FDA 510(k) Premarket Notification

K130817 LTN - LAPAROSCOPIC SURGICAL MESH

CLEARED

Apr 17, 2013
23 days to decision

K130817 · Product code: **OXK** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k130817/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Mesh, Surgical, Collagen, Large Abdominal Wall Defects (OXK)
Date received	Mar 25, 2013
Decision date	Apr 17, 2013
Days to decision	23 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Lifecell Corp.**
Location	Washington, DC, US
Contact	JOHN BLEWITT
Website	http://www.lifecell.com/
510(k) history	10 submissions · 10 cleared · 2005-2013