510(k) Summary

I. SUBMITTER

Stryker Endoscopy
5900 Optical Ct.
San Jose, CA 95138

Contact Person: Katie Farraro, PhD, RAC
Senior Manager, Regulatory Affairs
Phone: 408-754-2285

Date Prepared: July 10, 2026

II. DEVICE

Name of Device:	AIR+ All-Inside Meniscal Repair Device
Common Name:	Suture Retention Device
Classification Name:	Nonabsorbable poly(ethylene terephthalate) surgical suture (21 CFR §878.5000)
Regulatory Class:	II
Product Code:	GAT

III. PREDICATE DEVICE

Device Name:	AIR+ All-Inside Meniscal Repair Device
Company Name:	Stryker
510(k) Number:	K153087

IV. OBJECTIVE

The purpose of this Special 510(k) submission is to obtain Food and Drug Administration (FDA) authorization to market modifications to the AIR+ All-Inside Meniscal Repair Device. Specifically, this submission proposes to introduce models of the AIR+ device for use in adolescents.

V. DEVICE DESCRIPTION

The AIR+ All-Inside Meniscal Repair Device is a suture retention device comprised of two molded suture retention anchors pre-tied with #2-0 braided ultra-high molecular weight polyethylene (UHMWPE) suture. The suture-anchor construct is pre-loaded on a deployer. The device is offered in two configurations, including curved up and curved down, to provide options to surgeons for access to the desired zone of the meniscus. The AIR+ All-Inside Meniscal Repair Device is provided sterile for single use only.

VI. INTENDED USE

The AIR+ All-Inside Meniscal Repair Device is intended for use as a suture retention device to facilitate arthroscopic soft tissue procedures. The AIR+ All-Inside Meniscal Repair Device is indicated for use in meniscal repairs and allograft transplant procedures in adolescents. The AIR+ All-Inside Meniscal Repair Device is intended to be used for anchoring the allograft to the meniscal rim during allograft transplant procedures.

VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The modified AIR+ All-Inside Meniscal Repair Device is identical to the predicate device in terms of intended use, operational principle, design, shelf life, sterilization, biocompatibility, and performance attributes. It is equivalent to the predicate device in terms of indications for use. The only difference between the modified device and predicate device is that the modified device is indicated for use in adolescents, and the predicate device is indicated for use in adults. The subject implants and instruments are compatible with adolescent knees, which are similar in size to adult knees and thus these differences are not critical to the surgical use of the device or intended therapeutic action when used as labeled. The difference between the modified AIR+ device and the predicate device does not raise new questions of safety and effectiveness, and these devices are substantially equivalent based on the criteria described in 21 CFR §807.100.

VIII. PERFORMANCE DATA

Non-clinical benchtop testing was previously performed on the predicate AIR+ All-Inside Meniscal Repair Device. For the proposed indications for use in adolescents, there were no new risks or significantly modified risks requiring new risk control measures, no design changes nor procedural modifications, and no new functional performance requirements. As such, new verification and/or validation activities were not required. Results from the device's previous verification testing activities remain applicable to demonstrate that the modified device meets all of the applicable requirements and specifications.

IX. CONCLUSIONS

The information presented within this Special premarket submission demonstrates that the modified AIR+ All-Inside Meniscal Repair Device for use in adolescents is substantially equivalent to the predicate device for use in adults, and will perform as safely and effectively within the intended use.

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K262369

Please provide the device trade name(s).

AIR+ All-Inside Meniscal Repair Device, Curved Up;
AIR+ All-Inside Meniscal Repair Device, Curved Down

Please provide your Indications for Use below.

The AIR™+ All-Inside Meniscal Repair Device is intended for use as a suture retention device to facilitate arthroscopic soft tissue procedures. The AIR™+ All-Inside Meniscal Repair Device is indicated for use in meniscal repairs and allograft transplant procedures in adolescents. The AIR™+ All-Inside Meniscal Repair Device is intended to be used for anchoring the allograft to the meniscal rim during allograft transplant procedures.

