



Summary of Studies Supporting USDA Product Licensure

Establishment Name	Elanco US Inc.
USDA Vet Biologics Establishment Number	196
Product Code	14P5.20
True Name	Canine Coronavirus Vaccine, Killed Virus
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Duramune Cv-K - Elanco US Inc.
Date of Compilation Summary	October 12, 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	A total of 2,172 dogs of various ages and breeds were administered either one or two doses of vaccine 14-21 days apart by either the IM or SC route. A total of 4,079 doses were administered.																																																				
Study Animals	Privately owned and research facility canines.																																																				
Challenge Description	NA																																																				
Interval observed after challenge	Followed for 4-7 days after each vaccination																																																				
Results	<p>Frequency of Events:</p> <table border="1"> <thead> <tr> <th rowspan="2">Observation of Reaction</th> <th rowspan="2">1st Dose</th> <th rowspan="2">2nd Dose</th> <th colspan="2">No. Combined</th> </tr> <tr> <th>Number</th> <th>Percent</th> </tr> </thead> <tbody> <tr> <td>No Adverse Events</td> <td>1772</td> <td>1463</td> <td>3235</td> <td>79.3%</td> </tr> <tr> <td>Look at site</td> <td>67</td> <td>96</td> <td>163</td> <td>4.0%</td> </tr> <tr> <td>Turn in Circle</td> <td>11</td> <td>15</td> <td>26</td> <td>0.6%</td> </tr> <tr> <td>Scratch at site</td> <td>276</td> <td>240</td> <td>516</td> <td>12.7%</td> </tr> <tr> <td>Chew at site</td> <td>8</td> <td>27</td> <td>35</td> <td>0.85%</td> </tr> <tr> <td>Vocalize as in pain</td> <td>28</td> <td>12</td> <td>40</td> <td>0.99%</td> </tr> <tr> <td>Anorexia</td> <td>0</td> <td>4</td> <td>4</td> <td>0.09%</td> </tr> <tr> <td>Granuloma</td> <td>12</td> <td>32</td> <td>44</td> <td>1.1%</td> </tr> <tr> <td>Other*</td> <td>0</td> <td>16</td> <td>16</td> <td>0.4%</td> </tr> </tbody> </table> <p>*No further detail available</p>	Observation of Reaction	1st Dose	2nd Dose	No. Combined		Number	Percent	No Adverse Events	1772	1463	3235	79.3%	Look at site	67	96	163	4.0%	Turn in Circle	11	15	26	0.6%	Scratch at site	276	240	516	12.7%	Chew at site	8	27	35	0.85%	Vocalize as in pain	28	12	40	0.99%	Anorexia	0	4	4	0.09%	Granuloma	12	32	44	1.1%	Other*	0	16	16	0.4%
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