April 24, 2026

Broncus Medical, Inc.
Antoinette Clay
Sr. Regulatory Affairs Specialist
125 Nicholson Lane
San Jose, California 95134

Re: K260009
Trade/Device Name: LungPoint Virtual Bronchoscopic Navigation (VBN) Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: January 1, 2026
Received: January 2, 2026

Dear Antoinette Clay:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See

the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jessica Lamb, PhD
Assistant Director
Imaging Software Team
DHT8B: Division of Radiological Imaging
Devices and Electronic Products
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K260009

Device Name
LungPoint Virtual Bronchoscopic Navigation (VBN) Software

Indications for Use *(Describe)*
The LungPoint Virtual Bronchoscopic Navigation (VBN) Software is indicated for displaying images of the tracheobronchial tree to aid the physician in guiding endoscopic tools or catheters in the pulmonary tract to a location in the tracheobronchial tree or lung tissue, and to enable marker placement within soft lung tissue in adults and pediatrics. It does not make a diagnosis and it is not an endoscopic tool.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Administrative Information

General Information

Manufacturer & 510(k) Submitter:	Broncus Medical, Inc. 125 Nicholson Lane San Jose, CA 95134 USA Phone: (650) 428-1600 Fax: (650) 428-1542
Establishment Registration Number:	3007867778
Primary Contact:	Antoinette M. Clay Sr. Regulatory Affairs Specialist aclay@broncus.com (650) 428 1600 Extn. 318
Secondary Contact:	Gloria Dy Sr. Regulatory Affairs Specialist (650) 428-1600 gdy@broncus.com
Date Prepared:	March 23, 2026
Device Subject to this 510(k) Submission:	LungPoint Virtual Bronchoscopic Navigation (VBN) Software
Description:	LungPoint Virtual Bronchoscopic Navigation (VBN) Software is a device that is used by medical practitioners and physicians (typically bronchoscopists such as pulmonologists or thoracic surgeons) to plan procedures and navigate to targets in the lung. It guides a bronchoscope and endoscopic tools to a pre-specified target in or adjacent to the bronchial tree by providing a path, which is displayed on a 3D reconstruction of a CT scan.
Trade Name:	LungPoint Virtual Bronchoscopic Navigation (VBN) Software
Generic/Common Name:	Picture Archiving and Communication System
Device Classification Name:	System, Image Processing, Radiological
Regulation Number:	21 CFR 892.2050
Product Code:	LLZ
Classification:	Class II

Predicate Device

Trade Name	LungPoint Virtual Bronchoscopic Navigation (VBN) Software
Predicate Device Common Name:	Picture Archiving and Communication System
Predicate 510(k) Number	K090095
Classification Name	System, Image Processing, Radiological
Regulation Number	21 CFR 892.2050
Product Code	LLZ
Classification	Class II

Device Description

LungPoint Virtual Bronchoscopic Navigation (VBN) software is a device that is used by medical practitioners and physicians (typically bronchoscopists such as pulmonologists or thoracic surgeons) to plan procedures and navigate to targets in the lung. It guides a bronchoscope and endoscopic tools to a pre-specified target in or adjacent to the bronchial tree by providing a path, which is displayed on a 3D reconstruction of a CT scan. The software allows visualization of the inside and outside of the bronchial tree; helps guide the tools in or adjacent to the bronchial tree; allows visualization of a predefined target in lung tissue; and assists with placement of markers into soft lung tissue to guide radiosurgery and thoracic surgery.

LungPoint VBN device displays images of the anatomy to aid the physician in guiding endoscopic tools or catheters during navigation through the same anatomy.

LungPoint VBN software provides fluoroscopic guidance capability to allow physicians to navigate to targets in the lung, including soft lung tissue. This is accomplished by overlaying acquired and segmented 3D CT anatomical image data onto live fluoroscopic X-ray images of the same anatomy to enable fluoroscopic guidance of accessories to the target.

