FDA 510(k) Premarket Notification

K140013 SOPIX INSIDE, SOPIX2 INSIDE

CLEARED

Sep 5, 2014
246 days to decision

K140013 · Product code: **MUH** · Radiology
Source: https://www.510kdatabase.net/k140013/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Extraoral Source, Digital (MUH)
Date received	Jan 2, 2014
Decision date	Sep 5, 2014
Days to decision	246 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Sopro - Acteon Group**
Location	Mt. Laurel, NJ, US
Contact	RICK ROSATI
510(k) history	4 submissions · 4 cleared · 2014-2016