

	<b>Original Submission Date</b>	<b>Description of Submission</b>
<b>1.0 Executive Summary</b>	Feb. 2009 Amendment	Executive Summary
<b>2.0 Summary of Safety and Effectiveness Data</b>	Nov. 2007 Amendment	SSED
<b>3.0 Device Description</b>	Nov. 2007 Amendment	Section IV, Preclinical (section 1)
3.1 Device Components	Nov. 2007 Amendment	SSED (page 2)
3.1.1 Properties of the Protein	Nov. 2007 Amendment	Section IV, Preclinical (section 2.1.1)
3.1.1.1 Identification of Human BMP Genes	Nov. 2007 Amendment	Section IV, Preclinical (section 2.1.1)
3.1.1.2 Mechanism of BMP-7 induced Bone Formation	Nov. 2007 Amendment	Section IV, Preclinical (section 2.1.3)
3.1.2 Properties of the Bone Graft Substitute	Feb. 2009 Amendment	Executive Summary (page 1, para 2)
<b>4.0 Preclinical Studies (TOC)</b>		
4.1 Introduction to Pharmacology Studies	Nov. 2007 Amendment	Section IV, Preclinical (section 2.3.1)
4.2 Collagen Pharmacology	Nov. 2007 Amendment	Section IV, Preclinical (section 2.1.2 and 2.3.1)
4.2.1 Vertebral Fusion Studies	Nov. 2007 Amendment	Section IV, Preclinical (section 2.3.3)
4.2.2 Dosing Studies	Nov. 2007 Amendment	Section IV, Preclinical (section 2.2)
4.3 General Toxicology Studies	Nov. 2007 Amendment	Section IV, Preclinical (section 4)
4.3.1 Developmental toxicity	Nov. 2007 Amendment	Section IV, Preclinical (section 4.9)
4.4 Biodistribution Studies	Nov. 2007 Amendment	Section IV, Preclinical (section 3)
4.4.1 Tumor Biology	Nov. 2007 Amendment	Section IV, Preclinical (section 4.7 and 4.8)
4.5 OP-1 Pre-clinical Immunogenicity	Feb. 2009 Amendment	OP-1 Immunogenicity
<b>5.0 Clinical Studies (TOC)</b>		
5.1 Indication for Use: Natural History and Alternate Practices and Procedures	Feb. 2009 and Nov 2007 Amendment	Executive Summary (page 1, para 4) and Section V, Clinical (section 1.1)
5.2 Pilot Study	June 2006 Original PMA	CSR S99-01 US (sections 2 and 7-13)
5.3 Pivotal Study		
5.3.1 Overview to PMA	Nov. 2007 Amendment	Section V, Clinical (section 1)
5.3.2 Introduction of Studies Conducted	Nov. 2007 Amendment	Section V, Clinical (section 1.2)
5.3.2.1 Overview of Pivotal Study S01-01US	Nov. 2007 Amendment	Section V, Clinical (section 1.2.1)
5.3.2.2 Overview of Extension Study 06-UPLF-01	Nov. 2007 Amendment	Section V, Clinical (section 1.2.2)
5.3.3 Investigational Plan		
5.3.3.1 Rationale for Indication and Population Studied	Nov. 2007 Amendment	Section V, Clinical (section 1.1)
5.3.3.2 Study Design	Nov. 2007 Amendment	Section V, Clinical (sections 1.2.1 and 1.2.2)
5.3.3.3 Choice of Control and Surgical Model	Nov 2007 Amendment June 2006 Original PMA	Section V, Clinical (section 1.1) and CSR S01-01US (section 9.4.1)
5.3.3.4 Selection of Study Population; Inclusion / Exclusion Criteria	Nov. 2007 Amendment	SSED (section 9.3) CSR 06-UPLF-01 (section 9.3.1 and 9.3.2)
5.3.3.5 Method of Assigning Treatment; Blinding	June 2006 Original PMA	Study Report CSR S01-01US (sections 9.4.3 and 9.4.6)
5.3.3.6 24 Month Primary Efficacy Measurements	Feb. 2009 Amendment	Executive Summary (page 2-5)
5.3.4 Extension Study	Nov. 2007 Amendment	Section V, Clinical (section 1.2.2)
5.3.4.1 Rationale for Extension Study	Feb. 2009 Amendment	Executive Summary (page 5 -6)
5.3.5 Patient Accounting	Nov. 2007 Amendment	Section V, Clinical (section 2)

5.3.6 Investigators and Investigational Sites	June 2006 Original PMA	Study Report CSR S01-01US (section 16.1.4)
5.3.7 Demographics and Baseline Characteristics	Nov. 2007 Amendment	Section V, Clinical (section 3)
5.3.8 Efficacy Results	Nov. 2007 Amendment	Section V, Clinical (section 4)
5.3.8.1 Primary Efficacy Measurements	Nov. 2007 Amendment	Section V, Clinical (section 4.1)
5.3.8.2 Secondary Efficacy Measurements	Nov. 2007 Amendment	Section V, Clinical (section 4.2)
5.3.8.3 Additional Efficacy Measurements	Nov. 2007 Amendment	Section V, Clinical (section 4.3)
5.3.9 Radiographic Findings		
5.3.9.1 Medical conformity of OP-1	Feb. 2009 Amendment	Executive Summary (page 2-5)
5.3.9.2 Insensitivity of Plain Films for Evaluating Presence of Bone in OP-1 Patients	Feb. 2009 Amendment	Executive Summary (page 2-6)
5.3.10 Safety Results		
5.3.10.1 Deaths	Nov. 2007 Amendment	Section V, Clinical (section 5.3)
5.3.10.2 Neoplasms	Nov. 2007 Amendment	Section V, Clinical (section 5.4)
5.3.10.3 Heterotopic Ossification	Nov. 2007 Amendment	Section V, Clinical (section 5.5)
5.3.10.4 Subsequent Surgical Procedures	Nov. 2007 Amendment	Section V, Clinical (section 5.6)
5.3.10.5 Immunogenicity	Nov. 2007 Amendment	Section V, Clinical (section 5.7)
5.3.11 Postmarketing Safety Surveillance	Nov. 2007 Amendment	Section V, Clinical (sections 6.1-6.2)
5.4 Conclusions Drawn from the Study	Feb. 2009 and Nov. 2007 Amendment	Executive Summary (page 7-9), Section V, Clinical (sections 8.2.3, 8.3, and 8.4)
5.5 Addendum		
5.5.1 Pilot Study CSR - S99-01US	June 2006 Original PMA	CSR S99-01US (page 90-183)
5.5.2 Pivotal Study CSR - S01-01US	June 2006 Original PMA	CSR S01-01US (page 6412-6556)
5.5.3 Extension Study CSR - 06-UPLF-01	Nov. 2007 Amendment	CSR 06-UPLF-01 (page 1-127)
<b>6.0 Statistical Analysis</b>		
6.1 Statistical Methods		
6.1.1 Extension Study	Nov. 2007 Amendment	Statistical Analysis Plan 06-UPLF-01
6.1.2 Pivotal Study	June 2006 Original PMA	Statistical Analysis Plan S01-01US
<b>7.0 Bibliography and Selected References</b>		
<b>8.0 Packaging and Sterilization</b>		
<b>9.0 Proposed Labeling</b>		
9.1 Proposed Package Insert	June 2006 Original PMA	Section VII Labeling (part 1)
9.2 Proposed Surgeon Training	June 2006 Original PMA	Section VII Labeling (part 2)
9.3 Proposed Additional Surgeon Information		* to be discussed with FDA following panel meeting and panel input.
9.4 Proposed Contraindications, Precautions, Warnings	June 2006 Original PMA	Section VII, Labeling (part 1)
<b>10.0 Post Approval Study * to be discussed with FDA following panel meeting and panel input.</b>		