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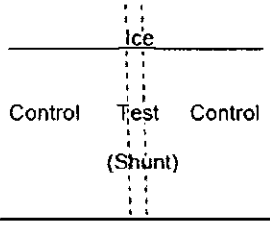
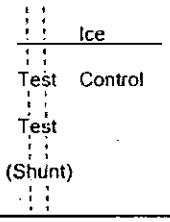
5.0 510(k) Summary

The proposed device, ShuntCheck III is substantially equivalent to its predicate, ShuntCheck v2.2 (K080168) by virtue of a common indication for use and similar technical characteristics. Performance test results confirm that ShuntCheck III performed as intended and that minor differences from the predicate device do not impact safety or effectiveness.

Submitter:	NeuroDx Development LLC 3333 Street Rd, Suite 210, Bensalem PA 19020	
Contact:	Frederick J. Fritz, CEO, 609-865-4426 (telephone) 215-645-1268(fax)	
Date Prepared:	October 2, 2012	
Trade Name:	ShuntCheck	
Classification:	Class II Central Nervous System Fluid Shunt and Components 21 CFR 882.5550	
Product Code:	JXG	
Predicate Device(s):	The subject device is equivalent to the following devices: ShuntCheck (version 2.2) (K080168)	
Device Description:	ShuntCheck is a non-invasive device which detects flow in a CSF shunt via transcutaneous thermal dilution. The device consists of a single use disposable thermosensor array patch which is connected to a data acquisition unit (a DAQ) which is connected to a laptop or tablet computer. The device also includes a Micro-Pumper which vibrates the shunt valve during the test procedure to generate a temporary increase in flow in patent but temporarily non-flowing shunts. The shunt is cooled transcutaneously by placing an instant ice pack over the shunt cephalic to the thermosensor. The thermosensor array patch, which is placed on the skin over the shunt "downstream" of the ice, reads the change in skin temperature over the shunt as cooled fluid flows downstream and also at a two nearby control locations. Data is transferred through the DAQ and captured in the computer. If the device detects a characteristic downstream transcutaneous temperature dip, the computer reports "flow confirmed" and presents a time-temperature graph of test data. If no temperature dip is detected, the unit reports "flow not confirmed" and presents a time-temperature graph.	
	ShuntCheck III	**ShuntCheck v2.2**
Indications for Use:	ShuntCheck® is an aid to the detection of flow in implanted cerebrospinal fluid (CSF) shunts. ShuntCheck includes Micro-Pumper, a component which may be used to generate flow in suspected temporarily non-flowing, patent shunts during the ShuntCheck test. ShuntCheck cannot alone diagnose CSF shunt function or malfunction. The clinical diagnosis of CSF shunt function or malfunction, incorporating the flow information from ShuntCheck, should be made only by a qualified neurosurgeon.	ShuntCheck is an aid to the detection of flow in implanted cerebrospinal fluid (CSF) shunts. ShuntCheck cannot alone diagnose CSF shunt function or malfunction. The clinical diagnosis of CSF shunt function or malfunction, incorporating the flow information from ShuntCheck, should be made only by a qualified neurosurgeon.
Contraindications	The Micro-Pumper should not be used when conducting ShuntCheck tests on patients under the age of five, patients with small or slit ventricles or	

