March 4, 2022

Kinetic Innovative Seating System LLC
Susan Farricielli
President / Managing Partner
26 N. Main Street, Office Bldg
Branford, Connecticut 06405

Re: K211919
Trade/Device Name: KISS Dynamic Solid Drop Seat, Model S1520
KISS Dynamic Back Support, Model B1620
Regulation Number: 21 CFR 890.3920
Regulation Name: Wheelchair Component
Regulatory Class: Class I
Product Code: KNN
Dated: December 11, 2021
Received: December 15, 2021

Dear Susan Farricielli:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

for Heather Dean, PhD
Assistant Director, Acute Injury Devices Team
DHT5B: Division of Neuromodulation
and Physical Medicine Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211919

Device Name
KISS Dynamic Solid Drop Seat, Model S1520
KISS Dynamic Back Support, Model B1620

Indications for Use *(Describe)*
The KISS Dynamic Solid Drop Seat and Back Support devices are wheelchair components intended for medical purposes that are generally sold as an integral part of a wheelchair but may also be sold separately as a replacement part.

The KISS Dynamic Solid Drop Seat and Back Support are intended to assist posture and positioning for a person seated in a wheelchair by way of providing a solid seating platform or back support with dynamic motion.

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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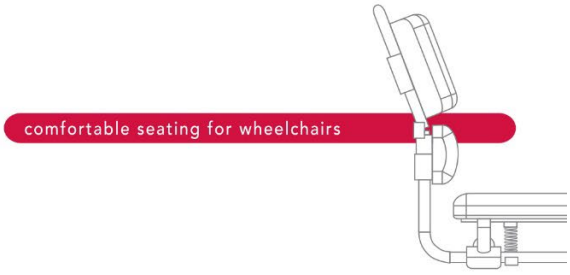
KiSS
Kinetic Innovative Seating System, LLC



510(k) SUMMARY

as required by 21CFR 807.92

KISS DYNAMIC SEATING SYSTEM *(bundled devices):*

KISS SOLID DROP SEAT

KISS DYNAMIC BACK SUPPORT

K211919

Owner Information: Kinetic Innovative Seating System, LLC
26 N. Main Street, office bldg.
Branford, CT 06405

Phone: (203) 488-1758
Fax: (203) 643-8006
Email: info@kissforwheelchairs.com
Contact person: Susan Farricielli

Date of revised Summary preparation: February 23, 2022

Name of the devices:

Proprietary name(s) – **KISS Dynamic Solid Drop Seat, Model S1520**
KISS Dynamic Back Support, Model B1620

Common name(s) – drop seat / back support

Classification name – wheelchair component (21 CFR 890.3920, Product Code KNN)

Legally marketed device compared for a determination of substantial equivalence:

The KISS seat is substantially equivalent to K942312; product code KNN; device name, Alden Lineage Wheelchair Cushion. Both devices are wheelchair seating components, regulation number 890.3920.

The reference device for the KISS seat is K982989; product code IOR; regulation number 890.3850; device name, Quickie suspension wheelchair series model XTR with the Rock Shox® monoshock suspension by Sunrise Medical. K982989 has physical characteristics that are substantially equivalent to the KISS device. Both devices support a person seated upright in a wheelchair. Both devices have a provision for suspension under the seat.

The KISS back support is substantially equivalent to K923364; product code KNN; device name, Tilt Adjustable Back Recline Seating System by Labac Systems. Both devices are wheelchair seating components, regulation number 890.3920.

The reference device for the KISS back support is K123975; product code IOR; regulation number 890.3850; device name, Quickie and Zippie Series wheelchair with the Freestyle or Mono™ backrest by Sunrise Medical. K123975 has physical characteristics that are substantially equivalent to the KISS device. Both devices support a person seated upright in a wheelchair. Both devices have a provision for controlled movement of the back.

