Site Selection Report

REFERENCES	
Protocol ID: H-34 DELTA REVISION	
Study title:	**An open label, observational, prospective, longitudinal cohort study to evaluate safety, clinical and radiographic outcomes of total hip arthroplasty with DELTA Revision acetabular cup.**
Potential Investigator:	**Dr. Jerzy Białecki**
Site:	**Samodzielny Publiczny Szpital Kliniczny im. Prof. Adama Grucy CMKP Księdza Stanisława Konarskiego, 13 - 05-400 Otwock, Poland**
Date of visit: 11/Sep/2020 (remote site selection visit performed according to Sponsor's instructions)	

PERSONNEL	
Sponsor personnel (including roles)	**Site personnel (including functions)**
Adam Kogut (CRA)	**Dr Jerzy Białecki (PI)**
	Paweł Bartosz (SI)
	Julia Macias (SI)

AUTHOR OF THE REPORT (AMCL)	
Printed name: ADAM KOGUT	**Date: ___ / ___ / _____**
Signature:	

REVIEWER OF THE REPORT (RMCL)	
Printed name: GLORIA VITI	**Date: ___ / ___ / _____**
Signature:	

Checklist

	Items discussed with investigator/study team	Yes	No	N/A	Comments
1.	Device use and application	☒	☐	☐	Device use and application were discussed with the study team, including indication to use study device only for the revision.
2.	Study protocol and procedure	☒	☐	☐	Study related procedures, Inc./Excl. criteria and other related aspects were discussed based on the Protocol no. 1.0 dated 04Feb2020. The site staff was informed that revised Protocol version will be prepared.
3.	Subject recruitment / feasibility	☒	☐	☐	Site team was informed that the device can only be used for the revision according to IFU and not for primary reasons. The site staff responded that this does not change their recruitment plans as they already use DELTA Revision cup in accordance with the IFU only. The site staff is planning to enrol 2-3 subjects per week on average.
4.	Monitoring procedures	☒	☐	☐	Monitoring procedures reviewed with the site staff: no issues raised by the team.
5.	Equipment and facilities	☒	☐	☐	The study device will be kept at the ward according to the site's clinical practice, the ISF and subject's binders will be kept in a monitoring room available for authorized personnel only. Radiology department is located in a different part of the hospital.
7.	e-CRF	☒	☐	☐	eCRF version 1.0 dated 21 July 2020 discussed with the site staff: no issues raised by the team.
6.	Principal Investigator and study team	☒	☐	☐	The study team consists of Dr Jerzy Białecki (PI), Dr Paweł Bartosz (SI) and Dr Julia Macias (SI). Both SIs will be responsible for subjects' recruitment, consenting, SD and e-CRF completion. As per PI there are 4-5 surgeons at his clinic that performs implantations and he expects that a few of them may want to perform surgery of their own patients. As per PI, the study team may assist during the implantation of study device in such cases. PI asked to check with the Sponsor if they can avoid putting those surgeons on the Delegation List (action#2).
7.	ICH-GCP	☒	☐	☐	PI and site staff are familiar with ICH-GCP and ISO 14155.
8.	Randomisation	☐	☐	☒	No randomization required for the trial.
9.	Laboratory	☐	☐	☒	No laboratory involved in the trial.

10.	Device accountability and storage	☒	☐	☐	Device accountability and storage will be performed according to the site's clinical practice.
11.	EC/RA procedure and regulatory requirements	☒	☐	☐	EC requirements were discussed with the study team. The study was submitted on 23Ju2020 and approved by EC on 09Sep2020.
12.	Contract and compensation	☒	☐	☐	The site confirmed that Prof. Jarosław Czubak is authorized to represent the Institution and to sign the financial agreement.
13.	Study documents provided/received	☒	☐	☐	
14.	Miscellaneous	☒	☐	☐	The site maintains both electronic and paper SD. The site staff confirmed they can anonymize X-rays and upload them to eCRF. PI stated that at the hospital they have additional 2 clinics using the study device and PI asked how the other clinics could join the study. CRA suggested that it will be discussed with the Sponsor, however, at this stage the other clinics can refer their patients to the study team (action#1).

ACTION LOG		
Action Item	**Responsibility**	**Date completed**
1. To check with the Sponsor how other 2 hospital clinics could join the study. See section# 14.	**CRA/Sponsor**	**G.V.21Sep20: according to the CRA's suggestion, at this study's stage, the 2 other clinics can refer their patients to the study staff at their hospital. The CRA will communicate the Sponsor's answer to the site staff within Follow-Up letter.**
2. To check with the Sponsor if PI can avoid putting additional surgeons on the Delegation List. See section# 6.	**CRA/Sponsor**	**G.V.21Sep20: considering that the study is observational, other surgeons can perform Delta revision cup implantations and not be listed in the delegation list if the following conditions are both respected:** **1. study team and/or PI has to assist to the surgery;** **2. PI has to countersign the medical charts related to the implant.** **If the both above mentioned items cannot be respected, the other surgeons have to be included in the delegation log. The CRA will communicate the Sponsor's answer to the site staff within Follow-Up letter.**

3. To check with the Sponsor if Polish versions of study scores can be submitted to EC for review. Having EC approved Polish versions would allow the staff to provide each subject with scores for subject's completion instead of reading questions to the subject.	**CRA/Sponsor**	**G.V.21Sep20: the Polish versions of OHS scores (only) will be submitted to EC within the EC submission for the amendment of protocol to be done within 20 Nov 2020; site staff will be informed as soon as the Sponsor will receive the EC approval.** **The CRA will communicate the Sponsor's answer to the site staff within Follow-Up letter.**

** if the answer is "No" specify in clarification/comments*

LEGEND:	
NA:	Not Applicable
GCP:	Good Clinical Practise
EC:	Ethics Committee
RA:	Regulatory Authority

Recommendation

I recommend:

☒ to include this site in the study

☐ to include this site in the study only if the following conditions are fulfilled:
XXXXXX

☐ not to include this site in the study