

**K213547 SKORE Smooth Condoms - SKORE Colors & Flavors,  
SKORE Smooth Condoms - SKORE Vanilla**Dec 23, 2021  
45 days to decisionK213547 · Product code: **HIS** · Obstetrics & Gynecology  
Source: <https://www.510kdatabase.net/k213547/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Condom (HIS)
Date received	Nov 8, 2021
Decision date	Dec 23, 2021
Days to decision	45 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ttk Healthcare Limited</b>
Location	Puducherry, IN
Contact	Daniel J S
510(k) history	3 submissions · 3 cleared · 2021-2023

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k213547/>. Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated May 25, 2026