FDA 510(k) Premarket Notification

K992114 KSEA CALCUSPLIT

CLEARED

Aug 18, 1999
57 days to decision

K992114 · Product code: **FFK** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k992114/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lithotriptor, Electro-hydraulic (FFK)
Date received	Jun 22, 1999
Decision date	Aug 18, 1999
Days to decision	57 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Karl Storz Endoscopy**
Location	Culver City, CA, US
Contact	KEVIN A KENNAN
510(k) history	35 submissions · 35 cleared · 1995-2005