

Regulatory Submission for Device Approval

1. Device Information

Device Name:

Model Number:

Manufacturer:

Intended Use:

2. Regulatory Classification

Classification:

3. Supporting Documents

- Technical File
- Clinical Evaluation Report
- Risk Management File
- Safety and Performance Data

4. Declaration

I hereby declare that the information provided above is true and accurate to the best of my knowledge.

Applicant Name:

Date: