K961119

510(k) Summary

1. **Summary**

Summarized below is the safety and effectiveness information compiled in support of claims of substantial equivalence (as defined in the FD&C Act).

2. **Submitter:**

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Date of Submission: March 15, 1996

Device trade name: CAREFREE® Scented Pantyliner
CAREFREE® Lightly Scented Pantyliner

Device common name: Panty Shield

Device classification: Scented or scented deodorized menstrual pad
(Ref. 21 CFR 884.5425)

4. **The modified device** is substantially equivalent to CAREFREE® Panty Shield, a Pre-Amendments device what was on the market prior to May 28, 1976.

5. **Description**. The modified device and the Pre-amendments device are both ultrathin, beltless, absorbent feminine napkins made of absorbent material. A fragrance is added for aesthetic purposes.

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510(k) Summary *(continued)*

6. **Intended Use**: The modified device and the pre-amendments device are both used to absorb small amounts of menstrual or other vaginal discharge.

7. **Technological Characteristics**
The modified device and the pre-amendments device are both comprised of a nonwoven cover, repellent barrier, perfume, adhesive, and release paper. They are available as lightly scented and scented products

8. **Performance Data**
Johnson & Johnson Worldwide Absorbent Products and Materials Research has conducted a thorough program to evaluate the safety of the Modified Device. This program consisted of the following:

Pre-Clinical Testing

1. *Acute Exposure Oral Toxicity - Rats*

The purpose of this study was to evaluate the single dose oral toxicity of the two perfumes using a single exposure and a 14-day post-exposure observation period. The acute oral LD_{50} for the two perfumes was found to be greater than 5 mL/kg of a 1.1% solution.

2. *CHO Mammalian Cell Cytotoxicity Assay*

The purpose of this study was to assess the biocompatibility of the two perfumes by measuring their cytotoxicity in the CHO-K1-BH4 mammalian cell line. Results showed a reduction in viability of the hamster ovary cells for both perfumes

3. *Guinea Pig Sensitization Maximization Test (Magnusson-Kligman)*

The purpose of this study was to determine the contact dermal sensitization potential of the two perfumes in guinea pigs. Two studies were performed. In the first study, exaggerated levels of both perfumes were used. Results of this study showed that under these conditions, both perfumes caused weak to moderate sensitization in guinea pigs.

In the second study, the concentrations of the perfumes tested were close to actual perfume levels in the pad. The results of this second study indicate that under the conditions of the test and at the concentrations tested, neither perfume caused sensitization in guinea pigs.

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510(k) Summary *(continued)*

Pre-Clinical Testing *(continued)*

4. *Primary Dermal Irritation Study - Rabbits*

The purpose of this study was to determine the potential irritant and/or corrosive effects of the perfumes on the skin of rabbits. The Dermal Irritation Toxicity Category for both perfumes was considered to be Class IV - Mild or Slight Irritation at 72 Hours. The Primary Dermal Irritation Index for both fragrances was considered "slight"

5. *Primary Eye Irritation Study - Rabbits*

The purpose of this study was to evaluate the potential eye irritation and/or corrosive effects produced by the two perfumes. Both perfumes were found to be non-irritating at the concentrations tested.

Clinical Testing

6. *Repeated Insult Patch Test (RIPT) - Humans*

The purpose of this study was to demonstrate, by epidermal contact, the primary or cumulative irritation and/or sensitization potential of the perfumes. Under the conditions of this study, neither perfume indicated a potential for dermal irritation and/or sensitization

9. **Conclusions**

The modification to this device does not raise **new** types of safety or effectiveness questions. Accepted scientific methods were utilized to assess the effects of the modification. On the basis of the testing information we conclude that the data provided demonstrate that the Modified Device is safe for its intended use.

Based on the 510(k) Substantial Equivalence Decision-Making Process review as shown and the testing information provided, we believe that the Modified Device is substantially equivalent to the Pre-Amendments Device.