Supplementary information

Supplementary Table 1 Study inclusion and exclusion criteria

Inclusion criteria
1. Men or women aged between 20 and 74 years.
2. Subjects who were scheduled for an elective colonoscopy.
3. An ability to complete the entire procedure and to comply with study instructions.
4. Willing to complete and sign a written informed consent form.
Exclusion criteria
1. Subjects with severe chronic constipation, defined as fewer than one bowel movement per week for a period >1 year.
2. Subjects with a known or suspected acute exacerbation of chronic inflammatory bowel disease.
3. Subjects with significant gastrointestinal disease, such as gastrointestinal obstruction or perforation, active ulcerative colitis, toxic colitis, or a toxic megacolon.
4. Subjects with ascites of any etiology.
5. Subjects with renal insufficiency, defined as serum creatinine >1.5 times the upper limit of normal.
6. Subjects with a history of abdominal surgeries or who were scheduled to undergo surgery for any of the following conditions:
6.1 Acute surgical abdominal conditions (e.g., acute obstruction or perforation, etc.).
6.2 Any prior colorectal surgery within the previous 3 months of study screening, excluding appendectomy, hemorrhoid surgery, or prior endoscopic procedures.
6.3 History of ileostomy, right or transverse colostomy, subtotal colectomy with ileosimoidostomy, with ≥50% of colon removed, excluding right or left hemicolectomy.
6.4 History of gastric bypass or stapling history.
7. Subjects with any serious cardiovascular diseases or related interventions, as follows:
7.1 History or current evidence of prolonged QT, unstable angina pectoris, untreated arrhythmia, uncontrolled hypertension, cardiomyopathy, congestive heart failure (New York Heart Association [NYHA] Functional Classification, grades 3 and 4).
7.2 Myocardial infarction within the previous 3 months of study screening.
7.3 Percutaneous transluminal coronary angioplasty or coronary artery bypass graft surgery within the previous 3 months of study screening.
7.4 Subjects had undergone a cardiovascular stent procedure or carotid artery stenting, and continues to receive an anticoagulant regimen within 1 year prior to screening.
7.5 Currently using digitalis preparations or any medications known to prolong the QT interval.
8. Subjects with a history of seizures or were at risk of seizure, such as subjects taking medications that lower the seizure threshold (e.g., tricyclic antidepressants), subjects withdrawing from alcohol or benzodiazepines, or subjects with known or suspected hyponatremia.
9. Subject had clinically significant abnormal laboratory values of electrolytes at study screening, including phosphorus, sodium, potassium, calcium, chloride, and magnesium.
10. Subjects with a history of biopsy-proven acute phosphate nephropathy.
11. Subjects with a history of phenylketonuria.
12. Subjects had severe dehydration, or severe abdominal pain associated with nausea and vomiting at study screening.
13. Subjects had problems with swallowing or gastric reflux, or subjects were at risk of aspiration.
14. Pregnant women, lactating women or women of childbearing potential who were not using an effective method of birth control (e.g., oral contraception, intrauterine device, surgical sterilization, hysterectomy).
15. Subjects with hypersensitivity to any ingredients in the study medications.
16. Participation in any other investigational study within 30 days prior to receiving the study medication.
17. Any condition that in the opinion of the investigator would jeopardize the evaluation of the study medication's efficacy or safety.

Supplementary Table 2 Summary of subject dispositions (which are presented as the numbers of study subjects with percentage)

Total Screened	472	
Group	**Quiklean**	**Klean-Prep/Dulcolax**
Randomized	228 (100%)	228 (100%)
Completed the study	222 (97.4%)	220 (96.5%)
Did not complete the study	6 (2.6%)	8 (3.5%)
Reason(s) for Premature Discontinuation		
Adverse events	0 (0.0%)	0 (0.0%)
Withdrawal of consent	6 (2.6%)	8 (3.5%)
Unable to tolerate study medication	0 (0.0%)	0 (0.0%)
Violation and/or significant deviation of study protocol	0 (0.0%)	0 (0.0%)
Lost to follow-up	0 (0.0%)	0 (0.0%)
Other	0 (0.0%)	0 (0.0%)
Analysis set	**Quiklean**	**Klean-Prep/Dulcolax**
Intent-to-treat analysis set (%)	222 (97.4%)	220 (96.5%)
Safety analysis set	222 (97.4%)	220 (96.5%)
Per-protocol analysis set	208 (93.7%)	209 (95.0%)
Subject excluded from the per-protocol analysis set*	14 (6.3%)	11 (5.0%)
Primary exclusion reason		
Did not meet the criteria	0 (0.0%)	0 (0.0%)
Less than excellent compliance	3 (1.4%)	2 (0.9%)
Primary endpoint could not be evaluated	12 (5.4%)	10 (4.5%)
Received bowel preparation medication	0 (0.0%)	0 (0.0%)

Subject 1-S008-R1008 in the Klean-Prep/Dulcolax cohort and Subject 1-S126-R1122 in the Quiklean cohort each satisfied the exclusion criterion of less than excellent compliance and could not be evaluated for the primary endpoint.

