SITE INITIATION VISIT REPORT

Protocol:
PI Name:
PI Address:
Date of Visit:
Monitor(s):
Other Sponsor Personnel Present:
Site Personnel Present at Visit (include names and titles):

PROCEDURAL REVIEW

The following was reviewed and discussed during the site initiation visit.

PROTOCOL & INVESTIGATOR RESPONSIBILITIES

Activity	YES	NO	NA	COMMENTS
Do the investigator and staff understand the investigational plan (protocol and all requirements) and the importance of protocol adherence to ensure a well controlled study?				
Does the investigator understand and accept his/her responsibility to conduct the clinical investigation in accordance with 21 CFR 812, 813, 21 CFR 50, 54 & 56, ICH Guidelines and any other applicable regulation?				Review GCP Power Point Presentation with Investigator and study staff.
Were inclusion/exclusion criteria explained?				
Were patient screening / enrollment procedures and/or expectations, withdrawals explained?				
Does the investigator have access to an adequate number of subjects to conduct the investigation?				
Does the investigator have sufficient time from other obligations to carry out the responsibilities to which the investigator is committed by applicable regulations?				
Does the investigator have sufficient staff to support protocol activities? Have there been any changes in staff? Describe personnel and training for the following roles (if these have changed since pre study qualification visit): • Research Nurse /Clinical Research Coordinator • Data Entry / Assistant • Regulatory Affairs • Budget / Contract • Management • Other:				

PROCEDURAL REVIEW
The following was reviewed and discussed during the site initiation visit.

PROTOCOL & INVESTIGATOR RESPONSIBILITIES

Activity	YES	NO	NA	COMMENTS
The role of all study staff is defined and documented on the Delegation of Duties log. (All study staff must sign this log as it also functions as the signature log for the study).				
Were the following documents reviewed with the PI and study staff? • Operator's Manual • Procedure Manual • Other:				
Have the facilities remained adequate for the study?				

CRF COMPLETION / SOURCE DOCUMENTATION / REQUIRED REPORTING

Activity	YES	NO	NA	COMMENTS
Have the investigator(s) and staff been instructed on CRF completion and the requirements for and study specific source documentation necessary for the study?				
Have data correction procedures been reviewed in detail with the investigator and staff so they can perform the documentation correctly for the study?				
Do all staff have their eCRF certificate? (if eCRF or electronic signatures will be used)				
Has the procedure for collection of CRFs been discussed?				
Has unanticipated device effect and adverse event / serious adverse event reporting and documentation been reviewed?				
Have the procedures for required reporting of protocol violation / deviations been reviewed?				
Does the Investigator agree to maintain study records for the required period of time?				

TEST ARTICLE

Activity	YES	NO	NA	COMMENTS
Does the investigator understand the investigational status of the test article and the requirements for accountability?				
Is the site prepared to use the device exclusively for this study?				
Were test article (device) shipping, dispensing (accountability logs) and return records reviewed?				
If test article (devices) are present at site, have they all been logged in to the accountability log appropriately?				
Is study device and supplies stored in a secure limited access area? Describe				
Describe Temperature Control Measures (if applicable)?				
Other:				

INFORMED CONSENT				
Activity	**YES**	**NO**	**NA**	**COMMENTS**
Did the investigator understand and agree to his responsibility for obtaining informed consent from the subjects prior to participation?				
Did the investigator and staff understand and agree to their responsibility to document the informed consent process?				
Does the investigator and staff understand their obligations concerning subject privacy and confidentiality? • Describe HIPAA procedures at site (U.S. only) Describe any issues regarding confidentiality at site.				

STUDY MATERIALS				
Activity	**YES**	**NO**	**NA**	**COMMENTS**
Does the site have sufficient quantities of the investigational devices to begin the trial?				
Does the PI and study staff understand their responsibilities regarding study supplies confidentiality, storage and security?				
Does the PI and study staff understand their responsibilities for return of supplies to the Sponsor (used and unused) at the end of the study or upon request?				
Has the site received all study documents (i.e. study binder, CRF, study specific forms) necessary for the start of the study?				
Does the site have enough CRFs to begin study?				
Other:				

MONITORING / REGULATORY AUDITS				
Activity	**YES**	**NO**	**NA**	**COMMENTS**
Does the Investigator agree to monitoring/audit visits and to allow access of source documents to sponsor, sponsor representatives, IRB and FDA?				
Were monitoring procedures / expectations reviewed with the PI and study staff?				
Was the monitoring visit log signed?				
Was the next monitoring visit scheduled?				

