Review Summary

July 23, 2026

Pharmaceuticals and Medical Devices Agency

The following is the summary of the review of the following medical device submitted for marketing approval conducted by the Pharmaceuticals and Medical Devices Agency (PMDA).

Classification	:	Medical products 4, Orthopedic products
Term name	:	Absorbable adhesion prevention dressing
Brand name	:	cs barrier
Applicant	:	Seikagaku Corporation
Date of application	:	August 20, 2025
Date of approval	:	April 20, 2026
Application classification	:	☐New medical device ☒Improved medical device (with clinical data) ☐Improved medical device (without clinical data)
New approval / partial change		☒New approval ☐Partial change
Review category	:	☐Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry ☐Cardiopulmonary Circulation ☐Dentistry and Oral Medicine ☒Gastroenterology, Genitourinary, and Reproductive Medicine ☐Ophthalmology and Otorhinolaryngology ☐Orthopedic and Plastic Surgery ☐Robotics, IoT, and other devices (not classified as other categories) ☐Program D1 ☐Program D2
Items warranting special mention	:	☐Designated as medical devices with high medical need ☐Designated as specific-usage medical device ☐Application in accordance with conditional early approval system for medical devices (Type 1) ☐Application in accordance with conditional early approval system for

medical devices (Type 2: “Physical operation of items’ extrapolative and inclusive approval” (Phoenix))

☐Application in accordance with the notification on pre- and post-market rebalancing (☐1st step ☐2nd step)

☐Application in accordance with “Improvement design within approval for timely evaluation and notice” (IDATEN)

☐Designated as orphan medical device

☐Application in accordance with the 0929 notification

☐Other ( )

Expert Discussion : ☐Yes ☒No

1. Submitted data

(1) Background of the development

The product is an absorbable adhesion barrier intended for use in patients undergoing abdominal or pelvic surgery. It is applied beneath the abdominal incision and to the sites of peritoneal injury (e.g. the abdominal wall, abdominal organs, uterus, and uterine adnexa), in order to reduce the frequency, extent, and severity of postoperative adhesions. The product consists of a powder substance, a handheld dispenser filled with the powder substance, and a dedicated applicator. The objective of development of this product is to introduce a product that fully addresses both the needs for usability and efficacy. The intended use of this product is substantially equivalent to that of already approved products by other manufacturers.

(2) Non-clinical data

The following non-clinical data were submitted (data items were based on applicant submission data).

- Physical and chemical properties: (Powder substance) description, purity tests, etc, (Handheld dispenser) visual inspection, air pressure test, etc, (Applicator) visual inspection, tube bending test, etc.
- Biological safety: (Powder substance) cytotoxicity test, skin sensitization test, intracutaneous reactivity test, pyrogen test, acute and subacute systemic toxicity tests, subchronic systemic toxicity test, chronic systemic toxicity test, intramuscular implantation test, hemolysis test, bacterial reverse mutation test, chromosomal aberration test, in vivo micronucleus test, and other tests were omitted based on the evaluation, (Applicator) cytotoxicity test, skin sensitization test, intracutaneous reactivity test, pyrogen test, acute systemic toxicity test.
- Other safety: Tensile strength measurement and histopathological evaluation tests at rat abdominal wall incision sites, mortality and abscess formation evaluation tests in rats following inoculation with rat cecal contents, etc.
- Pharmacokinetics: Absorption, distribution, metabolism, and excretion tests using radiolabeled powder substance.
- Stability and durability: (Powder substance) long-term storage test, (Handheld dispenser and Applicator) long-term storage test and accelerated test.
- Performance: Test on sprayable area (open surgery and laparoscopic surgery)
- Efficacy and mechanism of action: Anti-adhesion effect test in a rat cecum-abraded adhesion model, histopathological test on the mechanism of anti-adhesion using the rat cecum-abraded adhesion model, etc.
- Directions for use: Spray performance evaluation using a trocar for robot-assisted laparoscopic surgery, and operability evaluation by physicians, etc.
- Usability: Documents related to compliance with JIS T 62366-1:2022

(3) Clinical data

The applicant submitted the results of domestic clinical studies. The outline of these studies is as follows (the clinical results section of the package insert is cited, and table numbers are modified as necessary).

1) Abdominal surgery

The study enrolled patients with rectal cancer who underwent open rectal resection. The powder substance of the product was applied beneath the midline abdominal incision (2 to 3 g of the powder substance was used).

At the time of ileostomy closure, images of the area beneath the midline incision were captured using a laparoscopic camera, and postoperative adhesions were evaluated by a third party (Central Review Board).

