FDA 510(k) Premarket Notification

K972921 SANKO INTRAORAL DENTAL X-RAY

CLEARED

Jan 6, 1998
151 days to decision

K972921 · Product code: **EHD** · Radiology
Source: https://www.510kdatabase.net/k972921/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, X-ray, Extraoral With Timer (EHD)
Date received	Aug 8, 1997
Decision date	Jan 6, 1998
Days to decision	151 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Sanko X-Ray Manufacturing Co., Ltd.**
Location	Virginia Beach, VA, US
Contact	WARREN E SACHS
510(k) history	1 submissions · 1 cleared · 1998-1998