

Degania Silicone

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ef. 510 K number K 953864

Product: Silclear Tubing with color coded stripe (Modification)
Trade name: Degania Silicone Silclear Tubing
Common name: Silicone Tubing
Product code: FPK (51 0 (k) product code of K943992)
Device Class: I
Classification Pane 1 : General & Plastic Surg
Establishment registration number: 8030107

510(K) SUMMARY

This summary of 510K safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807: 92.

DEVICE DESCRIPTION AND USE:

The Degania Silicone Silclear Tubing with color coded stripes is a transparent silicone tubing with radiopaque or regular colored stripes extruded inside the tubing wall.

The color coded tubing can be used in a variety of situations in the laboratory or hospital where coding is desirable.

MANUFACTURING:

The Degania Silicone Color Coded Tubing is manufactured according to Good Manufacturing Practices and tested according to Standard Operating Procedures in an Environmentally Controlled Area. The manufacturing processes are approximately the same for both the regular and the color coded tubing.

BIOCOMPATIBILITY:

The Degania Silicone Tubing (510(k) number K 943992) has been evaluated according to the U.S. FDA TRIPARTITE GUIDANCE and ISO 10993-1 in April/May 1995. The test selection was based on tissue contact for up to 30 days. The full laboratory report is held by Degania Silicone Ltd.

The colors are Masterbatch Silicone Pastes that are being used in other products that have been tested to USP Class VI. The Barium Sulfate has been used in other products that have been tested to USP Class VI and Tripartite (up to 30 day tissue contact).

Bette Lubin

Nov. 2, 1995

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 Product Advisor
 Degania Silicone Ltd.

Date