaguChek XS System Prothrombin time test

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See Related Information[22]

Date Initiated by Firm	September 13, 2018
Date Posted	November 02, 2018
Recall Status[1]	Open[3], Classified
Recall Number	Z-0360-2019
Recall Event ID	81093[23]
510(K)Number	K093460[24] K071041[25] K180684[26] K170960[27]
Product Classification	Test, time, prothrombin[28] - **Product Code** GJS[29]
Product	CoaguChek¿ XS System Prothrombin time test: CoaguChek XS PT Test 2X24 Strips, Catalog Number: 04625315160; CoaguChek XS PT Test 6 Strips, Catalog Number: 04625374160; CoaguChek XS PT Test 24 Tests, Catalog Number: 07797826160;
Code Information	Lot numbers: 28124111, 28124121, 28631911, 28631921, 28631924, 28632021, 28632213, 28632312, 28632412, 29415113, 29415123, 29494221, 29494312, 29494613, 29494711, 29778721, 29779012, 29779213, 29779214, 30497213, 30497311, 30497413, 30497423, 30497515, 31404314, 31404821, 32264116, 32264212, 32264316, 32264317, 32264411, 32264421, 33045913, 33046011, 33046113, 33046312, 33046314, 33046321, 33046322, 33449612, 33449712, 33449723, 33449817
Recalling Firm/ Manufacturer	Roche Diagnostics Corporation 9115 Hague Rd Indianapolis IN 46256-1025
For Additional Information Contact	SAME 317-5214343
Manufacturer Reason for Recall	Abnormally high INR test results with the affected CoaguChek test strips
FDA Determined Cause [2]	Nonconforming Material/Component
Action	Roche issued URGENT MEDICAL DEVICE RECALL AMENDMENT letters dated 11/5/18 advising customers patients, HCPs, IDTFs, HCP distributors and HCP/patient distributors. Distributors are advised to take the following actions: - Read the Urgent Medical Device Recall Amendment for Healthcare Professionals and Clinics Furnishing PT/INR Test Strips to Patients for Home Testing Use (TP-00454). - Distribute a copy of the Urgent Medical Device Recall Amendment TP-00454 to healthcare professionals to whom you have directly shipped affected test strips. - Stop distribution of all affected CoaguChek XS PT Test Strip lots. - Complete all sections of the fax form (TP-00462) and fax it to number 1-888-627-2279 or email it to roche3866@stericycle.com. - Return all affected product following the instructions outlined in this Urgent Medical Device Recall Amendment. Independent Diagnostic Testing Facilities should take the following action: - Read the Urgent Medical Device Recall Amendment for CoaguChek Patients (TP-00453) and Urgent Medical Device Recall Amendment for Healthcare Professionals and Clinics Furnishing PT/INR Test Strips to Patients for Home Testing Use (TP-00454). - Distribute a copy of the Urgent Medical Device