FDA 510(k) Premarket Notification

K954352 BITE BLOCK

CLEARED

Jan 25, 1996
129 days to decision

K954352 · Product code: **JXL** · Neurology
Source: https://www.510kdatabase.net/k954352/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Block, Bite (JXL)
Date received	Sep 18, 1995
Decision date	Jan 25, 1996
Days to decision	129 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**United States Endoscopy Group, Inc.**
Location	Mentor, OH, US
Contact	GRETCHEN YOUNKER
510(k) history	94 submissions · 92 cleared · 1991-2020