Version – 04 April 2011

Corrective Action Final Report

Purpose of this Form:
Complete this form to provide Medsafe with a final report about a medical device corrective action conducted in New Zealand.

Corrective Action Information	
Name of Sponsor	
Medsafe Reference	[*Medsafe reference number for this action.*]
Reporter	[*Name of person reporting on behalf of the sponsor.*]
Affected Device	
Report Date	

Issue	
Date Corrective Action Notice Distributed	
Customer List detailing Acknowledgement dates	[*Include here or attach separate page*]
Have all affected customers responded to this corrective action?	[*If no, the sponsor should provide information about the when and how many times they attempted to contact the non-responding customers.*]
Root Cause of Issue	
Details of Manufacturer's CAPA	[*Information about the action taken by the manufacturer to prevent a reoccurrence of the issue that lead to this corrective action.*]