FDA 510(k) Premarket Notification

K830019 AMNIO CENTESES KIT W/NEEDLE

CLEARED

Jan 18, 1983
14 days to decision

K830019 · Product code: **HIO** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k830019/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sampler, Amniotic Fluid (amniocentesis Tray) (HIO)
Date received	Jan 4, 1983
Decision date	Jan 18, 1983
Days to decision	14 days
Third-party review	No

APPLICANT

Company	**Universal Medical Instrument Corp.**
Location	Mchenry, IL, US
510(k) history	21 submissions · 21 cleared · 1977-1996