K022157

AUG 2 8 2002

510(k) Summary of Safety and Effectiveness

The following 510(k) Summary of Safety and Effectiveness has been prepared pursuant to requirements for 510(k) summaries specified in 21 CFR § 807.92(a).

807.92(a)(1) - Submitter Details:

Submitter name:	Adi Ickowicz - Corporate Director of Regulatory Affairs, IP and Quality
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Contact Person:	Adi Ickowicz - Corporate Director of Regulatory Affairs, IP and Quality
Date:	May 30, 2002

807.92(a)(2) - Device Details:

Trade Name and Common Name:	RF Tent
Classification:	21 CFR 892.1000 Magnetic Resonance Diagnostic Device.
Class:	II
Product Code:	LNH - Magnetic Resonance Imaging System
Performance Standards:	No applicable performance standards have been issued for this product code under section 514 of the Food and Drug and Cosmetic Act.

807.92(a)(3) - Predicate Devices:

The RF Tent is a new accessory of the PoleStar N-10 Intraoperative Magnetic Resonance Device (K002242), but it can also be considered as a modification to the presently installed copper sheeting solution to create an area of substantially reduced Electromagnetic Interference (EMI) in the area enclosed by the RF Tent.

807.92(a)(4) – Device Description:

To acquire high-quality MR images, it is necessary to isolate the MRI scanner from external sources of EMI (Electromagnetic Interference). Generally, copper sheeting is installed in the OR walls to isolate the OR from external interference. This solution is relatively expensive, and also requires the OR to be out of use during the installation process. Once the copper sheeting is installed, all procedures involving the PoleStar N-10 intraoperative MRI must be performed in the dedicated shielded room.
The RF Tent presented in this premarket notification expands the capability of the PoleStar N-10 (K002242), by providing a low cost, simple and effective alternative to the fixed copper shielding. Because it is portable, it also allows the PoleStar N-10 to be used in more than a single dedicated OR. Thereby increasing the flexibility of the use of the system.

807.92(a)(5) – Device Intended Use:

The RF Tent is intended to create an area of substantially reduced Electromagnetic Interference (EMI) in the area enclosed by the RF Tent during image acquisition by the PoleStar N-10 (K002242).

807.92(a)(6) – Substantial Equivalence Comparison Table:

The RF Tent and the presently implemented installed copper sheeting have the same intended use; to create an area of substantially reduced Electromagnetic Interference (EMI) in the area enclosed by these means. Both solutions use conductive means to provide similar attenuation levels.

Odin RF Tent's intended use is similar to the presently implemented installed copper sheeting, with the following main advantages:

- **Initial Cost** – The purchase and installation cost of the copper sheeting is approximately ten times more than the RF Cage.
- **Installation** – Installation of copper sheeting requires the OR to be out of use for approximately three months. There is no installation required for the RF Tent.

- **Dedicated OR** – Because the RF is portable, the PoleStar N-10 does not have to be used in a dedicated OR.

Performance Data:

Substantial equivalence was based on performance data. Signal to Noise results are provided in Attachment 2 of the 510(k) submission.

Conclusions:

The RF Tent adressed in this premarket notification, has the same intended use and technological basis as the presently implemented installed copper sheeting used with the legally marketed Intraoperative Magnetic Resonance Device PoleStar N-10 (K002242). Based on the analysis and tests performed by Odin Medical Technologies regarding the proper function of the RF Tent. We believe that the RF Tent can be safely and effectively used.

P.O.BOX 548. Yokneam Elit 20692, Israel Tel. 972-4-9591010, Fax. 972-4-9591011

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 8 2002

Mr. Adi Ickowicz
Corporate Director of Regulatory
Affairs, IP and Quality
Odin Medical Technologies, Ltd.
P.O. Box 548
Yokneam Elit 20692
ISRAEL

Re: K022157
Trade/Device Name: RF Tent
Regulation Number: 21 CFR §892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: 90 LNH
Dated: June 30, 2002
Received: July 2, 2002

Dear Mr. Ickowicz:

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 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); 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.

This letter will allow you to begin marketing your device as described in your 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 Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K022157

Device Name: **RF Tent**

Indication For Use:

The RF Tent is intended to create an area of substantially reduced Electromagnetic Interference (EMI) in the area enclosed by the RF Tent during image acquisition by the PoleStar N-10 (K002242).

(PLEASE DO NOT WRITE BELOW THE LINE – CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K022157