MEDICAL DEVICES AGENCY
COMPETENT AUTHORITY (UK)

CLINICAL INVESTIGATION APPLICATION FORM PCA 2

Documentation to be included with the notification

This Form must be completed in type face or block letters.

Where appropriate the following information should be provided by accompanying documentation.

Please indicate the page number(s) of the relevant documentation against each section.

NOTE
The depth of detail and requirement for items marked with a * to be supplied with the initial notification will depend upon the classification of the device, novelty of design, materials used, and risks associated with the device (see Guidance Document No 2).

COMPETENT AUTHORITY USE ONLY

File Reference Number

18 GENERAL INFORMATION

PAGE(S) - RANGE

18.1 Description of the intended purpose of device.

18.2 A copy of the Local Research Ethics Committee opinion, whether fully approved, partially approved or approved with conditions.

18.3 *Copy of informed consent.

18.4 *Reference to important relevant scientific literature (if any) with an analysis and bibliography.

19 INVESTIGATION PARAMETERS AND DESIGN

19.1 Aims and objectives of clinical investigation (bearing in mind which essential requirements are being addressed by the clinical investigation in question).

19.2 Type of investigation i.e. whether the use of a controlled group of patients is planned.

19.3 Number of patients, (with rationale).

19.4 Duration of study with start and finish dates and proposed follow-up period, (with rationale).

19.5 Criteria for patient selection. Inclusion and exclusion criteria. Criteria for withdrawal.

20 DATA COLLECTION/ANALYSIS/STATISTICS

20.1 Description of end points and the data recorded to achieve the end points, method of patient follow-up, assessment and monitoring during investigation.

20.2 Description of procedures to record and report serious adverse events and adverse device related events.

20.3 Description and justification of statistical design, method and analytical procedures (if relevant).

21 DEVICE DETAILS

21.1 *Brief description of device and other devices designed to be used in combination with it. It is helpful if the information includes a drawing/ photograph of the device.

21.2 *Indentification of any features of design that are different from similar previously marketed product (if relevant).

21.3 *Details of any new or previously untested features of the device including, where applicable, functions and principles of operation.

21.4 *Summary of any experience with any similar devices manufactured by the company including length of time on the market and a review of performance related complaints.

21.5 *Identification of hazards and estimated risks associated with the manufacture and use of the device (EN 1441) together with a description of the actions that have been taken to minimise or eliminate the identified risks.

21.6 *Description of materials coming into contact with the body; why such materials have been chosen; standards with which they comply (if relevant).

21.7 *Identification of any pharmacological components of device.

21.8 *Identification of any tissue of animal origin.

21.9 *Identification of any special manufacturing conditions required and if so how such requirements have been met.

21.10 *Description of packaging used for sterilisation of device.

21.11 *A summary of the relevant standards applied in full or in part, and where standards have not been applied, descriptions of the solutions adopted to satisfy the Essential Requirements.

21.12 *Instruction for use, and where relevant, installation of the device. Alternatively enclose a copy of the manufacturer's instructions for use that will accompany the device and be issued to the user.

MEDICAL DEVICES AGENCY
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CLINICAL INVESTIGATION APPLICATION* FORM PCA 1

PART 1: *About the Notification*

Complete this form in type face or block letters. Form PCA 2 must be used for all notifications (see page 2 of Clinical Investigation Guidance Document No 2).

PLEASE NOTE: The full fee should be sent to MDA Corporate Finance, Room 1101 Hannibal House at the same time as the notification is made to the Competent Authority. (See Clinical Investigation Guidance Documents for details).

1 Enter the date documentation sent to the Competent Authority.

Day • Month • Year

2 First or re-submission. Tick the appropriate box.

First ☐ Re-submit ☐

Original File Reference Number CI/ /

COMPETENT AUTHORITY USE ONLY

File Reference Number CI/ /

Date Received • •

3 If this is part of multi-centre clinical investigation, enter details of other Countries that will be/have been approached.

4 All notifications must be prefaced by this statement signed by the manufacturer's duly authorised signatory (where this is the manufacturer's authorised representative, please also complete 7 over page).

Failure to complete this declaration or to supply all necessary information could result in the notification being returned or cancelled.

