



Summary of Studies Supporting USDA Product Licensure

Establishment Name	Elanco US Inc.
USDA Vet Biologics Establishment Number	196
Product Code	14P5.22
True Name	Canine Coronavirus Vaccine, Killed Virus
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Duramune Cv-K Half Volume - Elanco US Inc.
Date of Compilation Summary	December 26, 2017

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.

Study Type	Efficacy
Pertaining to	Canine coronavirus
Study Purpose	To demonstrate effectiveness against intestinal disease due to canine coronavirus
Product Administration	
Study Animals	
Challenge Description	
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance. Study data, however, are no longer available.
USDA Approval Date	December 3, 1984

Study Type	Safety																																							
Pertaining to	ALL																																							
Study Purpose	Demonstrate safety of product under typical use conditions																																							
Product Administration	Two doses were administered subcutaneously approximately two weeks apart.																																							
Study Animals	A total of 675 dogs, privately owned and from commercial kennels were enrolled in the study. From these dogs 234 were 6 weeks of age or younger, at first vaccination. Three geographical sites were represented.																																							
Challenge Description	NA																																							
Interval observed after challenge	Animals were observed 30 minutes after each vaccination and daily for two (2) weeks after each vaccination.																																							
Results	<p>Frequency of adverse events:</p> <table border="1"> <thead> <tr> <th></th> <th>Number of Animals</th> <th>Percent of Animals</th> </tr> </thead> <tbody> <tr> <td>No observed adverse events</td> <td>628</td> <td>93.0%</td> </tr> <tr> <td>Injection Site Lesion</td> <td>1</td> <td>0.1%</td> </tr> <tr> <td>Diarrhea-one day of loose stools</td> <td>23</td> <td>3.4%</td> </tr> <tr> <td>Heavy Breathing</td> <td>1</td> <td>0.1%</td> </tr> <tr> <td>Death-Hit by Car *</td> <td>1</td> <td>0.1%</td> </tr> <tr> <td>Death-depression,decreased appetite, weight loss **</td> <td>1</td> <td>0.1%</td> </tr> <tr> <td>Lameness (leg cramp) *</td> <td>1</td> <td>0.1%</td> </tr> <tr> <td>Decreased appetite, weight loss, diarrhea, and dehydration *</td> <td>4</td> <td>0.6%</td> </tr> <tr> <td>Gastroenteritis (vomiting) *</td> <td>2</td> <td>0.3%</td> </tr> <tr> <td>Laceration *</td> <td>1</td> <td>0.1%</td> </tr> <tr> <td>Prolapsed nictitan gland *</td> <td>7</td> <td>1.0%</td> </tr> <tr> <td>Pyoderma *</td> <td>5</td> <td>0.7%</td> </tr> </tbody> </table> <p>*Affirmed by study investigator to have cause other than vaccination **Cause of death was not determined by study investigator. Signs appeared 4 days after vaccination and death 8 days later.</p> <p>The injection site lesion was detected after the second vaccination and resolved within 15 days.</p>		Number of Animals	Percent of Animals	No observed adverse events	628	93.0%	Injection Site Lesion	1	0.1%	Diarrhea-one day of loose stools	23	3.4%	Heavy Breathing	1	0.1%	Death-Hit by Car *	1	0.1%	Death-depression,decreased appetite, weight loss **	1	0.1%	Lameness (leg cramp) *	1	0.1%	Decreased appetite, weight loss, diarrhea, and dehydration *	4	0.6%	Gastroenteritis (vomiting) *	2	0.3%	Laceration *	1	0.1%	Prolapsed nictitan gland *	7	1.0%	Pyoderma *	5	0.7%
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