Table 1: Postoperative Adhesions in Abdominal Surgery

		cs barrier group (n=58) Note 1)	Untreated group (n=60) Note 1)	Test
Presence/absence of adhesions Number of participants (%)	No adhesions	32 (55.2)	4 (6.7)	p<0.001 Note 4)
	With adhesions	26 (44.8)	56 (93.3)	
Severity of adhesion Note 2) Number of participants (%)	Score 0	32 (55.2)	4 (6.7)	p<0.001 Note 5)
	Score 1	9 (15.5)	6 (10.0)	
	Score 2	14 (24.1)	33 (55.0)	
	Score 3	3 (5.2)	17 (28.3)	
Extent of adhesion Note 3) Number of participants (%)	Score 0	32 (55.2)	4 (6.9)	p<0.001 Note 5)
	Score 1	8 (13.8)	9 (15.5)	
	Score 2	5 (8.6)	7 (12.1)	
	Score 3	13 (22.4)	38 (65.5)	

Note 1) Of 118 evaluable participants for efficacy, 58 participants were in the cs barrier group and 60 participants in the untreated group (extent of adhesion evaluated in 58 of the untreated participants).

Note 2) Severity of adhesion

Score 0: No

Score 1: Mild (filmy adhesions without vascularity)

Score 2: Moderate (adhesions of moderate thickness with partial vascularity)

Score 3: Severe (thick adhesions with prominent vascularity)

Note 3) Extent of adhesion

Score 0: No

Score 1: Less than 1/3 of the total incision length

Score 2: 1/3 or more but less than 2/3 of the total incision length

Score 3: 2/3 or more of the total incision length

Note 4) Fisher's exact test

Note 5) Wilcoxon rank sum test

For all adverse events reported, a causal relationship to the product was ruled out.

The incidence of all serious adverse events is shown in Table 2.

Table 2: Incidence of all serious adverse events

Serious adverse event	cs barrier group (n=64)	Untreated group (n=64)
Ileus paralytic	7.8%	6.3%
Anastomotic leak	6.3%	4.7%
Urinary tract infection	4.7%	1.6%
Pelvic infection	3.1%	0%
Abdominal abscess	1.6%	3.1%
Dehydration	1.6%	3.1%
Intestinal obstruction	1.6%	3.1%
Decreased appetite	1.6%	1.6%
Medical device site cellulitis	1.6%	1.6%
Anal abscess	1.6%	0%
Pelvic abscess	1.6%	0%
Peritonitis	1.6%	0%
Pneumonia aspiration	1.6%	0%
Sepsis	1.6%	0%
Stoma site abscess	1.6%	0%
Stoma site cellulitis	1.6%	0%
Rectal cancer	1.6%	0%
Anaemia	1.6%	0%
Electrolyte imbalance	1.6%	0%
Cerebrovascular accident	1.6%	0%

Myoclonus	1.6%	0%
Cardio-respiratory arrest	1.6%	0%
Intra-abdominal haemorrhage	1.6%	0%
Gastrointestinal stoma complication	1.6%	0%
Stoma complication	1.6%	0%
Suture rupture dehiscence	1.6%	0%
Bile duct stent insertion	1.6%	0%
Lung lobectomy	1.6%	0%
Mechanical ileus	0%	4.7%
Gastrointestinal anastomotic leaks	0%	4.7%
Duodenal ulcer haemorrhage	0%	3.1%
Intestinal anastomosis complication	0%	3.1%
Abdominal wall infection	0%	1.6%
Bacteraemia	0%	1.6%
Rectal cancer metastatic	0%	1.6%
Lymphorrhoea	0%	1.6%
Shock	0%	1.6%
Interstitial lung disease	0%	1.6%
Ascites	0%	1.6%
Diarrhoea	0%	1.6%
Enteritis	0%	1.6%
Vomiting	0%	1.6%
Acute kidney injury	0%	1.6%
Dysuria	0%	1.6%
Prostatitis	0%	1.6%
Pyrexia	0%	1.6%
C-reactive protein increased	0%	1.6%
Anastomotic stenosis	0%	1.6%
Deep vein thrombosis postoperative	0%	1.6%
Nephrectomy	0%	1.6%

2) Obstetrics and Gynecology

This study enrolled patients who underwent laparoscopic myomectomy. The powder substance of the product was applied at the uterus, uterine adnexa, and other adhesiolysis site within the pelvic cavity (1 to 3 g of the powder substance was used).

For all adverse events reported, a causal relationship to the product was ruled out.

The incidence of all serious adverse events is shown in Table 3.

Table 3: Incidence of all serious adverse events

Serious adverse event	cs barrier group (n=10)
Urinary tract infection	10.0%

2. Review Results

As a result of the review of the submitted data, PMDA concluded that the product could be approved.

<Intended use>

cs barrier is intended to be used in patients undergoing abdominal or pelvic surgery to apply beneath the abdominal incision and to the sites of peritoneal injury (e.g. the abdominal wall, abdominal organs, uterus, and uterine adnexa), in order to reduce the frequency, extent, and severity of postoperative adhesions.