

SEP 10 1996

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July 2, 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,

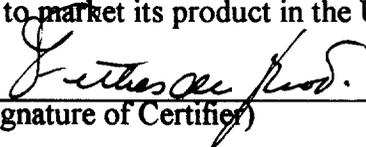
has been a manufacturer of digital tampons since 1974, and was the first to introduce a 100% cotton tampon in 1988.

The subject of this submittee's summary is a: "digital tampon for feminine hygiene". It is of essentially the same make and construction as the brand "Kotex" manufactured by Kimberly-Clark Corp. and "O.B." manufactured by Johnson & Johnson, currently sold in the US and which are approved by the FDA. The only distinguishing characteristic is the use of a patented technique for the use of hydrophilic fibers in addition to thermoplastic fibers in the non-woven fabric of the envelope.

The SanPoint product comprises a digital tampon with the absorbant material being 75 % non-chlorine bleached rayon viscose, 25 % non-chlorine bleached cotton, with a non-woven cover of thermobonded rayon-polypropylene (without chemical binder), and used to absorb menstrual and other vaginal discharges, when inserted in the vagina. The tampon also has a 100 % non-chorine bleached 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)

July 2, 1996

(Date)

(Premarket Notification 510(k) No)