

PLEASURE LATEX PRODUCTS SDN. BHD. (402137-W)
FDA 510 (K) PREMARKET NOTIFICATIONS DEVICE LIST

Rev: 05

Device Name	Surface Texture	Width	Lubricant	Colour	Flavour	Regulation Number	Product Code	510 (k) Number	Decision Date
"SURE" Latex Ultrasonic Probe Cover	Plain	51 ± 2 mm	Unlubricated	Natural	-	892.1570	90 ITX	K022156	11-Sep-2003
Colored and Flavored Male Latex Condom	Smooth ,Dotted , Ribbed , Contoured (3in1)	52 ± 2 mm	Silicone / N-9 with PEG	RD, BL, GN, BK	ST, MT, VL, LR	884.5300 884.5310	85 HIS 85 LTZ	K023333	23-Jun-2003
Latex Condom with Dotted-Ribbed-Contoured	Dotted-Ribbed-Contoured (3in1)	53 ± 2 mm	Silicone (Polydimethylsiloxane)	Natural	-	884.5300	85 HIS	K021875	5-Sep-2002
Male Latex Condom with Ribbed Surface	Ribbed	52mm	Silicone (Polydimethylsiloxane)	Natural	-	884.5300	85 HIS	K020272	26-Apr-2002
Multiple Male Latex Condom	Plain	52 ± 2 mm	Silicone (Polydimethylsiloxane)	Natural	-	884.5300	85 HIS	K002571	16-Nov-2000
Spermicidal Lubricated Male Latex Condom	Plain	53mm	Nonoxynol-9 with Polyethylene Glycol	Natural	-	884.5310	85 LTZ	K001377	8-Jun-2000
Male Latex Condom with Dotted Surface	Dotted	53mm	Silicone	Natural	-	884.5300	85 HIS	K001221	19-May-2000
Male Latex Condom with Vanilla flavour, 56mm width	Plain	56mm	Silicone	Natural	Vanilla	884.5300	85 HIS	K994311	21-Mar-2000
Male Latex Condom, 56mm	Plain	56mm	Silicone	Natural	-	884.5300	85 HIS	K994312	21-Mar-2000
"SURE" Condom (Natural Rubber Latex Contraceptive)	Plain	53mm	Silicone	Natural	-	884.5300	85 HIS	K982380	26-Feb-1999

FDA REGISTER

1. Registration No.: 9613994
2. Owner/Operator ID : 9032729
3. Device Listing For Non-Spermicidal Condom : D009946
4. Device Listing For Spermicidal Condom : D009950
5. Device Listing For Probe Cover : D009939

COLOUR

1. RD - Red
2. BL - Blue
3. GN- Green
4. BK - Black

FLAVOUR

1. ST - Strawberry
2. MT - Mint
3. VL - Vanilla
4. LR - Licorice

Your truly,
 PLEASURE LATEX PRODUCTS SDN.BHD.

Irene Ting
 QA Manager
 Date: 18th Feb 2021