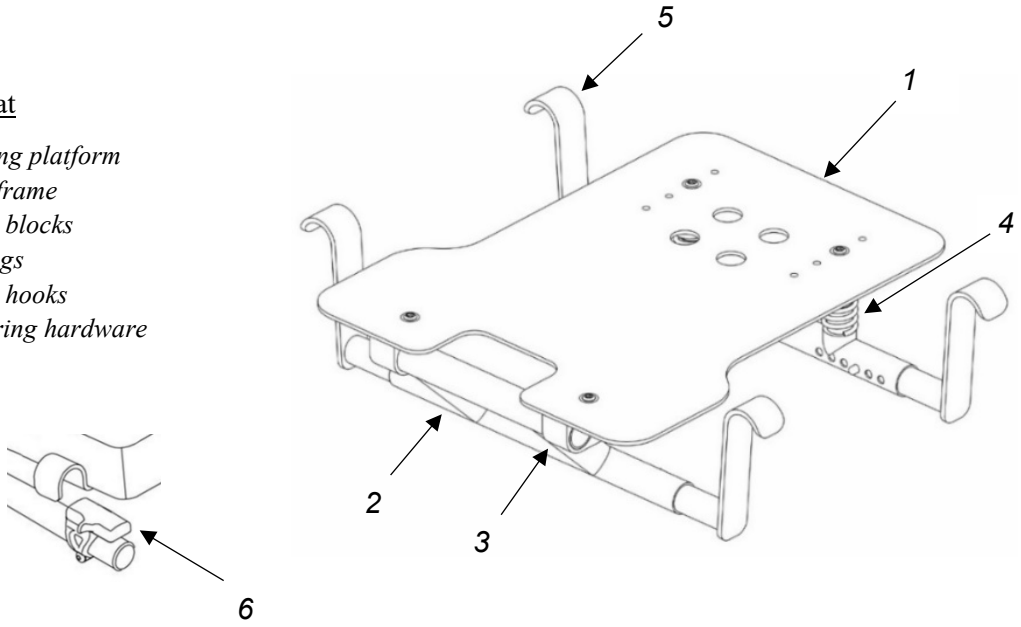
Device description:

The KISS devices are wheelchair components intended for medical purposes generally sold as an integral part of a wheelchair but may also be sold separately as a replacement seat and back support. The KISS devices are intended to assist posture and positioning for a person seated in a wheelchair by way of providing a solid seat and back support with dynamic motion.

The KISS Seat consists of (1) a solid seating platform, (2) an adjustable seat frame, (3) pivot blocks, and (4) springs. The KISS seat replaces the standard cloth seat on a wheelchair frame. It attaches to the wheelchair with (5) four drop hooks and is locked in place with (6) securing hardware.

KISS Seat

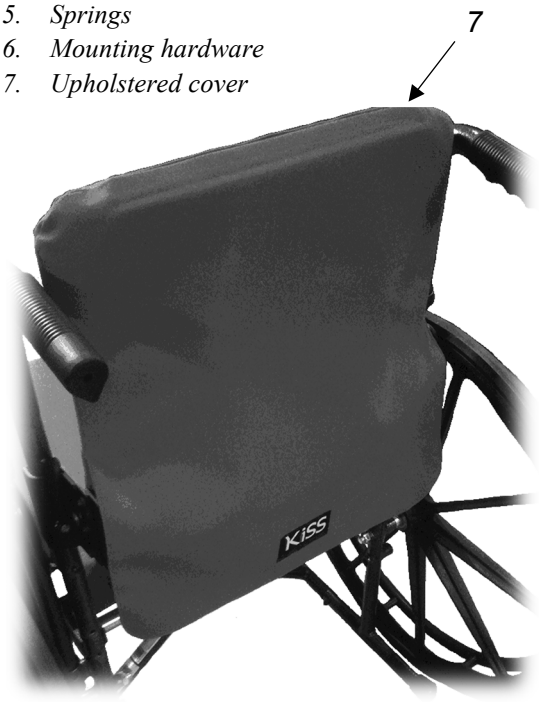
1. *Seating platform*
2. *Seat frame*
3. *Pivot blocks*
4. *Springs*
5. *Drop hooks*
6. *Securing hardware*

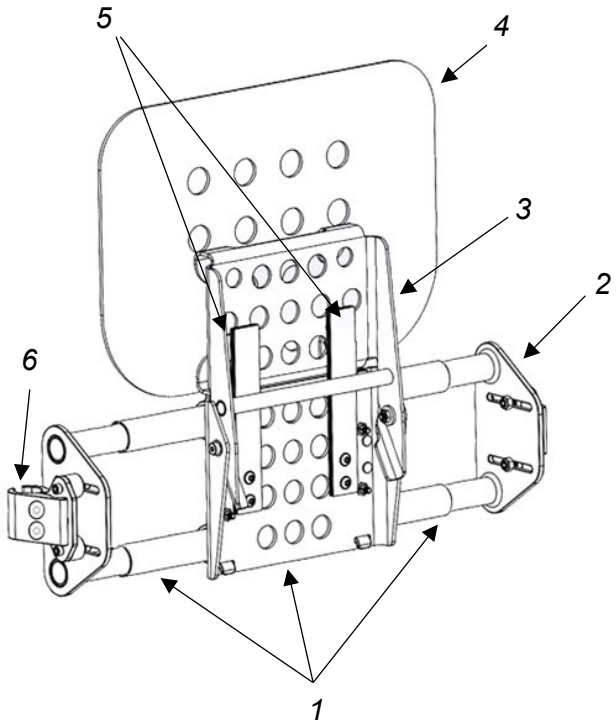


The KISS Back Support consists of (1) a lumbar support with (2) mounting brackets and (3) an upper back support with a solid ventilated (4) backrest. The lumbar support and the upper back support are hinged together with (5) springs therebetween. (6) Mounting hardware connects the KISS back support to the wheelchair frame in place of the standard cloth backrest. (7) A removable upholstered cover encases the back support assembly.

KISS Back Support (rear view)

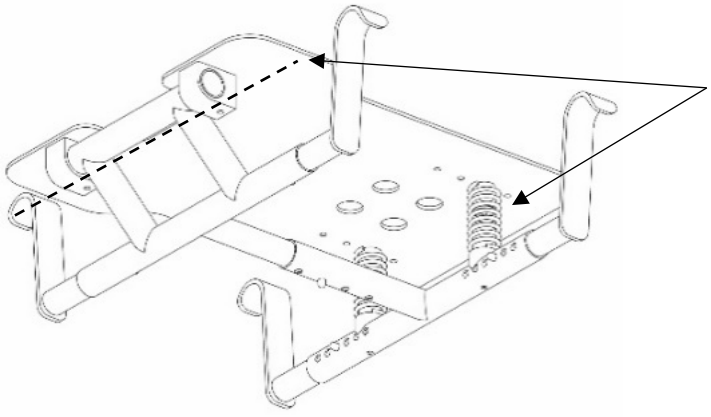
1. *Lumbar support*
2. *Mounting brackets*
3. *Upper back support*
4. *Backrest*
5. *Springs*
6. *Mounting hardware*
7. *Upholstered cover*





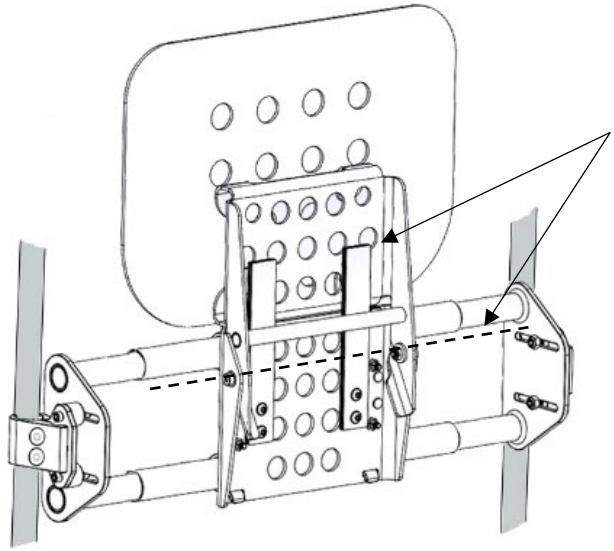
How the devices functions:

The KISS Seat assists upright seated posture by way of providing a solid seating platform with a dynamic seating interface that translates forces into motion. Springs under the seat respond to shifts in weight up and down and side to side. Movement is initiated at the hip and knee joints. The pelvis rotates and weight gets redistributed. KISS' solid seating platform eliminates the hammock effect of the standard cloth seat on a wheelchair. The springs provide suspension under the pelvis, where most of the user's weight is concentrated and absorb impact during wheelchair travel over bumps and thresholds.



