Month xx, yyyy

U.S. Food and Drug Administration

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Center for Biologics Evaluation and Research (CBER)

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WO71, G112

Silver Spring, MD 20993-0002

CBERDCC\_eMailSub@fda.hhs.gov

**Subject: IDE G23xxxx, Report R0xx**

To Whom it may Concern

Included in this submission please find Report R0xx. This is a final progress report and IDE Withdrawal Request for IDE G23xxxx.

IDE and Sponsor Information

* IDE Number:
* Device name and indication(s) for use:
* Sponsor's name:
	+ Address:

Children’s Hospital of Philadelphia

3401 Civic Center Blvd

Philadelphia, PA 19104

* Sponsor’s phone number:
* Sponsor’s fax number:
* Sponsor's email address:
* Additional authorized contact person:
* Additional contact email:

This was a single site Sponsor-Investigator IDE conducted exclusively at Children’s Hospital of Philadelphia.

This study completed report (final IDE progress report) provides a summary of this project for the entire duration of the study. ([day,month,year] to [day,month,year]).

The IRB has been notified and the study has been completed and closed out with the IRB.

Any remaining devices have been returned to the manufacturer or destroyed according to the manufacturers instructions and in compliance with institutional policy.

Thank you for incorporating these documents into this IDE file. If you have any questions, you may reach me at XXname@chop.eduXX or XXphoneXX.

Sincerely,

xxNAMExx

Sponsor-Investigator

Children’s Hospital of Philadelphia

Copy to: IND/IDE Support Program