REGISTRATION REPORT - SUMMARY AND FINAL RECOMMENDATIONS

McGhan Gel-Filled Mammary Prostheses

Sub	TGAIN	Device Description	File Nos
98/3	99427	McGhan Style 110 BIOCELL™ Textured Gel-Filled/Round Moderate Profile Mammary Implant	[redacted]
98/4	99428	McGhan Style 120 BIOCELL™ Textured Gel-Filled/Round High Profile Mammary Implant	[redacted]
98/5	99429	~~McGhan Style 153 BioDIMENSIONAL™ BIOCELL™ Textured Gel-Filled Mammary Implant~~ *WITHDRAWN*	[redacted]
98/6	99430	~~McGhan Style 410 BioDIMENSIONAL™ BIOCELL™ Textured Cohesive Gel-Filled Mammary Implant~~ *WITHDRAWN*	[redacted]
98/7	99431	McGhan Style 410FM BioDIMENSIONAL™ BIOCELL™ Textured Cohesive Gel-Filled Mammary Implant	[redacted]
98/8	99432	McGhan Style 150 BioDIMENSIONAL™ BIOCELL™ Textured Expandable Gel/Saline-Filled Mammary Implant with Adjustable Inner Lumen - Standard	[redacted]
98/9	9433	McGhan Style 150 BioDIMENSIONAL™ BIOCELL™ Textured Expandable [redacted]	[redacted]
~~98/10~~	~~99434~~	~~McGhan Style 177 McGhan INTRASHIEL™ Gel/Saline-Filled, Double Lumen, Round Mammary~~ [redacted] *WITHDRAWN*	[redacted]
98/11	99435	McGhan Style 40 INTRASHIEL™ Gel-Filled Round, Standard Profile Mammary Implant	[redacted]
98/12	99436	McGhan Style 45 INTRASHIEL™ Gel-Filled Round, High Profile Mammary Implant	[redacted]
~~98/13~~	~~99437~~	~~McGhan Style 46 McGhan INTRASHIEL™ Gel/Saline-Filled, Double Lumen, Round Mammary Implant~~ *WITHDRAWN*	[redacted]
98/14	99438	CUI Type RLD, DRIE, Round Low Profile Gel-Filled Mammary Implant	[redacted]
98/15	99439	CUI Type RHD, DRIE, Round High Profile Gel-Filled Mammary Implant	[redacted]
98/16	99440	CUI Type MLP, Microcell™, DRIE Low Profile Gel-Filled Mammary Implant	[redacted]
98/17	99441	CUI Type MHP, Microcell™, DRIE High Profile DRIE Gel-Filled Mammary Implant	[redacted]

Sponsor	**Device Technologies Australia P/L** [redacted]
Postal Address	Locked Bag 521 Frenchs Forest NSW 1640
Street Address	Unit 6, 10 Rodborough Road Frenchs Forest NSW 2086
Contact - Phone	[redacted]
Consultant Phone	Regulatory Concepts Pty Ltd [redacted]
Manufacturer	**McGhan Ltd** [redacted] Kilbride Industrial Estate Arklow County, Wicklow, Ireland
Manufact Steps	FPM [redacted]
Manufacturer	Biological Laboratories Europe Ltd, Ent ID: 27870 LI1 Carrentrila, Ballina, Co. Mayo, Ireland,
Manufact Steps	TMM (Sterility testing of exposed biological indicators). [redacted]

EVALUATION SUMMARY

Evaluation of the McGhan range of Gel filled mammary prostheses was conducted by a group of experts in the fields of Materials, Toxicology, Pathology, Immunology and Clinical Plastic Surgery under the auspices of the TDEC Advisory Panel on Biomaterials.

The component reports from these experts have been collated to form a Registration Report that was considered by the Therapeutic Devices Evaluation Committee (TDEC) in December 2000 (Files 1999/041113, 1999/041110, 1999/041101, 1999/041124, 1999/041122, 1999/041128, 1999/041123, 1999/041119, 1999/041130, 1999/041120, 1999/041118, ff 169-210, and addenda ff 213-214 and ff 215-216 that were presented as late papers. Each area of evaluation was considered for completeness or whether there were quality, safety or efficacy issues requiring clarification or further data.

The Committee was satisfied that the evaluators had been rigorous in examination of the data and that the evaluation criteria had been set against current knowledge in the field of silicone chemistry and toxicology in relation to mammaplasty. The Committee, however, were concerned (refer to TDEC Minutes 2000/3 if required and confidentiality will not be breached) at the lack of adequate information to be available for consideration by patients prior to giving consent for the procedure. TDEC issued several resolutions (refer to TDEC Resolutions 2000/3) that were pursued with the company. Final Draft Patient Information and Consent form have been reviewed within DRAS and determined to include the desirable elements of the TGA *Breast Implant Information Booklet, 2nd Edition* and Patient consent Form (File 2001/041159, 2001/041160, 2001/041156, 2001/048036, 2001/048041, 2001/048043, 2001/048034, 2001/048032, 2001/048027, 2001/048029, 2001/048031, ff 129 - 167). An appropriate Unique Device Identifier in the form of adhesive labels for affixing to a Patient Card and Patient's Hospital Record card will be packaged with each prosthesis (Files ibid. f171-172).