The KISS seat responds to shifts in weight up and down and side to side.

The KISS Back Support assists upright seated posture by way of providing a solid back support with a provision for movement of the upper back. The device is mounted to the wheelchair frame at the height, depth, and angle adjusted to the individual user. The lumber support is fixed in place and stabilizes the user in the seat. The upper back support moves about a horizontal axis in response to rearward force, relative to the lumbar support. Springs therebetween provide resilience and assist the user back to an upright seated position.



KISS' upper back support moves in response to rearward force. Springs assist the user back to an upright seated position.

Scientific concept for the KISS devices:

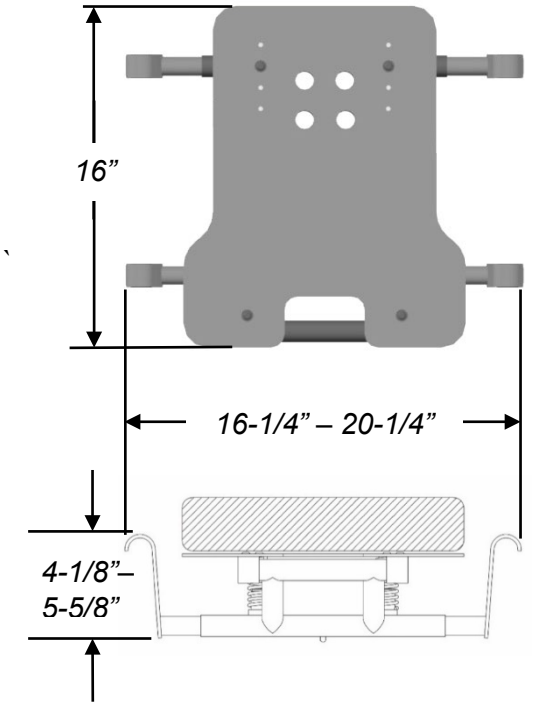
Investigations of sitting discomfort for individuals who sit for long periods of time have led to the development of ergonomic seating systems that enhance posture and comfort based on the premise that comfort is not achieved from a single, static position, but requires changes in posture through motion. The KISS devices are designed to translate forces generated by a wheelchair user's intentional or unintentional movement into motion. The intent is to allow, rather than block, the individual's specific movements. The devices are designed to absorb forces, which in turn initiates movement and disperses pressure in the wheelchair seat.

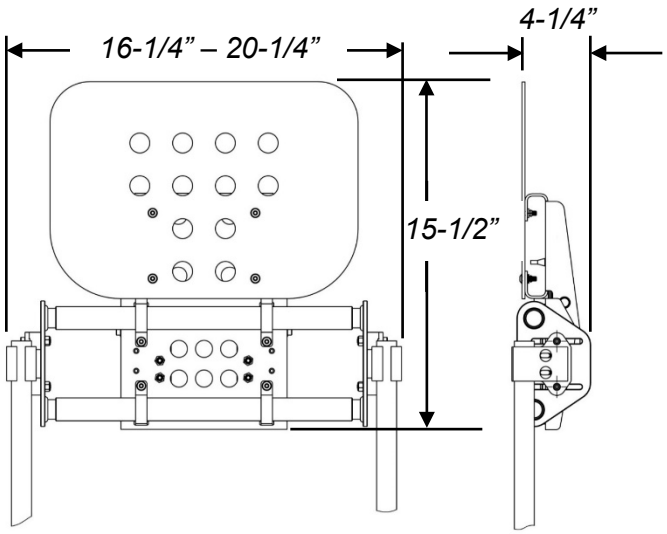
Significant physical and performance characteristics (Specifications):

The devices have a weight capacity of 250 LBS and fit manual wheelchairs 16" – 20" wide. The devices attach to tubular wheelchair frames 7/8" to 1-1/8" in diameter. The solid drop seat is designed to be used with a variety of wheelchair cushions. The back support is designed with a padded upholstered cover.

