

## Continuing Review Humanitarian Use Device (HUD)

<p>Complete and send this report at least 30 days prior to the approval expiration date</p> <ul style="list-style-type: none"> <li>• The PI or Designee must complete and sign this report</li> <li>• If the device was used during the last approval period, a copy of the signed consent form for the last subject consented, not redacted. <i>(if applicable)</i></li> </ul>			
1.	<table border="1" style="width: 100%;"> <tr> <td style="width: 50%;">Date of Report:</td> <td style="width: 50%;">Approval Expiration Date:</td> </tr> </table>	Date of Report:	Approval Expiration Date:
Date of Report:	Approval Expiration Date:		
2.	MetroWest Medical Center IRB Number:		
3.	Title:		
4.	Name of Principal Investigator:		
5.	<p>List all investigators who may potentially use this device and include CV and Medical license with this submission if not previously provided:</p> <p>_____</p> <p>_____</p>		
6.	Sponsor:		

A. Subject Accrual	
To date, how many subjects have received this device?	____ # Subjects
During this reporting period only, how many patients have received this device?	____ # Subjects

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<b>B. Informed Consent</b>		
1.	<p>If a patient received this device during the last approval period, please include a <b><u>complete copy of the Informed Consent for the last subject enrolled at your site.</u></b></p> <p><i>Please do not black out subject signature and dates. The language in the informed consent provides MWMCIRB with authority to review subject identifying information.</i></p>	<input type="checkbox"/> Attached
		<input type="checkbox"/> N/A, no consent for this device
		<input type="checkbox"/> N/A, not used during this period

*I certify that the information included in this report and its attachments is correct:*

<b>Name of Person Completing Form (contact person for questions):</b>	
Name:	
Title:	
Phone Number:	
Fax Number:	
Email Address:	
<b>Signature of Principal Investigator or Designee</b>	
Date:	Signature:

**PLEASE EMAIL COMPLETED FORMS AND REQUIRED DOCUMENTS TO [MWMCIRB@mwmc.com](mailto:MWMCIRB@mwmc.com) you will receive an acknowledgement once all required information has been submitted.**