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Category E Explanation-Guinea Pigs

Guinea Pig Sensitization Tests determine the allergenicity of materials. The maximization test and the patch test are required by the FDA Modified ISO 10993-1 matrix for preclinical evaluations of Class II and III medical devices. During the maximization test, an adjuvant and extract are injected intradermally. The adjuvant enhances the immune response and 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. The positive controls for the patch test result in hive formation during the challenge phase. As is the case with the maximization test, any abnormal findings are reported to the Attending Veterinarian for assessment. Over the duration of the year none of the 1627 guinea pigs used in these evaluations (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 and the Buehler Patch Test negates the use of topical analgesia. We also performed weight trends and the animals exhibited weight gain throughout the test procedures. The animals ambulated normally and only vocalized when handled (as is the case with untreated guinea pigs).