**IDE/PMA/510K Cases**

**Business Office Notification Form**

**Ver. 1/24/2017**

**Each time a Device is inserted, e-mail this form to the following MS Outlook recipient:**

**BWH IDE PMA Notification**<BWHInvDeviceNotif>

1. Patient Name:
2. Medical Record Number
3. Name of Clinical Trial:
4. IDE, PMA or 510K Number:
5. Investigational device charge code/EAP#:
6. IRB Protocol Number:
7. ClinicalTrials.gov #:
8. Primary Insurance

 [ ]  Medicare [ ]  Blue Shield of Mass [ ]  Harvard Pilgrim

 [ ]  Medicaid [ ]  TUFTS [ ]  Other: Insert Name-

Is Prior Approval Required? **[ ]  YES** **[ ]  NO**

If Prior Approval is required, enter PREAUTHORIZATION NUMBER

5. Patient Status:**[ ]  Outpatient—If outpatient enter date of procedure**

**[ ]  Inpatient – If Inpatient enter date of admission:**

6. Interventionalist’s Name

 Name of Practice:

7. Is this case part of an approved (qualifying) clinical trial?

**[ ]  YES** **[ ] NO**

10. Was the investigational device(s) provided free of charge? **[ ]  YES** **[ ]  NO**

11. What portions of the study are charges to the research fund?

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 Name of Person Completing Form Email contact Date