Please select the types of uses.

- [x] Prescription Use (21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

Please select the age group(s) for which the device(s) is to be used.

- [ ] Neonates/Newborns (Birth to < 29 days old)
- [ ] Infants (29 days old to < 2 years old)
- [ ] Children (2 years old to < 12 years old)
- [x] Adolescents (12 years old to < 22 years old)
- [ ] Adults (22 years old and greater)

510(k) Summary

I. SUBMITTER

Stryker Endoscopy
5900 Optical Ct.
San Jose, CA 95138

Contact Person: Katie Farraro, PhD, RAC
Senior Manager, Regulatory Affairs
Phone: 408-754-2285

Date Prepared: July 10, 2026

II. DEVICE

Name of Device:	AIR+ All-Inside Meniscal Repair Device
Common Name:	Suture Retention Device
Classification Name:	Nonabsorbable poly(ethylene terephthalate) surgical suture (21 CFR §878.5000)
Regulatory Class:	II
Product Code:	GAT

III. PREDICATE DEVICE

Device Name:	AIR+ All-Inside Meniscal Repair Device
Company Name:	Stryker
510(k) Number:	K153087

IV. OBJECTIVE

The purpose of this Special 510(k) submission is to obtain Food and Drug Administration (FDA) authorization to market modifications to the AIR+ All-Inside Meniscal Repair Device. Specifically, this submission proposes to introduce models of the AIR+ device for use in adolescents.

V. DEVICE DESCRIPTION

The AIR+ All-Inside Meniscal Repair Device is a suture retention device comprised of two molded suture retention anchors pre-tied with #2-0 braided ultra-high molecular weight polyethylene (UHMWPE) suture. The suture-anchor construct is pre-loaded on a deployer. The device is offered in two configurations, including curved up and curved down, to provide options to surgeons for access to the desired zone of the meniscus. The AIR+ All-Inside Meniscal Repair Device is provided sterile for single use only.

VI. INTENDED USE

The AIR+ All-Inside Meniscal Repair Device is intended for use as a suture retention device to facilitate arthroscopic soft tissue procedures. The AIR+ All-Inside Meniscal Repair Device is indicated for use in meniscal repairs and allograft transplant procedures in adolescents. The AIR+ All-Inside Meniscal Repair Device is intended to be used for anchoring the allograft to the meniscal rim during allograft transplant procedures.

VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The modified AIR+ All-Inside Meniscal Repair Device is identical to the predicate device in terms of intended use, operational principle, design, shelf life, sterilization, biocompatibility, and performance attributes. It is equivalent to the predicate device in terms of indications for use. The only difference between the modified device and predicate device is that the modified device is indicated for use in adolescents, and the predicate device is indicated for use in adults. The subject implants and instruments are compatible with adolescent knees, which are similar in size to adult knees and thus these differences are not critical to the surgical use of the device or intended therapeutic action when used as labeled. The difference between the modified AIR+ device and the predicate device does not raise new questions of safety and effectiveness, and these devices are substantially equivalent based on the criteria described in 21 CFR §807.100.

VIII. PERFORMANCE DATA

Non-clinical benchtop testing was previously performed on the predicate AIR+ All-Inside Meniscal Repair Device. For the proposed indications for use in adolescents, there were no new risks or significantly modified risks requiring new risk control measures, no design changes nor procedural modifications, and no new functional performance requirements. As such, new verification and/or validation activities were not required. Results from the device's previous verification testing activities remain applicable to demonstrate that the modified device meets all of the applicable requirements and specifications.

IX. CONCLUSIONS

The information presented within this Special premarket submission demonstrates that the modified AIR+ All-Inside Meniscal Repair Device for use in adolescents is substantially equivalent to the predicate device for use in adults, and will perform as safely and effectively within the intended use.