	where the ventricular catheter tip is within the brain parenchyma.	
Substantial Equivalence of Technological Characteristics	ShuntCheck III and its predicate ShuntCheck v2.2 detect flow through CSF shunts via transcutaneous thermal dilution. Both utilize an external cooling source to cool the skin over the shunt. Both utilize a single use disposable thermosensor patch comprised of multiple thermistors which adheres to the patient's skin via medical grade adhesive to monitor skin temperature directly over the shunt and at separate control skin locations. Both employ an electronic unit which conditions, amplifies and converts the thermosensor signal to digital form. Both employ custom software running on a digital device to provide step-by-step instructions, analyze thermosensor data and display a test result (Flow Confirmed or Flow Not Confirmed plus a time-temperature graph). ShuntCheck III utilizes a tablet or laptop computer while the predicate used a Personal Digital Assistant (PDA). Both employ a method for generating increased flow in temporarily non-flowing patent shunts. A detailed comparison of the technological characteristics of ShuntCheck III versus its predicate, ShuntCheck v2.2, follows	
	ShuntCheck III	**ShuntCheck v2.2**
Anatomical Sites	Thermosensor on clavicle Ice above sensor Micro-Pumping on shunt valve (on scalp)	Same Same If manual pumping is conducted, same
Where Used	Neurosurgery clinic, hospital emergency department	Same
Energy Used or Delivered	None	Same
Thermosensor	Single use only	Same
Thermosensor Thermistor Materials	Three fast response GE thermistors in Lexan cradles.	Same thermistors Thermistors adhered to patch
Thermosensor Patch Materials	Avery Medical grade adhesive & EVA foam	3M medical grade adhesive & Rogers medical grade Poron foam
Thermosensor Cable & Connector	Insulated wire, molded plastic connection box, RJ45 connector	Same
Thermistor Orientation	Single Test thermistor placed directly over the subcutaneous shunt flanked by two control thermistors which record ambient skin temperature: 	Two test thermistors which overly the subcutaneous shunt. Single control thermistor which flanks the proximal test thermistor: 
Thermosensor orientation	Single array patch indicates correct orientation	Same
Ice placement	Array patch indicates correct ice position	Same
Ice-to-thermistor distance	28 mm	16 mm

Ice	Commercially available 4½" x 6" instant cold pack	Commercially available water-filled 1" plastic ice cube
Device Hardware	NeuroDx supplied Data Acquisition Unit (signal conditioning and A to D converter – called "DAQ") which attaches by wire to a NeuroDx supplied CyberMed T10 tablet computer or a user supplied Windows 7 laptop or tablet. Handheld Micro-Pumper which is held against and vibrates the shunt valve to generate a temporary increase in shunt flow	BioDisplay Unit (a Dell Axim PDA with application software packed into an off-the –shelf robust case) is a single hand-held device for collecting and integrating data
Displayed Results	Computer displays "Flow Confirmed" or "Flow not Confirmed", time-temperature graph and temperature decrease (amplitude) on a single results screen. PDF of results screen is available for printing or saving.	BioDisplay Unit displays "Flow Confirmed" or "Flow not Confirmed". Time-temperature graph is accessed on subsequent display screen. Temperature decrease (amplitude) is determined by interpreting the time-temperature graph. Results cannot be downloaded or printed.
Display Device Materials	NeuroDx supplied tablet is in ruggedized case	Glass reinforced ABS case
DAQ Size & Materials	Length 3" x Width 2" x Depth 3/4" ABS case	Integrated into BioDisplay
Micro-Pumper	A handheld component which is held against and vibrates the shunt valve for 60 seconds, generating a temporary increase in shunt flow in patent shunts. This temporary increase can be detected thermally by ShuntCheck. Micro-Pumping therefore allows ShuntCheck to detect flow in temporarily non-flowing patent shunts.	Patent shunts flow intermittently. To differentiate temporarily non-flowing patent shunts from occluded shunts, ShuntCheck users have induced flow by changing patient position (supine to sitting) or via manual shunt pumping. In manual pumping, the valve dome (or reservoir) is depressed and released, creating a surge of CSF flow.
Micro-Pumper Size & Materials	Oval cylinder Length 3.5" x Width 2.5" x Height 3.25" Polyurethane plastic	N/A
Performance Specifications	Repeatability 0.03 Accuracy ± 0.3°C Sampling Rate	Repeatability 0.06 Same Same
Application Software	Windows 7 based software program is preloaded onto the NeuroDx supplied tablet PC or supplied to end-user for installation onto their PC	Windows Mobile based software preloaded onto the PDA-based BioDisplay
Pre-test Error Checks	Software checks that the computer is operating on battery power (not plugged into AC power), that the thermosensor and DAQ are connected and that thermosensor readings are in biological range.	Software checks that BioDisplay is operating on battery power (not plugged into AC power), that the thermosensor is connected and that thermosensor readings are in biological range.

	Additionally checks for temperature fluctuations indicating inadequate sensor to skin contact and alerts user correct contact.	
Post-Test Error Checks	Software conducts post-test check of data errors. Test errors are summarized and retesting is recommended	Software conducts post-test check of data errors. Test errors result in Flow Not Confirmed result; no retest recommendation
Software Data Output	Results are displayed either flow confirmed or flow not confirmed (bivariate output) according to a validated algorithm. Time-temperature graph and temperature decrease (amplitude) displayed on same screen.	Results are displayed either flow confirmed or flow not confirmed (bivariate output) according to a validated algorithm. Time-temperature graph available on a subsequent screen.
Standards Met	60601, ISO 10093-1	Same Same
Biocompatibility	All skin contacting materials are medical grade, biocompatible	Same
Sterilization	None	Same
Electrical Safety	60601 tested	Same
Mechanical Safety	Medical grade adhesive Micro-Pumper generates less ventricular suction than manual shunt pumping, no valve damage or alteration	Same If manual pumping is used to induce flow, ventricular suction generated exceeds that generated by Micro-Pumping
Chemical Safety	Biocompatible materials	Same
Thermal Safety	Over the counter instant ice pack placed for 60 seconds and used according to label	1" plastic ice cube placed for 60 seconds
Radiation Safety	No radiation	Same
Functional and Safety Non-Clinical Testing:	To verify that device design meets the functional and performance requirements, each device was submitted to bench testing and performance verification to confirm accuracy when reading resistances (thermistor input simulation) and the expected temperature output displayed by the device software. To verify that device design meets its safety requirements, a representative sample of the device has been subjected to safety testing in accordance with IEC 60601 and biocompatibility tests per ISO 10993. To verify the functionality of the device, bench testing was conducted in which the device was found to be substantially equivalent to the predicate device. Bench test results follow:	
ShuntCheck Bench Testing without Micro-Pumper	ShuntCheck bench testing employs a thermal bench which simulates the transcutaneous cooling of the ShuntCheck test. Flow is regulated with an infusion pump. The ShuntCheck thermosensor is placed over the embedded catheter and the ShuntCheck test is conducted normally.	
	ShuntCheck III	**ShuntCheck v2.2**
Detect flow of 10 ml/hr	100% (100% accurate)	100% (100% accurate)
Detect flow of 0 ml/hr	0% (100% accurate)	0% (100% accurate)
Threshold of detection	Between 3.5 and 5 ml/hr	Between 5 and 7.5 ml/hr

Detect 10 ml/hr flow with sensor misalignment	100% at 20° rotation 100% at 4mm lateral misplacement	0% at 20° rotation 0% at 4mm lateral misplacement
ShuntCheck Bench Testing with Micro-Pumper	Micro-Pumper bench testing employs a vertical bench where shunt valves are mounted under artificial skin to simulate the implanted shunt valve. Shunt tubing is connected at the proximal and distal end to height-adjustable fluid reservoirs to simulate pressure changes within the shunt system. At the distal end of the shunt catheter is a drop counter which measure the fluid flow rate. The Micro-Pumper vibrates the shunt valve for 60 seconds while flow rate is recorded. The test of ShuntCheck's ability to detect Micro-Pumper-generated flow employed the thermal bench described above.	
Shunt flow generated by 60 second Micro-Pumper application	Testing of eight shunt valves: • Flow in patent non-flowing shunts (at 0 ICP) 0.3 to 0.9 cc • Flow in clogged shunts 0.0 to 0.03 cc • Maximum flow (in patent flowing shunts) 0.9 to 2.8 cc These results indicate that Micro-Pumper generates flow in a patent, non-flowing shunts but does not generate flow in occluded shunts. It does not generate sufficient flow to cause overdrainage	
Micro-Pumper Impact on shunt valve function	Testing of eight shunt valves • Change in natural flow pre vs post Micro-Pumping <50% • Damage to valve (evidence of backflow) post Micro-Pumping 0% Testing of 5 programmable valve • Valve settings changed by Micro-Pumping 0% These results indicate that valve performance is unaltered by Micro-Pumper	
Test of ShuntCheck's ability to detect flow generated by Micro-Pumper	• Test of occluded shunt (no flow) – 0% detection • Test of patent, non-flowing shunt with Micro-Pumper generated flow of 15 to 100 ml/hr – 100% detection • Test of patent flowing shunt with Micro-Pumper generated flow of 15 to 200 ml/hr – 100% detection These results indicate that ShuntCheck can correctly detect the increased flow generated with the Micro-Pumper application	
Functional and Safety Clinical Testing:	Human clinical testing was conducted at Boston Children's Hospital to verify the safety and functionality of the Micro-Pumper component of the system. Pediatric hydrocephalus patients 5 years and older were tested. 38 asymptomatic patients were tested with ShuntCheck without Micro-Pumper. These same patients were tested a second time with ShuntCheck plus an earlier version of Micro-Pumper. Finally, 12 patients who were either asymptomatic or had confirmed functioning shunts and 4 patients with confirmed obstructed shunts were tested with ShuntCheck III including the proposed version of Micro-Pumper. (Shunt function or malfunction was confirmed via MRI imaging). Specific findings were:	
	Study Results	
Safety	Zero Adverse Events or safety issues were recorded	
Accuracy of ShuntCheck without Micro-Pumper	Flow Confirmed results in 38 asymptomatic patients (shunts expected to be patent) 15 of 38 or 39%	
Accuracy with proposed Micro-Pumper	Flow Confirmed results in 12 asymptomatic or confirmed functioning shunt patients • 9 of 12 or 75% Flow Not Confirmed in 4 patients with confirmed obstructed shunts • 4 of 4 or 100%	

	These results suggest that Micro-Pumper increases ShuntCheck's ability to detect flow in patent shunts.
Conclusion:	NeuroDx Development believes the ShuntCheck III to be substantially equivalent to the predicate device ShuntCheck (v2.2). This conclusion is based upon the both devices' similarities in principles of operation, technology, materials, and indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 7, 2013

NeuroDx Development, Inc.
% Mr. Fredrick J. Fritz
President and CEO
3333 Street Road, Suite 210
Bensalem, PA 19020

Re: K123554
Trade/Device Name: ShuntCheck III: Non-Invasive Transcutaneous Thermal Dilution System for Detecting Ventriculo-Peritoneal Shunt Flow
Regulation Number: 21 CFR 882.5550
Regulation Name: Central Nervous System Fluid Shunt and Components
Regulatory Class: Class II
Product Code: JXG
Dated: February 1, 2013
Received: February 4, 2013

Dear Mr. Fritz:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joyce M. Whang

for Victor Krauthamer, Ph.D.
Acting Division Director
Division of Neurological and Physical
Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123554

Device Name: ShuntCheck III: Non-Invasive Transcutaneous Thermal Dilution System for Detecting Ventriculo-Peritoneal Shunt Flow

Indications For Use:

ShuntCheck is an aid to the detection of flow in implanted cerebrospinal fluid (CSF) shunts. ShuntCheck includes Micro-Pumper, a component which may be used to temporarily increase CSF flow in suspected non-flowing, patent shunts during the ShuntCheck test. ShuntCheck cannot alone diagnose CSF shunt function or malfunction. The clinical diagnosis of CSF shunt function or malfunction, incorporating the flow information from ShuntCheck, should be made only by a qualified neurosurgeon.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Joyce M. Whang

(Division Sign Off)
Division of Neurological and Physical Medicine Devices (DNPMD)

510(k) Number K123554