Annual Report Addendum, 10/1/2009 to 9/30/2010, Facility No. 21-R-0209
Category E Explanation-Guinea Pigs

The Guinea Pig Maximization (Sensitization) Test is a procedure which determines the allergenicity of materials. This study is required by the FDA Modified ISO 10993-1 matrix for preclinical evaluations of Class II and III medical devices. In this procedure, an adjuvant and extract are injected intradermally. The adjuvant enhances the immune response which results in lesion formation at the injection site. These lesions, ranging in size from 3mm to 20mm, are not treated due to the possible interference or enhancement of the sensitization response. In order to determine the health status of these animals, daily observations are performed and animal health technical personnel evaluate the sites. Any abnormal findings are reported to the Attending Veterinarian for assessment. During this period none of the guinea pigs used in this evaluation (defined as Category E) required additional veterinary care for problems related to the lesions.

In order to address pain and distress, the Attending Veterinarian researched analgesics and an appropriate oral medication which would not affect the animals' fluid intake was not available. The nature of the Guinea Pig Maximization Test negates the use of topical analgesia. We also performed weight trends and the animals exhibited weight gain throughout the test procedure. The animals ambulated normally and only vocalized when handled (as is the case with untreated guinea pigs).