When under fluoroscopy guidance, the software enables users to segment previously acquired 3D CT or other datasets and overlay and register these 3D segmented data sets with live fluoroscopy X-ray images of the same anatomy in order to support catheter/device navigation.

The LungPoint VBN software is installed on standard off-the-shelf computers. Computers and monitors are installed on a cart and include a navigation tracking tool provided by a third-party supplier.

Indications For Use

The LungPoint Virtual Bronchoscopic Navigation (VBN) Software is indicated for displaying images of the tracheobronchial tree to aid the physician in guiding endoscopic tools or catheters in the pulmonary tract to a location in the tracheobronchial tree or lung tissue, and to enable marker placement within soft lung tissue in adults and pediatrics. It does not make a diagnosis and it is not an endoscopic tool.

Summary of Indications for Use Modification

This 510(k) submission expands the original indication to include pediatric patients. The expansion is supported by additional performance testing and validation demonstrating that the device performs safely and effectively for pediatric airway planning and navigation.

The LungPoint VBN software is designed to assist medical practitioners, including bronchoscopists such as pulmonologists and thoracic surgeons, in planning procedures and navigating to targets in the lung. The software's performance in adult patients has been previously established, and the current submission includes validation data supporting its use in pediatric patients.

Table 1. Comparison of the LungPoint VBN Indications for Use and Modified Indications for Use

Characteristics	LungPoint VBN With Pediatric Indication (Subject device)	LungPoint VBN (Predicate device) K090095	Comment
Manufacturer	Broncus Medical Inc., San Jose, CA.	Broncus Medical Inc., San Jose, CA.	Same

Characteristics	LungPoint VBN With Pediatric Indication (Subject device)	LungPoint VBN (Predicate device) K090095	Comment
Device Classification	Class II	Class II	Same
Regulation Number	21 CFR 892.2050	21 CFR 892.2050	Same
FDA Product Code	LLZ	LLZ	Same
Intended Use and Indication For Use			
Intended Use	LungPoint Virtual Bronchoscopic Navigation (VBN) Software is intended to to assist physicians in planning and performing navigation of the pulmonary anatomy by displaying virtual bronchoscopic images and supporting guidance of endoscopic tools or catheters. The Archimedes System also includes fluoroscopy guidance functions that enable users to segment previously acquired 3D CT or other imaging datasets, overlay and register these datasets with live fluoroscopy X-ray images of the same anatomy, and support device or catheter navigation during bronchoscopic procedures.	LungPoint VBN software is intended to display images of the anatomy to aid the physician in guiding endoscopic tools or catheters during navigation through the same anatomy. The LungPoint VBN software is indicated for displaying images of the tracheobronchial tree to aid the physician in guiding endoscopic tools or catheters in the pulmonary tract to a location in the tracheobronchial tree or lung tissue, and to enable marker placement within soft lung tissue in adults to make a diagnosis. Not for pediatric use.	Similar - Subject device includes pediatric population
Indications for Use	LungPoint Virtual Bronchoscopic Navigation (VBN) Software is indicated for use in adult and pediatric patients (ages 2 to 17 years) undergoing diagnostic bronchoscopy to evaluate pulmonary abnormalities, including suspected cancerous lesions and non-cancerous nodules. The software displays images of the tracheobronchial tree to assist physicians in guiding endoscopic tools or catheters to a specific location within the pulmonary tract for obtaining tissue samples or for marker placement within soft lung tissue. The software does	LungPoint Virtual Bronchoscopic Navigation (VBN) Software is indicated for use in adult patients undergoing diagnostic bronchoscopy to evaluate pulmonary abnormalities, including suspected cancerous lesions and non-cancerous nodules. The software displays images of the tracheobronchial tree to assist physicians in guiding endoscopic tools or catheters to a specific location within the pulmonary tract for obtaining tissue samples or for marker placement within soft lung tissue. The software does not	Similar - Subject device includes pediatric population

