

## TABLE OF CONTENTS

1.0	Study Progress .....	3
1.1	PROTOCOL NEV-97-002 .....	3
1.2	Substudy NEV-97-002 .....	10
2.0	Risk Analysis .....	11
3.0	Device Changes .....	12
3.1	Attenuator Plate .....	12
3.2	Fixation System for Optimal Centration .....	12
4.0	Changes in Investigational Plan .....	15
5.0	Progress towards PMA Approval .....	16

### ATTACHMENTS:

1.1.E-1	Protocol NEV-97-001 Key Safety and Efficacy Variables .....	17
---------	---	----