For and on behalf of *(manufacturers name)*

I, *(please print full name)*

1 certify that the device in question complies with the Essential Requirements apart from those aspects covered by the investigation and that with regard to these aspects, every precaution has been taken to protect the health and safety of the patient and/or user,

2 certify that the information and documentation submitted with this notification is correct in detail and all the information requested has been supplied,

3 undertake to keep available for the Competent Authority for a period of 5 years all the documentation referred to in Annex 6 Council Directive 90/385/EEC/Annex VIII Council Directive 93/42/EEC.

Signed Date

Authority *(print)*

(State the capacity of the signatory who must be duly authorised to sign on behalf of the company or body).

***Regulation 7 of the Active Implantable Medical Devices Regulations 1992 (SI No 1992/3146) and Regulation 16 of the Medical Devices Regulations 1994 (SI No 1994/3017) refer.**

5 To be completed if a reproduced Clinical Application Form is used.

I, (*print*) _____

confirm that the Clinical Investigation Application Form(s) has been faithfully reproduced with no changes.

Signed _____

PART 2: *Manufacturer Information*

6 Enter the full name and postal address of the manufacturer (including country of the site where the product is being manufactured).

Manufacturer's Name

Address

Enter telephone and fax numbers including international codes.

Telephone number | Fax number

COMPLETE 7 BELOW IF THE MANUFACTURER IS NOT ESTABLISHED IN THE EUROPEAN COMMUNITY. IF NOT APPLICABLE GO TO PART 3.

7 Enter the name and address of the manufacturer's authorised representative responsible for this notification, if applicable.

Name

Address

Enter telephone and fax numbers including international codes.

Telephone number | Fax number

PART 3: *Device Information*

Enter manufacturer's trade name (if different from 6 above) associated with the device.

Manufacturer's Trade Name

9 Enter details of Notified Body approval of quality system or process at the site referred to at 6 above relevant to the clinical investigation device.

Notified Body Ref. No.	Details of Certification

10 Enter the device identification name and/or number.

Device name	and/or	Device number

11 Enter the generic name describing principal intended use.

Generic name

12 Class of Device. Note this refers to the Classification of the device under investigation for purpose intended.

Tick Device Classification				
AIMD	III	IIb	IIa	I

PART 4: *Clinical Trial Information*

13 Enter the number of devices in UK clinical trial and global number if part of a multi country trial.

Number of Devices in UK	Total Global number

14 Enter the proposed commencing and completion dates of clinical investigation in the UK.

Commencing	Day	Month	Year	Completion	Day	Month	Year

15 Enter the name and address of the person who should be directly contacted for information about this application including the post code (and country where appropriate) (UK contact preferred).

Title	Initials/Forename	Surname

Capacity

Address

15a Enter the contact's telephone and fax numbers including local and international codes (where appropriate).

Telephone number	Fax number

16 BELOW IS FOR USE AS A FINAL CHECK AND CONFIRMATION THAT THE INFORMATION IS ENCLOSED WITH THIS FORM

16 Complete the boxes by ticking and enclose the information with this form.

Copy of Local Research Ethics Committee opinion(s) enclosed. Note. For a multi-centre investigation at least one LREC opinion must be enclosed. (see Guidance Document No 1).	☐
Fee made payable to "Medical Devices Agency", for the sum of £_____	☐
Eight copies of the supporting documentation enclosed.	☐

PART 5: *Clinical Investigators and Institutes*

17 Principal clinical investigator appointed to co-ordinate the work in a multi-centre clinical investigation (if relevant). Enter the full name and address including the post code.

Note. This must be an appropriately qualified practitioner to comply with EN540.

Title	Initials/Forename	Surname

Academic Qualification

Institution (Hospital) Name

Address

17c Clinical investigator responsible for the conduct of the proposed clinical investigation. Enter the full name and address including the post code.

Title	Initials/Forename	Surname

Academic Qualification

Institute (Hospital) Name

Address

17d Clinical investigator responsible for the conduct of the proposed clinical investigation. Enter the full name(s) and address including the post code.

Title	Initials/Forename	Surname

Academic Qualification

Institute (Hospital) Name

Address

PLEASE COPY IF ADDITIONAL PAGES ARE REQUIRED

17a Clinical investigator responsible for the conduct of the proposed clinical investigation. Enter the full name and address including the post code.

Title	Initials/Forename	Surname

Academic Qualification

Institute (Hospital) Name

Address

17b Clinical investigator responsible for the conduct of the proposed clinical investigation. Enter the full name(s) and address including the post code.

Title	Initials/Forename	Surname

Academic Qualification

Institute (Hospital) Name

Address

PLEASE COPY IF ADDITIONAL PAGES ARE REQUIRED