Characteristics	LungPoint VBN With Pediatric Indication (Subject device)	LungPoint VBN (Predicate device) K090095	Comment
	not make a medical diagnosis and is not an endoscopic tool.	make a medical diagnosis and is not an endoscopic tool.	
Target Patient Population	Adult and pediatric patients (ages 2 to 17 years) with pulmonary abnormalities such as peripheral lung nodules or suspected malignancies who require diagnostic or therapeutic bronchoscopic procedures.	Adult patients with pulmonary abnormalities such as peripheral lung nodules or suspected malignancies who require diagnostic or therapeutic bronchoscopic procedures. Not for pediatric use.	Similar - Subject device includes pediatric population
Contraindications	None	None	Same
Use Condition	Surgical suite, endoscopy or bronchoscopy suite, used with a bronchoscope.	Surgical suite, endoscopy or bronchoscopy suite, used with a bronchoscope.	Same
Intended User	Physicians and medical practitioners, specifically bronchoscopists such as pulmonologists and thoracic surgeons	Physicians and medical practitioners, specifically bronchoscopists such as pulmonologists and thoracic surgeons	Same
Manufacturing Standards and Design			
Device Design	The LungPoint VPN System is comprised of the Planning and Navigation software The software is installed on off-the-shelf-computer. High-definition computer monitors display the images created by the software and allow for bronchoscopic navigation and live fluoroscopic images. An off-the-shelf infrared camera monitors the position of the C-Arm. These component subsystems are installed on a mobile workstation; collectively, this workstation is referred to as the LungPoint VBN System.	The LungPoint VPN System is comprised of the Planning and Navigation software. The software is installed on off-the-shelf-computer. High-definition computer monitors display the images created by the software and allow for bronchoscopic navigation and live fluoroscopic images. An off-the-shelf infrared camera monitors the position of the C-Arm. These component subsystems are installed on a mobile workstation; collectively, this workstation is referred to as the LungPoint VBN System.	Same

Characteristics	LungPoint VBN With Pediatric Indication (Subject device)	LungPoint VBN (Predicate device) K090095	Comment
Components/Materials	The LungPoint VPN Workstation, which includes the computer, monitor, keyboard, mouse, cart, C-Arm tracker and labeling, was tested to the appropriate EN 60601 standard.	The LungPoint VPN Workstation, which includes the computer, monitor, keyboard, mouse, cart, C-Arm tracker and labeling, was tested to the appropriate EN 60601 standard.	Same
Sterilization	Non-Sterile	Non-Sterile	Same
Calibration	The software contains a calibration feature process for the use of bronchoscopes and fluoroscopes. Calibration is performed during installation and setup of the system.	The software contains a calibration feature process for the use of bronchoscopes and fluoroscopes. Calibration is performed during installation and setup of the system.	Same
Hardware	The LungPoint VPN system utilizes off-the-shelf PCs (desktop and/or laptop) as its hardware platform. A minimum screen resolution of 1920 x 1080 or higher is required.	The LungPoint VPN system utilizes off-the-shelf PCs (desktop and/or laptop) as its hardware platform. A minimum screen resolution of 1920 x 1080 or higher is required.	Same
Operating System	64-bit Windows 7 Professional edition with Service Pack 1 or later (navigation workstation)	64-bit Windows 7 Professional edition with Service Pack 1 or later (navigation workstation)	Same
Technical Specifications	The LungPoint VBN Software is installed on a standard off-the-shelf computer and mounted on a cart with HD monitors and camera to track the position of the C-Arm.	The LungPoint VBN Software is installed on a standard off-the-shelf computer and mounted on a cart with HD monitors and camera to track the position of the C-Arm.	Same
Service Life	The LungPoint VBN Software System is designed and manufactured to withstand the stresses which can occur during normal conditions of use in a bronchoscopy suite over 5 years.	The LungPoint VBN Software System is designed and manufactured to withstand the stresses which can occur during normal conditions of use in a bronchoscopy suite over 5 years.	Same
Electrical Compatibility	Testing was performed by certified test laboratories for Electrical Safety: EN 60601-	Testing was performed by certified test laboratories for Electrical Safety: EN 60601-	Same

