

K904589 KODAK SURECELL(TM) STREP A CONTROL FLUID SETJan 18, 1991
101 days to decisionK904589 · Product code: **GTY** · Microbiology
Source: <https://www.510kdatabase.net/k904589/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antigens, All Groups, Streptococcus Spp. (GTY)
Date received	Oct 9, 1990
Decision date	Jan 18, 1991
Days to decision	101 days
Third-party review	No

APPLICANT

Company	Eastman Kodak Company
Location	Mchenry, IL, US
Contact	NORMAN H GEIL
Website	http://www.kodak.com
510(k) history	238 submissions · 238 cleared · 1977-2006

Eastman Kodak Company is a diversified imaging and materials manufacturer headquartered in McHenry, US. The company has a long history in advanced materials, chemicals, and imaging technologies. Eastman Kodak maintains a significant regulatory history in medical imaging devices. The company received FDA 510(k) clearances from total submissions, with clearances spanning from 1977 to 2006. The company's cleared devices focused primarily on radiology and medical imaging systems, including digital radiography systems, picture archiving and communication systems (PACS), and re...

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