MAR 2 4 2011

510(k) SUMMARY
For
NeuroLogica Corporation
NL4000 BodyTom™ Computed Tomography System

This 510(k) summary of Safety and Effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.87(h)

(1) **Submitter:** NeuroLogica Corporation
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Danvers, MA, 01923

Establishment Registration number: FDA #3004938766

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Date this summary was prepared: September 9, 2010

(2) **Device Name:**

Proprietary or Trade Name: BodyTom

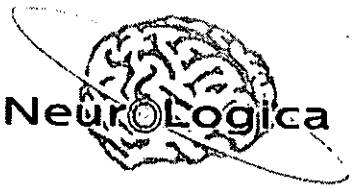
Device Model: NL4000

Classification Name: Computed Tomography X-ray System

Product code: 90JAK

Device classification: Class II

Regulation number: 21 CFR 892.1750



(3) Predicate device:

The legally marketed device to which substantial equivalence is being claimed is as follows:

- NeuroLogica Corporation, NL3000 CereTom™ CT – per Pre-Market Notification Submission K051765
- Hitachi Medical Systems America, Inc. ELCOS16™ - per Pre-Market Notification Submission K071806
- NeuroLogica Corporation, inSPira HD™ - per Pre-Market Notification Submission K090811

(4) Device Description:

The NL4000 BodyTom is essentially a larger bore version of our predicate NL3000 CereTom CT system. It is a high resolution, multi row, 85 cm bore, 60cm field of view, x-ray computed tomography system. The lightweight translating gantry consists of a rotating disk with a solid state x-ray generator, solid state detector array, collimator, control computer, communications link, power slip-ring, data acquisition system, reconstruction computer, power system, brushless DC servo drive system (disk rotation), and stepper drive system (translation). The power system consists of batteries which provide system power while unplugged from the charging outlet. The system software is based upon the CereTom software, however, does not contain application specific software for contrast imaging. In addition, the system has the necessary safety features such as emergency stop switch, x-ray indicators, interlocks, patient alignment laser, and 110 percent x-ray timer. The gantry has retractable rotating caster wheels and electrical drive system so the system can be moved easily to different locations.

(5) Intended Use:

The NL4000 BodyTom is intended to be used for non-contrast x-ray computed tomography applications for anatomy that can be imaged in the 85cm aperture.

(6) Comparison of Technological Characteristics with the predicate device:

NeuroLogica Corporation's NL4000 Computed Tomography System, for its intended use, is of comparable type in design, material, functionality, technology and is substantially equivalent to the following cleared predicate devices: NeuroLogica Corporation NL3000 CereTom™ (K051765), Hitachi ELCOS16™ (K071806) and NeuroLogica Corporation inSPira HD™ (K090811) including:

- **Material:** The BodyTom uses similar material to the above listed scanners such as solid state detectors, x-ray generator, slip ring, data acquisition ICs, rotational bearing, and motion control systems.
- **Design:** The BodyTom is similar in general design principle to the above listed scanners except it does not contain application specific software for contrast imaging.

7) General Safety and Effectiveness Concerns:

All components of the NL4000 BodyTom system subject to Federal Diagnostic Equipment Performance Standard and applicable regulations of 21 CFR Part 1020.30 and 1020.33 are certified to meet those requirements.

An initial report as per 21CFR Part 1002.10 will be filed with the Center for Device and Radiological Health (CDRH).

To minimize electrical, mechanical and radiation hazards, Neurologica adheres to recognized and established industry practices. The NL4000 BodyTom system is designed to meet UL60601-1, IEC 60601-1 and EN 60601-1 Medical Electrical Equipment - Part 1: General Requirements for Safety, IEC 60601-1-1, IEC 60601-1-2, IEC 60601-1-4, IEC 60101-2-28, and IEC 60101-2-32 and IEC 60601-2-44.

Relating to concerns per unnecessary radiation exposure, the BodyTom, like the CereTom, has software safeguards such as: security scanner ID/password log-in, dose display/reporting, lockout to prevent excessive dose, protocol protection, and quality assurance.

Substantial Equivalence Comparison

The NeuroLogica NL4000 BodyTom™ Computed tomography system has similarities/differences to the NeuroLogica NL 3000 CereTom® Computed Tomography system (K051765) as follows:

Similarities

1. Diagnostic imaging for Computed Tomography applications
2. Same Detector fabrication
3. Same Detector measurement electronics
4. Same mechanism to translate system
5. Similar caster wheels for transport
6. Same Laser alignment
7. Similar workstation
8. Computers and algorithms to compute tomographic images
9. Applications: Scout, Axial, Helical, Dynamic, contrast enhanced
10. Display(DICOM 3.0) and connectivity(PACS) capability
11. Emergency Stop switch
12. Slipring to transmit electrical power to rotating disk
13. Mobility via transport wheels
14. Battery system
15. Wireless transfer of Image Data
16. 2D, MPR, 3D Viewing & archiving
17. Quality assurance phantom and test software
18. Radiation Safeguards Hardware (110% timer, warning light, etc)
19. Radiation Safeguards Software (login, excessive dose lockout, dose reporting,etc)
20. Same Wireless communication with Workstation
21. Same Manufacturing Quality System
22. Same Design Control System
23. Same Software Development methodology
24. Same Validation and Verification methods

Differences:

1. Size of Bore/Field of View (CereTom = 32/25 cm, BodyTom = 85/60 cm)
2. Applicable software modifications to accommodate larger Bore
3. Motorized transport system on BodyTom
4. X-ray tube type (Rotating Anode(BodyTom) vs. fixed Anode (CereTom))
5. Type of Batteries (SLA vs. LiPO)

The NeuroLogica NL4000 BodyTom™ Computed tomography system has similarities/differences to the Hitachi ECLOS16 Computed Tomography system (K071806) as follows:

Similarities

1. Diagnostic imaging for Computed Tomography applications
2. Similar Multi slice Detector fabrication
3. Similar Detector measurement electronics
4. Laser alignment
5. Similar workstation with Windows Operating System
6. Computers and algorithms to compute tomographic images
7. Applications: Scout, Axial, Helical, Dynamic, contrast enhanced
8. Display(DICOM 3.0) and connectivity(PACS) capability
9. Emergency Stop switch
10. Slip ring to transmit electrical power to rotating disk
11. 2D, MPR, 3D Viewing & archiving
12. Quality assurance phantom and test software
13. Radiation Safeguards Hardware (110% timer, warning light, etc)
14. Rotating Anode X-ray Tube
15. Exactly the same X-ray Power (42 kilowatt)
16. Whole Body sized bore (BodyTom = 85, ECLOS = 70cm)

Differences:

1. Motorized transport system on BodyTom
2. ECLOS has a moving patient table, BodyTom has translate mechanism to move on floor
3. BodyTom is battery Powered
4. Caster Wheels for mobility on BodyTom, ECLOS is fixed mount
5. Number of Slices (ECLOS = 16, BodyTom = 32)
6. BodyTom uses wireless link to communicate with workstation

The NeuroLogica NL4000 BodyTom™ Computed tomography system has similarities/differences to the NeuroLogica NL1000 inSPira® SPECT system (K090811) as follows:

Similarities

1. Same mechanism to translate system
2. Similar caster wheels for transport
3. Same Laser alignment
4. Similar workstation
5. Display(DICOM 3.0) and connectivity(PACS) capability
6. Emergency Stop switch
7. Slipring to transmit electrical power to rotating disk
8. Mobility via transport wheels
9. Battery system
10. Wireless transfer of Image Data
11. 2D, MPR, 3D Viewing & archiving
12. Same Manufacturing Quality System
13. Same Design Control System
14. Same Software Development methodology
15. Same Validation and Verification methods

Differences:

1. inSPira is a SPECT system, BodyTom is a CT system
2. Motorized transport system on BodyTom
3. Type of Batteries (SLA vs. LiPO)

Company	NeuroLogica	NeuroLogica	Hitachi	NeuroLogica
Model/Name	**NL4000 BodyTom**	**NL 3000 CereTom**	**ECLOS16**	**NL1000 inSPira**
Predicate/Submission 510(k) number	**Submission**	**Predicate K051765**	**Predicate K071806**	**Predicate K090811**
Type of System	Computed tomography	Computed tomography	Computed tomography	Single Photon Emission CT
Aperture (cm)	85	32	70	29
Image Field of View (cm)	60	25	50	20
Detector material	Solid State CdWO4	Solid State CdWO4	Solid State Ceramic	NaI, PMT
Detector configuration	32 x 1.25mm	8 x 1.25mm	16 x 1.25	3 x 24
MTF at 0% (lp/cm)	17	17	17	N/A
Xray Tube type	Rotating Anode	Fixed Anode	Rotating Anode	N/A
Heat storage (MHU)	3.5 and 5.0	0.3	5	N/A
Cooling	Oil	Air	Oil	N/A
Xray fan angle (deg)	54	62	Unknown	N/A
Max X-ray Power (kW)	42	1.2	42	N/A
ɔtate Speed (seconds)	1,2	1,2,4,6	0.8	1,2
ɔantry weight, kg	1200	400	1320	850
Wireless	Yes	Yes	No	Yes
Mobile	Yes (Motorized)	Yes (manual)	No	Yes (manual)
Battery system	Yes (LiPO)	Yes (SLA)	No	Yes (SLA)
Wheels	Wheels (6 inch)	Wheels (3 inch)	No	Wheels (4 inch)
Input voltage	1phase 110-240Volt	1phase 110-240Volt	208VAC, 3- phase	1phase 110-240Volt
Input power max	3.6kw	1.5kw	75kVA	1.5kw
PACS / DICOM 3.0	Yes	Yes	Yes	Yes
2D scout	Yes	Yes	Yes	NA
bolus tracking	Yes	Yes	Yes	NA
Dynamic scan	Yes	Yes	Yes	NA
Axial/Helical	Both	Both	Both	NA
MPR	Yes	Yes	Yes	NA
3D Viewing	Yes	Yes	Yes	NA
Patient Table	Not Required (optional)	Not Required (optional)	Yes	Not Required (optional)
Scan motion	Scanner Moves	Scanner Moves	NA	Scanner Moves

Company	NeuroLogica	NeuroLogica	Hitachi	NeuroLogica
odel/Name	NL4000 BodyTom	NL 3000 CereTom	ECLOS16	NL1000 inSPira
Predicate/Submission 510(k) number	Submission	Predicate K051765	Predicate K071806	Predicate K090811
Radiation Safeguards Hardware				
- X-ray warning light	Yes	Yes	Yes	NA
-110% X-ray timer	Yes	Yes	Yes	NA
-E-Stop	Yes	Yes	Yes	Yes
- Internal lead shield	Yes	Yes	No	NA
-external Lead curtains	Yes	Yes	No	NA
-Operator x-ray on switch	Yes	Yes	Yes	NA
-Quality Test Phantom	Yes	Yes	Yes	NA
Radiation Safeguards Software				
- login ID/password	Yes	Yes	Unknown	Yes
-Administrator privileges	Yes	Yes	Unknown	Yes
-Dose display	Yes	Yes	Unknown	NA
- Dose report/audit	Yes	Yes	Unknown	NA
-Protocol override protection	Yes	Yes	Unknown	NA
- Protocols by age/weight	Yes	Yes	Unknown	NA
:cessive dose lockout	Yes	Yes	Unknown	NA
-QA test report	Yes	Yes	Unknown	NA
Quality Test Phantom	Included	Included	Included	Included
Biocompatibility	N/A	N/A	N/A	N/A
EM emissions	ETL testing	ETL testing	ETL testing	ETL testing
Sterility	N/A	N/A	N/A	N/A
Chemical Safety	N/A	N/A	N/A	N/A
Thermal Safety	ETL testing	ETL testing	ETL testing	ETL testing
IEC EN 60601 Electrical Safety Testing	ETL testing	ETL testing	ETL testing	ETL testing
IEC EN 60601 Mechanical Safety Testing	ETL testing	ETL testing	ETL testing	ETL testing
Materials	Substantial Equivalence Comparison	Substantial Equivalence Comparison	Substantial Equivalence Comparison	Substantial Equivalence Comparison
Where Used	Mobile or Fixed Radiology, ICU, ED, Surgical, Interventional,clinic, Office,	Mobile or Fixed Radiology, ICU, ED, Surgical, Interventional, Clinic, Office,	Radiology, Fixed ED, Clinic,Office	Mobile or Fixed Radiology, clinic, Office

Company	NeuroLogica	NeuroLogica	Hitachi	NeuroLogica
Model/Name	NL4000 BodyTom	NL 3000 CereTom	ECLOS16	NL1000 inSPira
Predicate/Submission 510(k) number	Submission	Predicate K051765	Predicate K071806	Predicate K090811
Anatomical Site	That which can be imaged in 60cm FOV and 85cm aperture.	That which can be imaged in 25cm FOV and 32cm aperture, primarily head and neck	Whole Body	That which can be imaged in 20cm FOV and 32cm aperture.
Indication for Use	The NL4000 BodyTom is intended to be used for x-ray computed tomography applications for anatomy that can be imaged in the 85cm aperture.	The NL3000 CereTom is intended to be used for x-ray computed tomography applications for anatomy that can be imaged in the 25cm field of view, primarily head and neck.	The ECLOS Computed Tomography system is an x-ray imaging device that produces cross-sectional images of the body at different angles. The system reconstructs, processes, displays, and stores the collected images. The device output can provide an aid to diagnosis when used by a qualified physician and is intended for general purpose CT applications.	The NL1000 is intended to be used as a diagnostic tool in nuclear imaging by obtaining three-dimensional images for any anatomy that can be imaged in the 20cm field of view.

Summary Analysis of Differences from Predicate Devices

The NL 4000 BodyTom CT system has several differences from the three predicate devices listed. However, many of the differences between one device were similarities between one or both of the other devices. Two examples are: **1)** X-ray tube type is similar to Hitachi ECLOS but different than NeuroLogica CereTom, and **2)** Mobile is similar to NeuroLogica CereTom but different than the Hitachi ECLOS. NeuroLogica is of the opinion that these overlapping differences have no effect on equivalence comparison because they do have similarities with at least one of the predicate devices.

Excluding the differences noted in the above paragraph, there are two differences cited that have no similarities with any of the predicates listed. Each of these differences will thus be addressed in the following synopsis to show that they have minimal risk on impact to Safety and Effectiveness of the proposed device:

1) **Type of Batteries**: The BodyTom uses Lithium Ion Polymer (LiPO) batteries as opposed to Sealed lead Acid (SLA) as used in the predicate CereTom. Performance of the LiPO batteries are much better than traditional Lead Acid (recognized in Literature to have a 4X advantage). In addition, there is a worldwide movement to remove lead from devices due to the disposal hazards to the environment. There were some concerns about the safety of the initial Lithium Ion batteries which if charged improperly could potentially catch fire, but the "Polymer" type of Lithium Ion batteries have overcome this hazard. There is an internationally recognized standard for LiPO batteries (ST/SG/AC.10/11/Rev.4 , UL 1642 , IEC 62133) which the BodyTom batteries have been tested/certified against. We therefore feel there is no degradation to safety and effectiveness due to this difference.
2) **Motorized Transport**: The CereTom and InSPira devices are mobile devices but are maneuvered by human power. The Hitachi device is stationary. The BodyTom uses motorized wheels to assist in moving the device to different locations. The hazards of motorized movement have been fully addressed and mitigated in our hazard analysis and found to have a very insignificant safety effect. The motorization is only used for transporting the scanner from one place to another and is disabled while the unit is in scanning mode. We therefore feel there is no degradation to safety and effectiveness due to this difference.

