The YODA Project
Research Proposal Due Diligence Assessment

Part 1: General Information	
YODA Project (Protocol) ID:	2019-4001
Date:	4 December 2019
Product Name:	HEALOS and Leopard Cage
Therapeutic Area:	Spine
Product Class:	Implant
Condition(s) Studied:	Degenerative Disc Disease
Protocol Number(s) and Title(s):	**NCT00316121** - 05-HEALOS-01- A Prospective, Multicenter, Randomized Study Comparing the Use of HEALOS® to Autograft in a Transforaminal Lumbar Interbody Fusion (TLIF) Approach

Part 2: Data Availability		
Data Holder has authority to provide clinical trial data or development partner has agreed to share clinical trial data.		Yes
Comments:		
Data Holder has sharable electronic clinical trial data or data can be converted to electronic format.		Yes
Comments:		
De-identification and redaction of clinical trial data in accordance with current HIPAA and EU criteria allows protection of participant privacy and confidentiality.		Yes
Comments:		
The product and relevant indication studied has either been approved by regulators in the US and EU, or terminated from development.		Yes
Comments:		
Data Holder has completed the clinical trial and trial has been completed for a period of at least 18 months (or results published in peer-reviewed biomedical literature).		Yes
Comments:	The data that supports the CSR (Dec 2013 primary analysis primary analysis) is consistent with what is published on ClinicalTrials.gov.	

Part 3: Data Availability Summary	
Based on the responses to the above Data Availability questions, the requested clinical trial data are available for a data sharing request.	Yes

Part 4: Proposal Review	
Question:	**Response:**
Summary-level CSR data is appropriate for the proposed analysis.	Yes
Participant-level data is appropriate for the proposed analysis.	Yes
A similar analysis is underway or completed/pending disclosure by Janssen.	No
Comments:	