Specifications	**KISS seat, model S1520**	**KISS back support, model B1620**
Width	16-1/4" – 20-1/4"	16-1/4" – 20-1/4"
Height	4-1/8" – 5-5/8"	15-1/2"
Depth	16"	4-1/4"
Weight	1.78 LBS	8 LBS
Weight Capacity	250 LBS	250 LBS

KISS seat





KISS back support

The KISS seat moves in response to shifts in weight up and down and side to side. Springs are positioned bilaterally under the pelvis, where most of the user's weight is concentrated. The springs provides up to 3/4" of suspension and up to 4° of rear displacement in the seat. Compression springs and low-friction plastic pivot blocks assist smooth dynamic motion. The drop hooks connect the KISS seat to the wheelchair frame. Two sets are included to position the seat height level with the seat rails on the wheelchair frame or with 1-1/2" of seat drop. Securing hardware locks the seating system in place. The seating platform is resin-infused recycled paper (Richlite®). The seat frame and drop hooks are made of aluminum with an anodized finish.

The KISS back support attaches to the upright canes (or *push bars*). The lumbar support is fixed in place and stabilizes the user in the seat. The upper back support flexes up to 30° with rearward force. Springs provide resilience and assist the user back to an upright seated position. The back support gets mounted to the wheelchair such that the horizontal pivot axis of the upper back support is ±7" from the top of the wheelchair seat rails. The mounting brackets adjust in width and are reversible for up to 4" of additional depth adjustment and up to 15° of overall angle adjustment. The upholstered cover fits over the back support assembly. The lumbar support, mounting brackets, and mounting hardware are anodized aluminum. The upper back support is powder-coated steel. The backrest is Richlite®. The upholstered cover is polyester. The padding is polyurethane foam encased in a layered lining comprised of polyester, fire barrier, and cotton fabric.

KISS Dynamic Solid Drop Seat

PART	*NAME*	*FUNCTION*	*MATERIAL*
1	SEATING PLATFORM	Provides solid postural support. For use with a wheelchair cushion.	Richlite® (resin-infused recycled paper)
2	SEAT FRAME	Rigid frame supports the seating platform and spring components. Adjusts in depth.	Aluminum with anodized finish
3	PIVOT BLOCKS	Connect the seating platform to the seat frame and permits smooth dynamic movement of the seat.	Delrin® (low-friction plastic)
4	SPRINGS	Spring assemblies connect to seat frame and seating platform. Provides up to 3/4” of seat suspension with up to 4° of rear displacement.	Compression springs, plastic, rubber
5	DROP HOOKS	Connects the KISS seat frame to the wheelchair frame. Adjusts to wheelchairs 16” to 20” wide. Positions seat height relative to the seat rails of the wheelchair frame: level or with 1-1/2” of seat drop.	Aluminum with anodized finish
6	SECURING HARDWARE	Locks KISS seat assembly to the wheelchair frame (supplied by third-party vendors).	AEL VERSAlock® or Bodypoint Clickit® (plastic & steel)

KISS Dynamic Back Support

PART	*NAME*	*FUNCTION*	*MATERIAL*
1	LUMBAR SUPPORT	Provides lower back support. Stabilizes the user in the seat.	Aluminum with anodized finish
2	MOUNTING BRACKETS	Adjusts to the wheelchair width. Provides up to 4” of additional depth and up to 15° of overall angle adjustment.	Aluminum with anodized finish
3	UPPER BACK SUPPORT	Moves with rearward force. Flexes up to 30° rearward.	Steel with powder-coated finish
4	BACKREST	Attaches to the upper back support. Provides solid postural support.	Richlite® (resin-infused recycled paper)
5	SPRINGS	Provide resilience to the upper back support. Assists the user back to an upright position.	Spring steel
6	MOUNTING HARDWARE	Secures the back support to the wheelchair. Fits tubular frames 7/8” to 1-1/8” in diameter.	Aluminum with anodized finish
7	UPHOLSTERED COVER	Pads and protects the user from the solid surfaces and moving parts. Cover is removable and washable. Padded inserts are removable.	Polyester, Tek Fire Barrier, and cotton fabric with Polyurethane foam padding

Intended use:

The KISS devices are wheelchair components intended for medical purposes that are generally sold as an integral part of a wheelchair but may also be sold separately as a replacement part. The KISS devices are intended to assist posture and positioning for a person seated in a wheelchair by way of providing a solid seating platform or back support with dynamic motion.