EVALUATION RECOMMENDATION

- From the submitted information, it is recommended that the Delegates approve each of the following products for entry in the Australian Register of Therapeutic Goods as registered devices:

98/3	McGhan Style 110 BIOCELL™ Textured Gel-Filled/Round Moderate Profile Mammary Implant
98/4	McGhan Style 120 BIOCELL™ Textured Gel-Filled/Round High Profile Mammary Implant
98/7	McGhan Style 410FM BioDIMENSIONAL™ BIOCELL™ Textured Cohesive Gel-Filled Mammary Implant
98/8	McGhan Style 150 BioDIMENSIONAL™ BIOCELL™ Textured Expandable Gel/Saline-Filled Mammary Implant with Adjustable Inner Lumen - Standard
98/9	McGhan Style 150 BioDIMENSIONAL™ BIOCELL™ Textured Expandable Gel/Saline-Filled Mammary Implant with Adjustable Inner Lumen – Low Pole
98/11	McGhan Style 40 INTRASHIEL™ Gel-Filled Round, Standard Profile Mammary Implant
98/12	McGhan Style 45 INTRASHIEL™ Gel-Filled Round, High Profile Mammary Implant
98/14	CUI Type RLD, DRIE, Round Low Profile Gel-Filled Mammary Implant
98/15	CUI Type RHD, DRIE, Round High Profile Gel-Filled Mammary Implant
98/16	CUI Type MLP, Microcell™, DRIE Low Profile Gel-Filled Mammary Implant
98/17	CUI Type MHP, Microcell™, DRIE High Profile DRIE Gel-Filled Mammary Implant

This recommendation for approval covers the range of sizes applicable to each device Style or Type.

- From the available information and testing performed on these devices, the evaluators consider that reasonable steps have been taken to establish their quality, safety and efficacy.

- With respect to the resolutions of TDEC, several conditions are proposed to be added to the Standard conditions of registration. They are as follows:

  - The sponsor shall develop, maintain and supply Patient Information containing:
    a) Generic information relating to breast implants; and
    b) Current product specific information; and
    c) A Patient Consent form which includes:
       (i) information on the specific breast implant(s) to be used; and
       (ii) a patient's acknowledgment of sufficient time to consider the information before consenting to the procedure

  - The sponsor is to provide with each Silicone Gel Mammary Implant a Unique Device Identifier for transfer to the patient record and other relevant documentation, for example, multiple adhesive labels.

  - In relation to Condition 19 of the Standard Conditions Applying to Registered or Listed Therapeutic Goods under Section 28 of the Therapeutic Goods Act 1989, the sponsor shall provide to the Director, Conformity Assessment Branch, Therapeutic Goods Administration:
    a) a summarised report in respect of problems relating to the condition, use or application of the registered therapeutic devices between 1 July and 1 October following the date of the registration of the registered Silicone Gel filled Mammary Prostheses;
    b) and then submit annual summarised reports between 1 July and 1 October for the following **five years.**

GUIDANCE FOR ADMIN OFFICER

a. Additional information to be put in each letter of notification:

Conditions as noted below

b. Additional Conditions to be applied to each Certificate:

The sponsor shall develop, maintain and supply Patient Information containing:

d) Generic information relating to breast implants; and
e) Current product specific information; and
f) A Patient Consent form which includes:
   (iii) information on the specific breast implant(s) to be used; and
   (iv) a patient's acknowledgment of sufficient time to consider the information before consenting to the procedure

The sponsor is to provide with each Silicone Gel Mammary Implant a Unique Device Identifier for transfer to the patient record and other relevant documentation, for example, multiple adhesive labels.

In relation to Condition 19 of the Standard Conditions Applying to Registered or Listed Therapeutic Goods under Section 28 of the Therapeutic Goods Act 1989 , the sponsor shall provide to the Director, Conformity Assessment Branch, Therapeutic Goods Administration:

c) a summarised report in respect of problems relating to the condition, use or application of the registered therapeutic devices between 1 July and 1 October following the date of the registration of the registered Silicone Gel filled Mammary Prostheses;
d) and then submit annual summarised reports between 1 July and 1 October for the following five years.

c. Additional information to be entered in each ARTG entry:

1. **ARTG Registration Name:** McGhan "Specific Product Name – Model No" (as per cover page) Prostheses Breast, Permanently Implantable {McGhan Ltd, Wicklow, Ireland}

2. Additional conditions set out above should be included in the text portion of the Conditions field in each Register entry.

[redacted]

Devices Registration and Assessment Section
29 June 2001

APPROVAL COMMITTEE – comments: [redacted]

[redacted] [redacted] [redacted]

Signed Signed Signed Date