Characteristics	LungPoint VBN With Pediatric Indication (Subject device)	LungPoint VBN (Predicate device) K090095	Comment
	1: Edition 3.1. and Electromagnetic Compatibility: EN IEC 60601-1-2:2014	1: Edition 3.1. and Electromagnetic Compatibility: EN IEC 60601-1-2:2014	
Fluoroscopic Guidance	The user may utilize the virtual fluoroscopy view in conjunction with a fluoroscopy device to confirm the current position of the bronchoscope to provide additional guidance for an endoscopic tool in lung tissue. Once the user has navigated to the target, a standard bronchoscopic procedure using endoscopic tools can then be used to access the target using the fluoroscopic guidance capabilities of the system	The user may utilize the virtual fluoroscopy view in conjunction with a fluoroscopy device to confirm the current position of the bronchoscope to provide additional guidance for an endoscopic tool in lung tissue. Once the user has navigated to the target, a standard bronchoscopic procedure using endoscopic tools can then be used to access the target using the fluoroscopic guidance capabilities of the system	Same
Labeling	Labeling on the system, cart and computer. The IFU/User Manual will reflect the pediatric indication. There is no pediatric restriction on the physical label.	Labeling on the system, cart and computer. The IFU reflects that the device is for adult use only. There is no pediatric restriction on the physical label.	Similar- Subject device includes pediatric population
Packaging	The LungPoint VBN Workstation is packaged in a wooden crate for transportation.	The LungPoint VBN Workstation is packaged in a wooden crate for transportation.	Same
Biocompatibility	Not Applicable. LungPoint VBN is non-invasive software. There is no patient contact.	Not Applicable. LungPoint VBN is non-invasive software. There is no patient contact	Same

Performance Data

Biocompatibility

No biocompatibility testing was conducted in the original submission which was cleared by FDA on March 13, 2009 (K090095) because the device is a software system that does not come into contact with the patient. The 510(k) Submission is to expand the original indication for use to allow pediatric use of the device does not raise any new questions of biocompatibility.

Sterilization

No sterilization testing was conducted in the original submission which was cleared by FDA on March 13, 2009 (K090095) because the device is a software system. The 510(k) Submission is to expand the original indication for use to allow pediatric use of the device does not raise any new questions of sterilization.

Service of Life/Shelf-Life Testing

Since this 510(k) Submission is for a software device, which is non-sterile and does not come into contact with the patient, shelf-life testing is not applicable.

Usability Testing

Usability testing to satisfy guidance recommendations of IEC 60601-1-6 and IEC 62366 was conducted and submitted with the original submission which was cleared by the FDA on March 13, 2009 (K090095). There is no change in the testing parameters or data in the scope of this submission. The 510(k) Submission is to expand the original indication for use to allow pediatric use of the device does not raise any new questions of use, safety or effectiveness.

Electrical Testing

The LungPoint VBN Software is installed on a standard off-the-shelf computer and mounted on a cart with HD monitors and camera to track the position of the C-Arm. This assembled Workstation was tested to the following electrical safety and electromagnetic compatibility requirements: Electrical Safety: EN 60601-1: Edition 3.1. and Electromagnetic Compatibility: EN IEC 60601-1-2:2014. Testing was performed by certified test laboratories.

The development of the LungPoint VBN products conform to IEC 62304:2006. Performance of the software is ensured through verification and validation testing in accordance with IEC 62304. Electrical and mechanical hazards to the operator and users of the LungPoint VBN System have been evaluated as compliant to IEC 60601-1: Revision 3.2. Electromagnetic Compatibility of the system has been verified in accordance with IEC 60601-1-2:2014.

These standards were met when the original 510(k) was cleared by the FDA on March 13, 2009 (K090095) and are continuously maintained to ensure compliance to the most recent standard. No new testing has been conducted in the scope of this 510(k) submission because only an extension to the indication for use to include the pediatric testing is being requested.

There are no changes to the Electrical Safety and Electromagnetic Compatibility of the LungPoint VBN software or system and no new risks have been identified in regards to the extension of the indication for use to the pediatric patient population.

