Summary of Studies Supporting USDA Product Licensure

Establishment Name	Great Vaccine Company
USDA Vet Biologics Establishment Number	000
Product Code	49K5.XX
True Name	Porcine Circovirus Vaccine, Killed Virus, Mycoplasma Hyopneumoniae Bacterin
Trade Name(s)/Distributor (if different from manufacturer)	**Tradename** — **Distributor** PigVacc Plus OinkVacc — ABC Distributing
Date of Compilation Summary	November 13, 2015

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.

Summary of Studies Supporting USDA Product Licensure

Study Type	Efficacy
Pertaining to	Circovirus, Porcine, Type 2 (PCV2)
Study Purpose	Pivotal efficacy against porcine circovirus-associated disease
Product Administration	One dose administered intramuscularly
Study Animals	Caesarian-derived, colostrum deprived piglets randomly divided into 20 vaccinates and 20 controls. Piglets were 12 days of age at the time of vaccination.
Challenge Description	All pigs were challenged 31 days after vaccination with PCV2.
Observation interval after last treatment	Lymphoid tissues examined 34 days after challenge
Results	Pigs were evaluated for the presence of PCV2 in lymphoid tissues, and pathologic changes in lymph nodes (lymphoid depletion). Tissues examined included tracheobronchial, mesenteric and sub-iliac lymph nodes, as well as the tonsil. **Results:** PCV2 was recovered from lymphoid tissues of 3/20 vaccinates and 17/20 control piglets. Lymphoid depletion was observed in lymph nodes of 3/20 vaccinates and 16/20 controls.
USDA Approval Date	September 10, 2012

Control ID	Virus	Lymphoid Depletion	Vacc ID	Virus	Lymphoid Depletion
1	+	+	1	-	-
2	+	+	2	-	-
3	-	-	3	+	+
4	+	+	4	-	-
5	+	+	5	-	-
6	+	+	6	-	-
7	+	+	7	-	-
8	+	+	8	+	+
9	+	+	9	-	-
10	-	-	10	-	-
11	+	+	11	-	-
12	-	-	12	-	-
13	+	+	13	+	+
14	+	+	14	-	-
15	+	+	15	-	-
16	+	+	16	-	-
17	+	+	17	-	-
18	+	+	18	-	-
19	+	+	19	-	-
20	+	-	20	-	-

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<table>
<tr><td>Study Type</td><td>Efficacy</td></tr>
<tr><td>Pertaining to</td><td>Mycoplasma hyopneumoniae</td></tr>
<tr><td>Study Purpose</td><td>Efficacy against respiratory disease</td></tr>
<tr><td>Product Administration (# doses, route of administration, interval between doses)</td><td>2 doses, given intramuscularly, 2 weeks apart</td></tr>
<tr><td>Study Animals (species, age at first product administration, number per treatment group)</td><td>Commercial pigs, 3 weeks of age. 32 vaccinates and 31 controls</td></tr>
<tr><td>Challenge Description (agent, route of administration, interval between last product dose and challenge)</td><td>Mycoplasma hyopneumoniae, given 3 weeks after final vaccination</td></tr>
<tr><td>Interval observed after challenge</td><td>Lungs evaluated 4 weeks after challenge</td></tr>
<tr><td>Results</td><td>The percent of the lung mass that was abnormal (consolidated) was calculated for every animal.

5-number summary for lung consolidation (%)
<table><tr><th>Treatment</th><th>Minimum</th><th>Q_1</th><th>Median</th><th>Q_3</th><th>Maximum</th></tr><tr><td>Controls</td><td>4.4</td><td>7.5</td><td>13.2</td><td>18.0</td><td>26.3</td></tr><tr><td>Vaccinates</td><td>0.0</td><td>2.0</td><td>5.3</td><td>10.5</td><td>20.8</td></tr></table>
Raw data shown on attached page.</td></tr>
<tr><td>USDA Approval Date</td><td>July 13, 2013</td></tr>
</table>

Lung consolidation scores (%), in order of rank:

Vaccinate	Control
0.1	0
0.1	0.3
0.1	1.0
0.1	2.3
0.1	2.5
0.2	3.0
0.3	3.1
0.3	4.5
0.3	6.7
0.5	8.2
0.5	8.2
0.6	10.8
0.7	11.0
1.1	11.3
1.3	12.1
1.8	12.5
1.9	14.1
2.0	14.8
5.3	15.1
5.7	18.0
10.2	20.1
10.7	23.2
10.9	24.8
33.3	35.0

Summary of Studies Supporting USDA Product Licensure

Study Type	Safety
Pertaining to	All fractions
Study Purpose	Field safety after single 2-ml dose administration
Product Administration (# doses, route of administration, interval between doses)	Single dose, given intramuscularly
Study Animals (species, age at first product administration, number per treatment group)	Commercial pigs, at least 1/3 at 3 weeks of age. 3 independent study sites, with at least 250 pigs per site, randomly divided among two batches of vaccine (T01 and T02 groups) and placebo (T03 group.
Challenge Description (agent, route of administration, interval between last product dose and challenge)	NA
Interval observed after challenge or final treatment	21 days
Results	

Frequency of adverse events	T01 min age	T01 others	T02 min age	T02 others	T03 min age	T03 others
Injection Site Swelling (transient, ≤2 cm diameter)	10	6	3	2	0	0
Respiratory Distress	0	0	0	1	0	0
Pain on injection	3	0	8	3	3	0
No adverse events	87	194	89	194	57	60

Date of USDA Study Approval	December 14, 2013