FINAL REPORT

INTRAMUSCULAR IMPLANTATION TEST WITH HISTOPATHOLOGY IN RABBITS ADMINISTERED TEST ARTICLE ELASTOMER SHELL

SUMMARY

An Intramuscular Implantation Test was performed to determine whether Elastomer Shell would induce a tissue contact irritation response. Six test and three negative control samples were implanted into the paravertebral muscle in each of three rabbits in order to ensure that four test and two control implant sites would be recovered after the ninety day implantation period. After ninety days the rabbits were humanely euthanized and refrigerated for a sufficient amount of time to allow the tissue to be cut without bleeding. After refrigeration the test article sample strips and negative control strips were dissected out with the surrounding tissue. In one of the three animals, one of the test sites was unable to be located upon gross dissection. Macroscopic examination of the tissue surrounding the four implanted test sites showed no significant irritation reactions when compared to the two implanted control sites, with the exception of one test site in one of the three animals. This test site exhibited a slight irritation reaction in relation to hemorrhage. Microscopic examination of the same tissue sites by a Board Eligible Pathologist verified the gross observations and confirmed the absence of necrosis. Therefore, under these test conditions, Elastomer Shell is considered to be non-toxic when implanted in rabbit muscle tissue.

FINAL REPORT

INTRAMUSCULAR IMPLANTATION TEST WITH HISTOPATHOLOGY IN RABBITS ADMINISTERED TEST ARTICLE GEL[redacted]

SUMMARY

An Intramuscular Implantation Test was performed to determine whether Gel[redacted] would induce a tissue contact irritation response. Six test and three negative control samples were implanted into the paravertebral muscle in each of three rabbits in order to ensure that four test and two control implant sites would be recovered after the ninety day implantation period. After ninety days the rabbits were humanely euthanized and refrigerated for a sufficient amount of time to allow the tissue to be cut without bleeding. After refrigeration the test article sample strips and negative control strips were dissected out with the surrounding tissue. Macroscopic examination of the tissue surrounding the four implanted test sites showed no significant irritation reactions when compared to the two implanted control sites. Microscopic examination of the same tissue sites by a Board Eligible Pathologist verified the gross observations and confirmed the absence of necrosis. Therefore, under these test conditions, Gel[redacted] is considered to be non-toxic when implanted in rabbit muscle tissue.

FINAL REPORT

INTRAMUSCULAR IMPLANTATION TEST WITH HISTOPATHOLOGY IN RABBITS ADMINISTERED TEST ARTICLE LEAF VALVE ASSEMBLY

SUMMARY

An Intramuscular Implantation Test was performed to determine whether Leaf Valve Assembly would induce a tissue contact irritation response. Six test and three negative control samples were implanted into the paravertebral muscle in each of three rabbits in order to ensure that four test and two control implant sites would be recovered after the ninety day implantation period. After ninety days the rabbits were humanely euthanized and refrigerated for a sufficient amount of time to allow the tissue to be cut without bleeding. After refrigeration the test article sample strips and negative control strips were dissected out with the surrounding tissue. Macroscopic examination of the tissue surrounding the four implanted test sites showed no significant irritation reactions when compared to the two implanted control sites. Microscopic examination of the same tissue sites by a Board Eligible Pathologist verified the gross observations and confirmed the absence of necrosis. Therefore, under these test conditions, Leaf Valve Assembly is considered to be non-toxic when implanted in rabbit muscle tissue.