Performance Testing – Bench Testing

Bench testing was conducted to show that LungPoint VBN can potentially exceed standard bronchoscopy practice for enabling the bronchoscopic biopsy of peripheral lung lesions. This testing was submitted with the original submission which was cleared by FDA on March 13, 2009 (K090095). There is no change in the testing parameters or data in the scope of this submission. The 510(k) Submission is to expand the

original indication for use to allow pediatric use of the device does not raise any new questions of use, safety or effectiveness.

Performance Testing – Animal Study

An animal study, with both animal and clinical testing was conducted to evaluate the accuracy of the VBN system and submitted with the original submission which was cleared by FDA on March 13, 2009 (K090095). There is no change in the testing parameters or data in the scope of this submission. The 510(k) Submission is to expand the original indication for use to allow pediatric use of the device does not raise any new questions of use, safety or effectiveness.

Performance Testing –VBN Validation

Validation testing to ensure clinical workflow, risk mitigation was conducted to evaluate the accuracy of the VBN system and submitted with the original submission which was cleared by FDA on March 13, 2009 (K090095). There is no change in the testing parameters or data in the scope of this submission. The 510(k) Submission is to expand the original indication for use to allow pediatric use of the device does not raise any new questions of use, safety or effectiveness.

Performance Testing – Verification and Validation of The New Patient Population

Verification and validation testing was conducted to evaluate the performance of the Archimedes Software System in processing pediatric CT scans, as documented in Verification & Validation Summary Report QT-01041 Rev. A, executed in accordance with Verification & Validation Plan D0330-032, Rev. B. The dataset comprised 50 pediatric CT scans from patients ranging in age from 0 years 3 months to 14 years 1 month. Successful airway reconstruction was achieved in all 50 cases (100%) following adjustment of the airway volume threshold to accommodate smaller pediatric airway dimensions.

Airway volumes ranged from 1.18 ml to 23.29 ml across the dataset. Segmentation accuracy was evaluated through automated outputs and manual visual review by trained clinical engineers. Manual correction was required in 19 of 50 vessel segmentation cases (38%) and 7 of 50 airway segmentation cases (14%). For a subset of 15 cases, airway diameter measurements generated by the system were compared to manually measured diameters at key tracheobronchial landmarks. Mean diameter error ranged from ±0.4 mm to ±0.6 mm across age groups, with maximum deviations of 0.9 mm to 1.4 mm, all within the pre-specified acceptable range of ±1.5 mm. Diagnostic utility, defined as generation of a navigable path and target overlay, was achieved in 50 of 50 cases (100%).

Risk Analysis Summary

The benefit-risk assessment supporting the expanded indication for pediatric use is based on new performance testing and system validation demonstrating that the device performs reliably for airway and vessel segmentation in pediatric patients aged 2 to 17 years. The device has an established history of safe and effective use in the adult population, and the validated pediatric threshold parameter ensures that segmentation accuracy is maintained for smaller airways.

Risk mitigation measures specific to pediatric patients include automatically applying an adjusted airway volume threshold, restricting user modification of this parameter, and providing clear guidance in the user manual regarding planning and navigation in smaller airways. These controls reduce the likelihood of improper tool selection or inaccurate navigation paths.

Based on the results of the pediatric performance testing and the established adult use history, expanding the indication for use to include patients aged 2 to 17 years does not introduce new safety or effectiveness concerns and does not raise new questions of risk.

Conclusion

Based on the comparison to the predicate device and the results of the performance testing, no changes to the software design or manufacturing processes are required to support the expanded indication for pediatric use. The software's performance and risk controls have been validated to ensure consistent reliability, accuracy, and safety for patients aged 2 to 17 years.

Established risk management measures, parameter controls, and post-market monitoring remain in place and have been updated where appropriate to address pediatric anatomical considerations.

This expanded indication builds upon the software's existing functionality and confirms that the device can be safely and effectively used for airway planning and navigation in pediatric patients, without introducing new questions of safety or effectiveness.