Health Canada Santé Canada

Class IV Medical Device Licence Evaluation Report

Administrative Information

Application Information			
Application number	Licence Name	Licence Number	Risk Class
Application Type	Licence Type	Manufacturer	Company ID

Scientific Review Information		
Reviewed by	Review Division:	Review Division Manager:
Date Review Assigned: Click here to enter a date.	Date Review Completed: Click here to enter a date.	

This report contains Confidential Business Information (CBI) that should be redacted: Yes/No

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1 Background Information

Application Bundle Information	
Primary Application	
Secondary Applications	

1.1 Device Description

1.1.1 General Description

Reviewer's Discussion

1.1.2 Modifications

Reviewer's Discussion

1.2 Design Philosophy

Reviewer's Discussion

1.3 Indications and/or Intended Use, and Contraindications

This application includes changes to device indications: Yes/No

Reviewer's Discussion

1.4 Implant Registration System

Reviewer's Discussion

2 Device Labels, Package Labelling and Documentation

2.1 Labels & Documentation

Reviewer's Discussion

2.2 Warnings, Precautions and Limitations

Reviewer's Discussion

3 Marketing History/Regulatory Status

3.1 Canadian

This device has been released via SAP: Yes/No
This device has been authorised via ITA: Yes/No

Reviewer's Discussion

3.2 International

Reviewer's Discussion

3.3 Incident Reports

Reviewer's Discussion

4 Manufacturing and Quality Control

4.1 Material Specifications

Reviewer's Discussion

4.2 Devices Containing Animal/ Human Material

Reviewer's Discussion

4.3 Device Specific Quality Plan

Reviewer's Discussion

4.4 Manufacturing Process and Quality Control Activities

Reviewer's Discussion

4.5 Process Validation Studies

Reviewer's Discussion

4.6 Sterilization, Packaging and Shelf-life Validation Studies

4.6.1 Sterilization/Validation/Re-sterilization/Bioburden

Reviewer's Discussion

4.6.2 Sterilant/Residual Toxicity Test

Reviewer's Discussion

4.6.3 Pyrogen Test

Reviewer's Discussion

4.6.4 Packaging and Packaging Stability

Reviewer's Discussion

5 Safety and Effectiveness Studies

5.1 List of standards

Reviewer's Discussion

5.2 Preclinical studies

5.2.1 Physical/Mechanical/Bench Testing

Reviewer's Discussion

5.2.2 Shelf Life Studies for the Product

Reviewer's Discussion

5.2.3 Software Verification and Validation

Version Tested:

Reviewer's Discussion

5.2.4 Biocompatibility Tests

Reviewer's Discussion

5.2.5 Animal Studies

Reviewer's Discussion

5.3 Clinical studies

Reviewer's Discussion

5.4 Literature Studies & Bibliography

6 Risk Assessment

Reviewer's Discussion

7 Conclusions

Start/Review Quality Report Card (You will need to click OK in the popup after clicking here)
Note: Changes cannot be made once the feedback results are concurred by SH.

8 Recommendation

Acceptance for licensing
Acceptance of the following amendments:
Acceptance with the following conditions:
Refusal:

Request for additional information:

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DO NOT DELETE – Ensure recommendation falls above this line

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Executive Summary – DRAFT

<Paste Executive Summary here>