COMPETENT AUTHORITY (UK)

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. PLEASE NOTE: The full fee should be sent to MHRA Corporate Finance, Market Towers, 1 Nine Elms Lane, London SW8 5NQ at the same time as the notification is made to the Competent Authority.

1. Enter the date documentation sent to the Competent Authority.

Day Month Year
. .

COMPETENT AUTHORITY USE ONLY

File Reference Number

CI / /

Date Received

. .

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

First

Re-submit

Original File Reference Number

CI / /

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 16 and Regulation 29 of the Medical Devices Regulation 2002 (SI No 0618) refer.

I. (*print*)

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

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

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 full name and postal 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*

8. Enter manufacturer's trade name (if different form 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

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 details of who will be monitoring the clinical trial.

Trial monitor

16 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

Title | Initials/Forename | Surname

Capacity

Address

16a Enter the contact's telephone and fax numbers including local and international codes (where appropriate).

Telephone number: | Fax number:

email:

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

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

Copy of Local Research Ethics Committee opinion(s):

Enclosed ☐

To Follow ☐

Fee made payable to " MHRA No 2 A/C ", for the sum of £_____. ☐

Eight copies of the supporting documentation enclosed ☐

18 On occasions it may be helpful to MHRA to liaise with the National Research Ethics Service (or equivalent services in Scotland, Wales and Northern Ireland) and specifically the relevant Research Ethics Committee (REC). We would also like to send the REC a copy of our final decision on this application for their information. Please complete the information requested and sign below to allow us to discuss this case with the ethics committee if necessary and send them our final decision.

Ethics Committee address:

Ethics Committee Ref No:

I. (*print*) _____

confirm that the UK Competent Authority may discuss this application with the Research Ethics Service and the relevant Research Ethics Committee named above and provide the REC with a copy of their final decision.

_____

Signed

19 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 EN ISO 14155.

Title	Initials/Forename	Surname

Academic Qualification

Institution (Hospital) Name

Address

19a 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

Institution (Hospital) Name

Address

19b 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

Institution (Hospital) Name

Address

PLEASE COPY IF ADDITIONAL PAGES ARE REQUIRED