[redacted]

18/03/2004 11:28

To: [redacted]@Health_gov_au
cc:
Subject: Submission 03-098 testing

Dear [redacted]

As we both very busy at this moment please see the attached note.

03-098 note.doc

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Note for Submission 2003/098

Deficiency:

1. In the provided Annex D.15 results from Static Impact and Fatigue Testing for the implants are provided but only for implants with textured envelopes. The smooth should also be tested.
2. Both tests listed there were conducted according to "experimental Standard NF S94-350", no information/details haw this standard is related to the EN 12180.

Observations

1. In the provided post- market data much higher ratio (about 100%) of complaints was registered for implants with textured surface.
2. Tear resistance tests were performed according to requirements specified in the EN 12180 and in compliance with the supplier (NuSil) methodology for the row polymer NuSil Med 6400 and for the smooth and textured envelopes of gamma sterilised hydrogel pre-filled breast implants (Annex D.4).
   Although thickness of the die from shells (about 0.5 mm) is lower than the standard's recommendation (2 mm), and that the surface is not smooth in the case of textured implants, the tear results achieved (36.8 KN/m – smooth and 22.9KN/m – textured) conform to the supplier specification (> 22.75 KN/m). The results show that despite the fact that textured envelopes are thicker (one extra layer of polymer) their tear resistance is much lower (about 35%) than the smooth ones.
3. Concentration of active hydrogen peroxide in the envelope was determined as 0.011% (2.25 mg in 20 g of the envelope - not specified if it was smooth or textured).
   Taking into account that the texturing agent is organic (cane sugar) and the highly oxidative cleaning agent could react with traces of the sugar, a possible link with the weakened textured surface could exist.