

K202403 SKORE (Colors & Flavors), SKORE (Colors)Apr 15, 2021
237 days to decisionK202403 · Product code: **HIS** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k202403/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Condom (HIS)
Date received	Aug 21, 2020
Decision date	Apr 15, 2021
Days to decision	237 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k202403/> Data sourced from FDA 510(k) public records (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. - Generated May 25, 2026