FDA 510(k) Premarket Notification

K030466 HANDYDOP

CLEARED

Sep 12, 2003
212 days to decision

K030466 · Product code: **KNG** · Radiology
Source: https://www.510kdatabase.net/k030466/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Monitor, Ultrasonic, Fetal (KNG)
Date received	Feb 12, 2003
Decision date	Sep 12, 2003
Days to decision	212 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Elcat, GmbH**
Location	Alpharetta, GA, US
Contact	JAY MANSOUR
510(k) history	1 submissions · 1 cleared · 2003-2003