FDA 510(k) Premarket Notification

K120154 INTRAUTERINE INSEMINATION (IUI) CATHETER

CLEARED

Mar 21, 2012
63 days to decision

K120154 · Product code: **MQF** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k120154/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Catheter, Assisted Reproduction (MQF)
Date received	Jan 18, 2012
Decision date	Mar 21, 2012
Days to decision	63 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Catheter Research, Inc.**
Location	Indianapolis, IN, US
Contact	BABACAR DIOUF
510(k) history	8 submissions · 8 cleared · 1994-2013