FDA 510(k) Premarket Notification

K944200 HI-Q HAND INSTRUMENTS, OB/GYN USE

CLEARED

Sep 15, 1995
382 days to decision

K944200 · Product code: **HET** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k944200/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laparoscope, Gynecologic (and Accessories) (HET)
Date received	Aug 29, 1994
Decision date	Sep 15, 1995
Days to decision	382 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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