

K161195 Royal Condoms (Natural, Black Grape, Coffee, Strawberry, and Chocolate Flavors)

Aug 25, 2016
120 days to decision

K161195 · Product code: **HIS** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k161195/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Condom (HIS)
Date received	Apr 27, 2016
Decision date	Aug 25, 2016
Days to decision	120 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	M3 Global Enterprises, LLC
Location	Beavercreek, OH, US
Contact	NEIL MEHTA
510(k) history	1 submissions · 1 cleared · 2016-2016

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k161195/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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