REGULATORY				
Activity	**YES**	**NO**	**NA**	**COMMENTS**
Approvals from Individual Country Agencies / Govt. • Ministry of Health approvals • Customs approvals for shipping of device (if applicable)				
Does the PI have final IRB approval for study and ICF? If no, list contingencies and collect copy of letters regarding any contingency requests.				
Does the PI and his study staff understand the requirement for IRB review and approval for this study and ICF?				
Does the PI and study staff understand the requirement for IRB review and approval of any study amendments, advertisements, addition of investigators, administrative updates or amendments?				
Does the PI and study staff understand the requirement for continuing review / annual renewal for the study without any lapse in approvals?				
Does the PI and study staff understand the requirements for reporting to the Sponsor and IRB of any serious adverse events, reports of unanticipated device events and other reports as required by the reviewing IRB and Sponsor?				
Does the PI and study staff understand the requirement to supply the Sponsor and IRB with an end of study (close out) report?				
Has the site received the regulatory books? Are all regulatory documents filed in the regulatory notebooks. Provide name and contact information of site personnel responsible for regulatory affairs.				
Review the contents of the site regualtory binders to ensure site has all required regulatory documentation to initiate the site.				
Are there any missing documents site needs to start study? List:				

List all Regulatory Documents at site with version # and dates:	
Protocol	
Amendment	
CRF	
CRF Instructions	
Manual of Operations	
Investigator Drug Brochure (if applicable)	
Procedure Manual	
Laboratory Manual	
Newsletters	
Memos from Sponsor	

COLLECTION OF REQUIRED REGULATORY DOCUMENTS				
Activity	**YES**	**NO**	**NA**	**COMMENTS**
IRB / EC Approval(s) • Obtain copy of IRB approval letter • Obtain copy of IRB approved Informed Consent(s) • Obtain copy of all correspondence to and from the IRB to date.				
Signed protocol and amendments, if any. List **all versions/dates** of protocols that have been presented to the IRB. List IRB approval dates • Collect copy of all signed protocol signature pages • Collect copy of all IRB Correspondence				IRB Approval Dates
IRB-approved consent form? Approval date? • Collect copy of all approved Informed Consent Forms				
IRB- approved non-English consent forms? • List version # and approval dates • Collect copies of any non-English version(s) of the Informed Consent and Certificates of Translation.				
Privacy Authorizations (HIPAA for US studies, PIPEDA documentation for Canadian studies, etc.) • Collect copy of all HIPAA Authorizations etc. All approved versions / all languages				
Any advertisements for subject recruitment? Are these advertisements IRB approved? • Collect copy of all IRB correspondence / approval letters re advertisements. • Collect copy of all advertisements published				

COLLECTION OF REQUIRED REGULATORY DOCUMENTS				
Activity	**YES**	**NO**	**NA**	**COMMENTS**
FDA 1572 (if applicable) or Investigator Agreements • Collect **originals of** all versions / dates • Site to retain copy				
CV's for Investigator and all personnel listed on the study • Collect copy of all CVs for study personnel • Collect copy of current medical licenses for physician investigators				
Financial disclosures for all investigators on study • Collect copy of all Financial Disclosure documents				
Radiology license? • Collect copy of radiology license(s) for date span of study at site				
Laboratory Certification • Obtain copy of state Lab License, CLIA, CAP (if accredited) and copy of lab normals (current year) for all protocol required tests				
Mammography Certification? Collect copy of MQSA certificate				
Insurance certificate of liability (If any) • Collect copy of insurance certificate				
Radiation Safety Committee • Collect copy of Radiation License • Collect copy of all correspondence and approval(s)				
Correspondence with Sponsor? • Collect copy of all correspondence with Sponsor to date.				
Ministry of Health / Customs, etc approvals List and collect copies of all correspondence / approvals.				
Site Signature Log (copy)				
Delegation of Duties Log (copy)				
Test Article Accountability Log(s) – (copy)				
Monitoring Visit Log (copy)				

COMMENTS
List all comments that would add information to report (not mentioned above) and detail important discussions with investigator/ and /or staff.

Action Items for Site:
Action Items for Sponsor / CRA:

Signature CRA		Date:
Signature Sponsor		Date: