

SanPoint

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Your ref

Our ref

Mariefred

May 9, 1996

510(K) SUMMARY

SanPoint AB, Bergåsa Industriområde, P.O.Box 55, S-647 22 Mariefred, Sweden, telephone 011-46-159-10610, fax 011-46-159-21317, here represented by

Talbot S. Lindström, Advokatfirman Delphi, Sergels Torg 12, P.O.Box 1432, S-11184 Stockholm, Sweden, telephone 011-46-8-6775400, fax 011-46-8-201884,

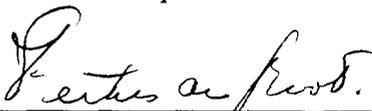
is a manufacturer of digital tampons since 1974, and the first to introduce a 100% cotton tampon in 1988.

The subjects of this submittee's summary are: "digital all-cotton tampons for feminine hygiene", and are of the same make and construction as the brand "Natracare" currently sold by our distributor Body Wise (UK) Ltd., Bristol, with office in Denver, USA, on the US and Canadian market, items which are approved by FDA.

The SanPoint product comprises a digital tampon of 100% peroxide bleached virgin cotton, and used to absorb menstrual and other vaginal discharges, when inserted in the vagina. The tampon also has a cotton string attached, enabling the user to remove the tampon after use.

An adequate instruction for use, as well as a clear warning for TSS, will accompany each package.

The purpose of this submitment is to enable SanPoint AB to market its product in the US as private brands.



(Signature of Certifier)

Hans Feikes de Groot

(Typed name)

May 9, 1996

(Date)

(Premarket Notification 510(k) No)