

K230049 SKORE Smooth, Dotted, Thin Condoms - SKORE Blues, SKORE Belgian Chocolate, SKORE Dots, SKORE NOTHING Strawberry, SKORE NOTHING Chocolate, SKORE SKIN THIN Ultra fine

Sep 7, 2023
244 days to decision

K230049 · Product code: **HIS** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k230049/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Condom (HIS)
Date received	Jan 6, 2023
Decision date	Sep 7, 2023
Days to decision	244 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	SKORE Bulbous Condoms - SKORE WARM, SKORE COOL; SKORE Benzocaine Condoms - SKORE NOTHING Climax Delay, SKORE DUO MAX, SKORE NOT OUT

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.net

Device record: <https://www.510kdatabase.net/k230049/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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