PIHAK BERKUASA PERANTI PERUBATAN
Medical Device Authority
KEMENTERIAN KESIHATAN MALAYSIA
Ministry of Health Malaysia
Portal: www.mdb.gov.my
Email: mdb@mdb.gov.my

INVESTIGATIONAL DEVICE (IDE) PROGRESS REPORT

All fields are mandatory unless stated otherwise.

IDE NO.:

SECTION A – BASIC ELEMENTS

1. Device Name:

2. Indication(s) for Use:

3. Sponsor's Name:	4. Address:
5. Phone No.:	
6. Fax No.:	
7. Contact Person:	8. Designation:
9. Phone No. (W):	10. Email:

SECTION B – STUDY PROGRESS

(Data from beginning of the study should be reported, unless otherwise indicated)

1. Summary (in relation to investigational plan):

2. No. of devices shipped:	3. No. of subjects enrolled (indication / model)

4. No. of Investigators / Investigational Sites *(kindly refer to Appendix A)* :

5. Summary of results:

6. Summary of anticipated & Unanticipated Adverse Effects

i. Anticipated	ii. Unanticipated

7. Description of deviations *(if any, since last progress report)*:

SECTION C – RISK ANALYSIS	
1. Summary of new adverse information (since last progress report) that may affect the risk analysis – *includes i) pre-clinical data, ii) animal studies, iii) foreign data, iv) clinical studies, etc.*	
2. Reprints of articles published from data collected from this study (supporting documents)	
3. New Risk Analysis *(based on new information & study progress, if any)*:	
SECTION D – OTHER CHANGES	
1. Changes in Manufacturing Practices & Quality Control *(including changes not reported in a supplemental application)* – Summary:	
2. Changes in the Investigational Plan Not Required to be Submitted in a Supplemental Application – Summary:	
SECTION E – FUTURE PLANS	
1. Progress Toward Product Approval *(with projected date of PMA)*:	
2. Plans to change the investigation:	
SECTION F – ATTESTATIONS & DECLARATION	
Signature: Name: Designation:	Company Stamp: Date:
SECTION G – OFFICIAL USE	
Notification No.:	Date:

APPENDIX A

TRIAL SITE DETAILS *(For multiple sites in Malaysia – Repeat as Needed)*				
No.	**Name of Trial Site**	**Name of PI**	**Name of EC**	**Authorisation / Opinion of EC**

SECTION H – SUPPORTING DOCUMENTS			
Documents	**Checklist**	**Required For**	**Remarks**
Published articles		Section C – No. 2	
IRB / EC Approval Letter		Appendix A	