FDA 510(k) Premarket Notification

K904801 ORION LIFE SYSTEMS REPLACEMENT GASTROSTOMY TUBE

CLEARED

Jan 16, 1991
84 days to decision

K904801 · Product code: **KGC** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k904801/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tube, Gastro-enterostomy (KGC)
Date received	Oct 24, 1990
Decision date	Jan 16, 1991
Days to decision	84 days
Third-party review	No

APPLICANT

Company	**Orion Life Systems, Inc.**
Location	Wheeling, IL, US
Contact	JOHN L LAEMMAR
510(k) history	33 submissions · 16 cleared · 1990-1995