

Send the form to: Department of Clinical Trials
Medical Products Agency
P.O. Box 26
SE-751 03 Uppsala
Sweden

Notification form Clinical investigation of medical devices

Send the completed notification form and attachments (original and four copies).

1. Sponsor:		2. Authorised Representative within the EEA (if applicable):	
Name		Name	
Address		Address	
Phone	Fax	Phone	Fax
e-mail		e-mail	

3. Contract Research Organization, CRO (not mandatory):		4. Monitor (not mandatory):	
Name		Name	
Address		Address	
Phone	Fax	Phone	Fax
e-mail		e-mail	

5. Coordinating Investigator in Sweden:	
Name	
Location	Phone
Address	Fax
	e-mail

6. Clinical Investigator (s) and investigation site(s) in Sweden
Name and location

7. Investigation site(s) outside Sweden (if applicable)
Location

8. Medical device to be investigated	
8.1 Manufacturer	8.2 Manufacturer's denomination of the device
8.3 GMDN code or other generic denomination	
8.4 Product class	I IIa IIb III Active implantable
8.6 Intended use	

8.7 Is the device CE-marked for other use than intended here?	Yes	No
8.8 Shall the device be entirely or partially implanted?	Yes	No
8.9 Is a medicinal product integrated with the device or shall a medicinal product act together with it?	Yes	No
8.10 Does the device contain tissues of human or animal origin or have such tissues been part in the manufacturing process?	Yes	No
8.11 Has an investigation of the present device (or version thereof) previously been notified to the Medical Products Agency (MPA)?	Yes MPA Dnr:	No
8.12 Has an application for clinical investigation of a medicinal product linked to this notification been submitted to MPA or will it be submitted?	Yes EudraCT nr:	No

9. Comparative device(s) (if applicable)				
9.1 Manufacturer		9.2 Manufacturer's denomination of the device/product		
9.3 GMDN code or other generic denomination of the product				
9.4 Product class				
I	IIa	IIb	III	Active implantable
9.5 Is the device CE-marked for the intended use here?		Yes	No	
9.6 Shall the device be entirely or partially implanted?		Yes	No	
9.7 Is a medicinal product integrated with the device or shall a medicinal product act together with it?		Yes	No	
9.8 Does the device contain tissues of human or animal origin or have such tissues been part in the manufacturing process?		Yes	No	

10. Title and objectives of the investigation
10.1 Title and code designation of the investigation
10.2 Primary objective
10.3 Secondary objective(s)
10.4 Summary of clinical investigation plan

11. Design of the investigation and time schedule				
11.1 Controlled study		Yes	No	
11.2 If controlled	Parallel groups	Cross over	Other comparison	
11.3 Randomization		Yes	No	
11.4 Masking	Open	Single blinded	Double blinded	Blinded evaluation
11.5 Number of subjects				
11.6 Gender		Men	Women	
11.7 Subjects <18 yrs		Yes	No	
11.8 Planned starting date				
11.9 Planned final date for inclusion of subjects				
11.10 Planned final date for follow up of last included subject				
11.11 Does the notification include a plan for post market clinical follow up?		Yes	No	

12. Mandatory attachments
12.1 Clinical Investigator's Brochure, CIB
12.2 Clinical Investigation Plan, CIP, including the Case Report Form, CRF
12.3 Declaration of conformity with Essential Requirements
12.4 Intended device labelling