Supplementary Table 3 List of subjects in the intent-to-treat analysis who were excluded from the per-protocol analysis set

Subject No.	Actual Treatment	Intent-to-treat	Per-protocol	Reason
1-S002-R1002	Quiklean	Y	N	Colonoscopy video quality is too low for assessment of the scale
1-S003-R1003	Klean-Prep/Dulcolax	Y	N	Colonoscopy video quality is too low for assessment of the scale
1-S005-R1005	Quiklean	Y	N	Colonoscopy video quality is too low for assessment of the scale
1-S007-R1007	Klean-Prep/Dulcolax	Y	N	Colonoscopy video missing
1-S008-R1008	Klean-Prep/Dulcolax	Y	N	Less than excellent compliance (only 6 cups) Colonoscopy video quality is too low for assessment of the scale
1-S011-R1011	Quiklean	Y	N	Colonoscopy video quality is too low for assessment of the scale
1-S016-R1013	Quiklean	Y	N	Colonoscopy video quality is too low for assessment of the scale
1-S020-R1015	Klean-Prep/Dulcolax	Y	N	Colonoscopy video quality is too low for assessment of the scale
1-S026-R1021	Klean-Prep/Dulcolax	Y	N	Colonoscopy video quality is too low for assessment of the scale
1-S028-R1023	Quiklean	Y	N	Colonoscopy video quality is too low for assessment of the scale
1-S031-R1033	Klean-Prep/Dulcolax	Y	N	Colonoscopy video quality is too low for assessment of the scale
1-S050-R1047	Quiklean	Y	N	Less than excellent compliance (only 4 cups)
1-S089-R1089	Klean-Prep/Dulcolax	Y	N	Colonoscopy video missing
1-S090-R1088	Quiklean	Y	N	Colonoscopy video missing
1-S092-R1091	Quiklean	Y	N	Colonoscopy video missing
1-S112-R1109	Klean-Prep/Dulcolax	Y	N	Colonoscopy video missing
1-S116-R1119	Klean-Prep/Dulcolax	Y	N	Less than excellent compliance (only 5 cups)
1-S123-R1118	Quiklean	Y	N	Less than excellent compliance (only 7 cups)
1-S124-R1120	Quiklean	Y	N	Colonoscopy video missing
1-S126-R1122	Quiklean	Y	N	Less than excellent compliance (only 7 cups) Colonoscopy video missing
1-S129-R1125	Quiklean	Y	N	Colonoscopy video missing
1-S131-R1127	Quiklean	Y	N	Colonoscopy video missing
1-S134-R1130	Klean-Prep/Dulcolax	Y	N	Colonoscopy video missing
1-S322-R1310	Klean-Prep/Dulcolax	Y	N	Colonoscopy video missing
1-S393-R1367	Quiklean	Y	N	Colonoscopy video missing

Supplementary Table 4 Summary of demographic and baseline characteristics (per-protocol analysis set)

Item/Category	Quiklean (n=208)	Klean-Prep/Dulcolax (n=209)	*P*-value
Sex			
Male	87 (41.8%)	84 (40.2%)	0.7656
Female	121 (58.2%)	125 (59.8%)	0.8162
Age (years)			
Mean±SD	47.1±11.5	47.3±11.5	0.8556
Median (Min, Max)	46.5 (21.0, 72.0)	47.0 (20.0, 73.0)	
Body weight (kg)			
Mean±SD	66.7±13.6	65.6 ±12.8	0.3788
Median (Min, Max)	65.8 (39.0, 117.0)	64.1 (40.0, 116.9)	
Height (cm)			
Mean±SD	163.5±8.4	162.8±8.5	0.3727
Median (Min, Max)	162.6 (145.0, 188.0)	162.0 (145.3, 187.7)	
Body mass index (kg/m^2)			
Mean±SD	24.8±3.9	24.7±3.9	0.6647
Median (Min, Max)	24.4 (15.8, 38.4)	24.1 (16.6, 39.5)	

P-values were determined using the independent *t*-test and Fisher's exact test for continuous and categorical variables, respectively.

