Questionnaire: Custom-Made Devices
Customer Request

customLINK

Must be completed by the attending physician

Date:		**Target Surgery Date:**	
Patient Name/ID:		**Hospital:**	
Physician Name:		Contact Person:	
Address:		Address:	
Phone:		Phone:	
e-mail:		e-mail:	

Patient Information

Patient Profile		**Description of Pathology and Reason for Treatment:**	**Data Provided**	**(X)**
Age:			CT Scans:	
Wt. (lb.):			X-Rays:	
Ht. (in.):			Operative Notes:	
BMI:			Other (Describe Below):	
Gender:				

Alternative Therapy Analysis

Are you aware of any product already cleared in the United States that would address your specific needs or the needs of your patient? **(Y/N)**

Alternative Products/ Therapies Considered	Why are these products/therapies unsatisfactory* for this particular case? (i.e. poses greater risk to patient or will result in substantial undesirable outcomes)

*Please Include sources/references to support rationale if available

Are any previously cleared devices available domestically to treat the current patient? **(Y/N)**

Please describe the analyses conducted to determine lack of domestic device availability:

Is the condition/pathology addressed by the custom product sufficiently rare enough to render clinical investigations impractical? **(Y/N)**

Please provide data/published literature references to support rare occurrence rates (i.e.: < 4,000 cases/year) or explain why references are unavailable below:

Physician Initials _____ Date _____

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Product Information

Please describe the requested product:

Product Name		**Detailed Description (Critical Requirements/Unique Features)**
Material		
Sizing (L, W,H, D, Angle)		
Coating(s)/Finish		
Compatibility (Interface/Mating Parts)		

(Y/N)

Are sketches, prints, etc. attached?

Is this a revision surgery?

If YES, please identify the component(s) that are already in the patient:

If YES, please describe the device in as much detail as possible, including the device manufacturer:

Was the prior device a custom ?

Physician Signature

Date

Must be completed by LinkBio Corp.

We attest:

- that the requested custom-made device is not generally available to, or generally used by, other physicians in the USA
- the requested custom-made device is not generally available in finished form for purchase or for dispensing upon prescription in the USA
- the requested custom-made device is not offered for commercial distribution through labeling or advertising in the USA
- the requested custom-made device is intended for use by an individual patient named in the order of a physician, and is to be made in a specific form for that patient

LinkBio Corporation Signature

Date