Comparison of indication statement:

The predicate devices' product code is KNN, classification 890.3920, wheelchair component. The Jay Basic Back and the Jay Adjustable Solid Seat by Sunrise Medical are solid postural supports for a person seated in a wheelchair. These devices are intended for posture and positioning in a wheelchair and are 510(k) exempt.

The reference devices' product code is IOR, classification 890.3850, mechanical wheelchair. K982989 and K123975 are Sunrise Medical's Quickie and Zippie series wheelchairs with provisions for suspension in the seat and controlled movement of the back. These devices are intended for individuals limited to a sitting position.

The KISS devices are solid postural supports for a wheelchair with provisions for movement of the seat and back support. The devices are intended for posture and positioning for a person seated in a wheelchair. The differences are not critical to the intended therapeutic use because the KISS devices do not alter the safety and effectiveness of the device when used as labeled.

Comparison of technological characteristics of the KISS devices to the reference devices:

The K982989 suspension series wheelchair and the KISS seat are similar in technological characteristics. Both devices provide suspension for a person seated in a wheelchair. The reference device is a wheelchair with suspension located under the wheelchair seat that provides up to 2.5" of rear wheel displacement. The KISS device is a wheelchair seat with suspension that provides up to 3/4" of rear seat displacement.

The K123975 Quickie & Zippie series wheelchair and the KISS back support are similar in technological characteristics. Both devices have solid back supports that move with rearward force. The predicate device is a wheelchair with a back support system. The KISS device is a back support system for a wheelchair. The Quickie Freestyle backrest system pivots about a horizontal axis at the middle of the backrest. The Quickie Mono™ backrest pivots about a horizontal axis at the base of the back. Elastomer springs on the Mono™ backrest assist the wheelchair user back to an upright seated position. The Quickie back support systems are modifications the Quickie series wheelchair. The KISS back support is a modification to a wheelchair because it replaces the standard cloth backrest on the wheelchair.

Device Comparison Table:

Description	***KISS seat***	***Reference Device K982989***
Indications for Use	For posture and positioning	To provide mobility to persons limited to a sitting position
Prescription / over-the-counter use	Prescription & Over-the-counter	Prescription & Over-the-counter
Size	Fits wheelchairs 16" – 20"	Wheelchair sizes 14" – 20"
Seat height	Level with wheelchair seat rails; with 1-1/2" seat drop option	Level with wheelchair seat rails with wheelchair frame adjustments
Design	Device consists of a seat frame and a solid seating platform with suspension therebetween. Seating system attaches to wheelchair frame with drop hooks and securing hardware.	Device is a suspension series wheelchair with a standard cloth seat. The Rock Shox® monoshock suspension is located under the seat and integrated with wheelchair frame.
Suspension	Compression spring assemblies located between the seat frame the solid seating platform responds to shifts in weight up and down and side to side. The device provides up to .75" of suspension with up to 4° of rear displacement in the seat.	The Rock Shox® assembly is mounted under the wheelchair seat and integrated with the wheelchair frame. The system provides shock absorption with up to 2.5" of rear wheel travel in response to uneven terrain.
Attachment to wheelchair	Suspension is integrated in seat assembly that attaches to wheelchair frame with drop hooks & securing hardware.	Suspension is integrated with wheelchair frame.
Seat Cushion	For use with a wheelchair cushion	For use with a wheelchair cushion
Weight capacity	250 lbs.	250 lbs.