Supplementary Table 5 Blood phosphorous changes from Visit 1/screening (baseline) (safety analysis set)

Phosphorous (mg/dL)	**Quiklean (n=222)**	**Klean-Prep/Dulcolax (n=220)**	***P*-value**
Visit 1 (screening)			
Mean±SD	3.5±0.6	3.6±0.5	0.8477[a]
Median (Min, Max)	3.5 (2.1, 5.1)	3.5 (2.2, 5.5)	
Visit 3 (colonoscopy)			
Mean±SD	7.3±1.5	3.3±0.8	
Median (Min, Max)	7.2 (2.9, 12.3)	3.2 (1.3, 10.4)	
Mean change from Visit 1 (baseline)			
Mean±SD	3.7±1.5	-0.3±0.8	<0.0001[b]
Median (Min, Max)	3.6 (-0.5, 8.6)	-0.3 (-2.5, 7.1)	
Intra-group *P*-value	<0.0001	<0.0001	
Visit 4 (post-colonoscopy follow-up)			
Mean±SD	3.4±0.5	3.5±0.6	
Median (Min, Max)	3.4 (2.1, 4.7)	3.6 (1.9, 5.9)	
Mean change from Visit 1 (baseline)			
Mean±SD	-0.2±0.6	-0.0±0.6	0.0001[b]
Median (Min, Max)	-0.1 (-2.0, 1.5)	0.0 (-1.8, 2.3)	
Intra-group *P*-value	<0.0001	0.8111	

Intra-group *P*-value: paired *t*-test.

[a]*P* value: independent *t*-test.

[b]*P* value: ANCOVA model for mean change.

Supplementary Table 6 Blood potassium changes from Visit 1/screening (baseline) (safety analysis set)

Potassium (mmol/L)	Quiklean (n=222)	Klean-Prep/Dulcolax (n=220)	*P*-value
Visit 1 (screening)			
Mean (SD)	3.87 (0.338)	3.89 (0.329)	0.4279[a]
Median	3.90	3.90	
(Min, Max)	(2.9, 4.8)	(3.1, 5.1)	
Visit 3 (colonoscopy)			
Mean (SD)	3.08 (0.307)	3.60 (0.324)	
Median	3.10	3.60	
(Min, Max)	(2.3, 4.3)	(2.8, 5.0)	
Mean change from baseline			
Mean (SD)	-0.78 (0.408)	-0.29 (0.406)	<0.0001[b]
Median	-0.80	-0.30	
(Min, Max)	(-2.4, 0.5)	(-1.5, 1.2)	
Intra-group *P*-value	<0.0001	<0.0001	
Visit 4 (post-colonoscopy follow-up)			
Mean (SD)	3.89 (0.333)	3.88 (0.314)	
Median	3.90	3.90	
(Min, Max)	(2.7, 5.2)	(3.2, 5.0)	
Mean change from baseline			
Mean (SD)	0.02 (0.350)	-0.02 (0.367)	0.4593[b]
Median	0.00	0.00	
(Min, Max)	(-0.9, 1.1)	(-1.5, 0.8)	
Intra-group *P*-value	0.3888	0.5212	

Intra-group *P*-value: paired *t*-test.

[a]*P* value determined by an independent *t*-test.

[b]*P* value determined by an ANCOVA model for mean change.

Supplementary Table 7 Blood sodium changes from Visit 1/screening (baseline) (safety analysis set)

Sodium (mmol/L)	Quiklean (n=222)	Klean-Prep/Dulcolax (n=220)	*P*-value
Visit 1 (screening)			
Mean±SD	136.4±2.1	136.4±2.4	0.9875[a]
Median (Min, Max)	136.0 (130.0, 143.0)	136.0 (129.0, 145.0)	
Visit 3 (colonoscopy)			
Mean±SD	137.7±2.6	136.9±2.5	
Median (Min, Max)	138.0 (130.0, 146.0)	137.0 (131.0, 145.0)	
Mean change from Visit 1 (baseline)			
Mean±SD	1.3±2.7	0.5±2.6	0.0003[b]
Median (Min, Max)	1.0 (-6.0, 9.0)	1.0 (-6.0, 6.0)	
Intra-group *P*-value	<0.0001	0.0052	
Visit 4 (post-colonoscopy follow-up)			
Mean±SD	136.2±2.4	136.6±2.3	
Median (Min, Max)	136.0 (129.0, 144.0)	137.0 (131.0, 146.0)	
Mean change from Visit 1 (baseline)			
Mean±SD	-0.1±2.3	0.2±2.4	0.0834[b]
Median (Min, Max)	0.0 (-6.0, 7.0)	0.0 (-8.0, 6.0)	
Intra-group *P*-value	0.4182	0.1878	

Intra-group *P*-value: paired *t*-test.

[a]*P* value determined by an independent *t*-test.

[b]*P* value determined by an ANCOVA model for mean change.