Features of the BodyTom battery system

BodyTom battery system is comprised of 144 batteries connected in series to produce a nominal terminal voltage of 540VDC. Capacity of each battery is nominally 30Ah. The entire battery pack therefore has approximately 16.2kWh or 58.3MJ of energy storage.

Safety:

1) Over-current - The battery pack is protected from over current at the battery pack level as well as the battery cell level with multiple redundancies.

   A) System level - A thermal magnetic main circuit breaker and a high power relay are placed in series between the battery pack and all loads. An electronic monitor of battery current is interfaced with control of the high power relay to allow disconnect should current be measured to be excessive.
   B) Battery level - Each battery is comprised of a number of smaller cells connected in parallel and available to the system via two large terminals. The connection of each cell to the terminals is through a set of fusable links designed to clear should a direct short between the terminals be present. In addition, there are 4 high-speed, semiconductor type fuses placed within the series string that are designed to open should a short circuit be present within the battery pack.

2) Over-voltage - The battery pack is protected from over voltage through multiple points of measurement and different methods of mitigation.

   A) System level - The entire pack voltage is monitored at all times. The most likely way to achieve an overvoltage situation is for the battery charging to be to operating incorrectly. The electronic monitoring of the battery pack voltage is interfaced with a digital ON/OFF control of the battery charging circuit to attempt to disable it if an over voltage situation occurs.
   B) Battery level - The voltage of each battery is individually measured. A charge current shunt is enabled to direct energy away from any cell that is measured to be excessive. Should the voltage increase beyond a reasonable limit, the system level protections will activate as if there is a system level problem.

3) Over-temperature - Each battery of the system is monitored individually for temperature. A thermal resistor is buried into each battery and the resistance

measured. Should the temperature exceed a reasonable limit, the system will respond by either disabling battery charging (if over-temperature is due to charging activity) or communicate to the BodyTom the status of the over-temperature situation to prevent further scan activity (if over-temperature is due to discharging activity). Should temperature exceed a safe limit, the electronic monitor will disconnect the battery from the load via opening of the high power relay.

Mechanical:

The system is protected from mechanical stress. Each battery, being comprised of a number of flat, prismatic cells, is housed in an aluminum shell. The batteries are then placed in a larger box made of .125" aluminum plate and covered with a Lexan plastic cover.

Validation testing:

A 50kW passive load is being used to simulate worst case load condition of the machine. The battery system is cycled through charge and discharge profiles that are expected in a severe duty installation.

8) Substantial Equivalency

Based upon the above considerations, NeuroLogica Corporation's NL4000 BodyTom Computed Tomography System is of comparable type in design, material, functionality, technology and is, for its intended use, substantially equivalent to the following cleared predicate devices listed above.

A product report will be issued according to 21 CFR 1002.10 to the FDA prior to first delivery of the NL4000 BodyTom.

Use of the NL4000 BodyTom does not result in any new potential safety risks.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

Neurologica Corporation
% Mr. Jay Kogoma
Responsible Third Party Official
Intertek Testing Services
2307 East Aurora Rd., Unit B7
TWINSBURG OH 44087

MAR 2 4 2011

Re: K102677
Trade/Device Name: BodyTom™
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: March 9, 2011
Received: March 10, 2011

Dear Mr. Kogoma:

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.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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 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/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) NUMBER (IF KNOWN): K102677

DEVICE NAME: BodyTom™

Indication for use: The NL4000 BodyTom is intended to be used for x-ray Computed Tomography applications for anatomy that can be imaged in the 85cm aperture.

Prescription Use x	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 In Vitro Diagnostic Devices (OIVD)

Mary S Pastel

Division Sign-Off

Office of In Vitro Diagnostic Devices
Evaluation and Safety

510(k) Number K102677

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