FDA 510(k) Premarket Notification

K123394 CORELEADER HYDRO-HEALER HYDROCOLLOID WOUND DRESSING

CLEARED

Jun 6, 2013
216 days to decision

K123394 · Product code: **FRO** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k123394/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dressing, Wound, Drug (FRO)
Date received	Nov 2, 2012
Decision date	Jun 6, 2013
Days to decision	216 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Coreleader Biotech Co., Ltd.**
Location	Taipei, Taiwan, TW
Contact	VINCENT HUANG
510(k) history	9 submissions · 9 cleared · 2011-2015

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k123394/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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