FDA 510(k) Premarket Notification

K813139 KODAK INTENSIFYING SCREEN SO-168

CLEARED

Dec 8, 1981
32 days to decision

K813139 · Product code: **EAM** · Radiology
Source: https://www.510kdatabase.net/k813139/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Screen, Intensifying, Radiographic (EAM)
Date received	Nov 6, 1981
Decision date	Dec 8, 1981
Days to decision	32 days
Third-party review	No

APPLICANT

Company	**Eastman Kodak Company**
Location	Mchenry, IL, US
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...