FDA 510(k) Premarket Notification

K112805 KIMGUARD ONE-STEP STERILIZATION WRAP

CLEARED

Jun 22, 2012
269 days to decision

K112805 · Product code: **FRG** · General Hospital
Source: https://www.510kdatabase.net/k112805/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wrap, Sterilization (FRG)
Date received	Sep 27, 2011
Decision date	Jun 22, 2012
Days to decision	269 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Kimberly-Clark Corp.**
Location	Mchenry, IL, US
Contact	Brenda Shelkey
Website	http://www.Kimberly-Clark.com
510(k) history	104 submissions · 103 cleared · 1978-2014

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k112805/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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