FDA 510(k) Premarket Notification

K973430 KODAK PRO-MEDICAL DIGITAL CAMERA SYSTEM

CLEARED

Jul 17, 1998
310 days to decision

K973430 · Product code: **GCJ** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k973430/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laparoscope, General & Plastic Surgery (GCJ)
Date received	Sep 10, 1997
Decision date	Jul 17, 1998
Days to decision	310 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Eastman Kodak Company**
Location	Mchenry, IL, US
Contact	PHIL AMATO
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...