



## Summary of Studies Supporting USDA Product Licensure

Establishment Name	Elanco US Inc.
USDA Vet Biologics Establishment Number	196
Product Code	48C5.20
True Name	Parvovirus Vaccine, Killed Virus, Erysipelothrix Rhusiopathiae-Leptospira Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Elanco US Inc. Parvo Shield L5E - CONG TY CO PHAN THU ONG MAI VA SAN XUAT THUOC THU Y THINH A - Elanco US Inc. Parvo Shield L5E - Elanco Canada Limited - Elanco US Inc. Parvo Shield L5E - Elanco US Inc. Parvo Shield L5E - Eli Lilly Philippines, Inc. Parvo Shield L5E - No distributor specified
Date of Compilation Summary	June 26, 2020

**Disclaimer: Do not use the following studies to compare one product to another. Slight differences in study design and execution can render the comparisons meaningless.**

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	<i>Erysipelothrix rhusiopathiae</i>
<b>Study Purpose</b>	To demonstrate effectiveness against disease caused by <i>Erysipelothrix rhusiopathiae</i> .
<b>Product Administration</b>	
<b>Study Animals</b>	Porcine
<b>Challenge Description</b>	
<b>Interval observed after challenge</b>	
<b>Results</b>	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only require publication of data submitted after that date.
<b>USDA Approval Date</b>	April 22, 1988

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	<i>Leptospira canicola</i> , <i>Leptospira grippotyphosa</i> , <i>Leptospira icterohaemorrhagiae</i> , <i>Leptospira pomona</i>
<b>Study Purpose</b>	To demonstrate effectiveness against <i>Leptospira spp.</i>
<b>Product Administration</b>	
<b>Study Animals</b>	Swine
<b>Challenge Description</b>	
<b>Interval observed after challenge</b>	
<b>Results</b>	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only require publication of data submitted after that date.
<b>USDA Approval Date</b>	March 18, 1983

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	<i>Leptospira</i> Hardjo (type Hardjoprajitno)
<b>Study Purpose</b>	To demonstrate effectiveness against <i>Leptospira</i> Hardjo
<b>Product Administration</b>	
<b>Study Animals</b>	Swine
<b>Challenge Description</b>	
<b>Interval observed after challenge</b>	
<b>Results</b>	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only require publication of data submitted after that date.
<b>USDA Approval Date</b>	March 18, 1983

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Porcine Parvovirus
<b>Study Purpose</b>	To demonstrate effectiveness against Porcine Parvovirus
<b>Product Administration</b>	
<b>Study Animals</b>	Swine
<b>Challenge Description</b>	
<b>Interval observed after challenge</b>	
<b>Results</b>	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only require publication of data submitted after that date.
<b>USDA Approval Date</b>	February 13, 1985

<b>Study Type</b>	Safety
<b>Pertaining to</b>	All fractions
<b>Study Purpose</b>	Safety by IM route in swine
<b>Product Administration</b>	
<b>Study Animals</b>	
<b>Challenge Description</b>	
<b>Interval observed after challenge</b>	
<b>Results</b>	Scientific data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission.