Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852
Re: Docket No. 02N-0555 General and Plastic Surgery Devices; Classification of Silicone Sheeting

Dear Staff:

This letter is in response to the above Docket No. regarding the Classification of Silicone Sheeting.

Silimed is in complete support of your proposal to classify silicone sheeting intended to manage hyperproliferative (hypertrophic and keloid) scars on intact skin into Class I (general controls) and to exempt the device from premarket notification.

We have done a review of the history of silicone sheeting and its extensive application for treatment of hyperproliferative scars on intact skin. Silicones have definitely proven beneficial in a variety of forms as effective topical products including modifying scarring. The attached bibliography supports treatment of hyperproliferative scars on intact skin.

Medical grade silicones have now been used in topical skin care products over the past 50 years. Medical grade silicone is the most biocompatible material available. The non reactivity of silicone prevents most other materials from interacting with it. They are in fact so non-reactive that they are used to establish the base line for all materials compatibility. It is used to coat all medical grade tubing, blood storage bottles, needles and syringes as it is one of the only materials that will not damage blood cells. Silicones have repeatedly demonstrated that they are versatile, non-toxic and beneficial as a topical product.

We appreciate the opportunity to provide comments regarding this issue. If you have any questions for us, please feel free to contact me.

Sincerely,

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ADDITIONAL PUBLICATIONS


ADDITIONAL PUBLICATIONS (cont'd)