Description	***KISS back support***	***Reference Device K123975***
Indications for Use	For posture and positioning	To provide mobility to persons limited to a sitting position
Prescription/over-the-counter use	Prescription & Over-the-counter	Prescription & Over-the-counter
Size	Fits wheelchair sizes 16" – 20"	Wheelchair sizes: Quickie IRIS: 14" – 22" Quickie 7: 12" – 20"
Height of Back Support	Mid back	Quickie IRIS: Shoulder height Quickie 7: Mid back

Design	Device consists of a lumbar support and an upper back support with springs there between. The lumbar support gets fixed to the wheelchair and stabilizes the user in the seat.	Quickie IRIS: Mono™ Backrest replaces the standard back rest on the wheelchair frame and provides solid postural support that moves with resilience. Quickie 7: Freestyle Backrest System is integrated with the wheelchair frame to provide solid mid-height back support that moves.
Movement	Upper back support moves relative to lower lumbar support about a transvers horizontal axis.	Quickie IRIS: Full-length Mono™ Backrest (with dynamic option) moves about a horizontal axis at the base of the back support system. Quickie 7: Freestyle Backrest System moves about a horizontal axis at the middle of the backrest.
Dynamic component	Two spring steel assemblies mounted between lumbar support and upper back support	Quickie IRIS: Two elastomer spring assemblies are integrated in mounting bracket of the Mono™ Backrest. Quickie 7: Freestyle Backrest System moves freely without springs
Wheelchair attachment	Attaches to a standard manual wheelchair frame	Mono™ Backrest attaches to Quickie IRIS wheelchair with a modification to the frame. Freestyle Backrest System is integrated with a modified frame for the Quickie 7 wheelchair.
Weight capacity	250 lbs	250 lbs / 350 lbs (Heavy Duty)

Assessment of performance data - Non-clinical data:

The KISS devices passed ISO 16840-3 Wheelchair seating – Part 3: Determination of static, impact and repetitive load strengths for postural support devices.

The KISS devices were installed on a Quickie series wheelchair and tested according to RESNA WC-1, Sections 1, 5 & 7 for static stability, maneuverability, dimensions, and seating measurements. Wheelchair stability with the KISS seat was increased on the rearward incline with the wheels locked and decreased on the rearward (wheels unlocked), forward and lateral inclines. Wheelchair stability with the KISS back support was increased on rearward inclines and decreased on forward and lateral inclines. Maneuverability, dimensions, and measurements were not changed.

ISO 898-7 was applied to test the durability of the clamping system and mechanical fasteners to hold the KISS seat in place. Selected securing hardware intended to be used with the KISS device was tested and passed.

Loaded Deflection was tested to determine the most effective position for placement of the springs under the KISS seat. The results indicate that the springs should be positioned under the pelvis and not exceed one adjustment position (1") to either side of this position.

A customized bench test to determine The Influence of the KiSS dynamic seat on a Wheelchair Cushion's Force-Deflection relationship was conducted to address FDA concerns with prior submission K120940 regarding off-loading from the wheelchair cushion when used with the KISS seat. The results indicate that the user should lift an additional 0.4" to fully offload from the wheelchair cushion.

The KISS seat was tested for Wheelchair Compatibility on an assortment of wheelchairs. The purpose was to identify restrictions and measure clearances needed to install the KISS seat on a wheelchair frame. The KISS seat fit the standard folding manual wheelchairs and not the ultralight models because of the design of the rigid frame.

Lab test results for ISO 10993-10: Biological evaluation of medical devices - Part 10 indicate biocompatibility for cytotoxicity, skin irritation and sensitization for the KISS back support upholstered cover. The upholstered cover was tested for resistance to ignition according to ISO 16840-10. Test #1 passed; Test #2 failed due to the sample continuing to emit visible smoke for 30 seconds after removal of the heater cartridge. The standard currently only allows 20 seconds, therefore the specimen did not pass the criteria after the initial test was performed.

Conclusion:

The performance report data indicate that the KISS devices installed on a wheelchair is as safe, as effective, and performs as well as the predicate and reference devices K982989 and K123975. The devices passed ISO and RESNA bench test standards. Clinical testing indicates the technology does not negatively affect interface pressure and has reduced peak interface pressures measured during propulsion. However, dynamic seating may reduce wheelchair stability, therefore, contraindications as noted in the proposed labeling must be observed.