FDA 510(k) Premarket Notification

K964661 HX-20/21-1 ENDOSCOPIC LIGATOR

CLEARED

Oct 30, 1997
344 days to decision

K964661 · Product code: **MND** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k964661/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ligator, Esophageal (MND)
Date received	Nov 20, 1996
Decision date	Oct 30, 1997
Days to decision	344 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Olympus America, Inc.**
Location	Lake Success, NY, US
Contact	SUBHASH PATEL
510(k) history	149 submissions · 149 cleared · 1994-2012