MAR 1 8 2005

K050237

Special 510(k) Summary of Safety and Effectiveness

The Following Special 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 –Quality and Regulatory Director
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Contact Person:	Adi Ickowicz –Quality and Regulatory Director
Date:	January 8, 2005

807.92(a)(2) - Device Details:

	Trade Name and Common Name: StarShield V3
Classification:	21 CRF 892.1000 Magnetic Resonance Diagnostic Device.
Class:	II MRDD were reclassified by FDA from Class III to Class II effective July 28, 1998.
Product Code:	LNH – Magnetic Resonance Imaging System

807.92(a)(3) – Predicate Devices:

The StarShield V3 is comparable to Odin's RF Tent

Medical Device Name	Applicant Name	510(k) Number	Classification
RF Tent	Odin Medical Thechnologies Ltd.	K022157	Class II device

Additional Substantial Equivalence Information is provided in the attached Substantial Equivalence Comparison Table.

807.92(a)(4) – Device Description:

The StarShieldV3 is an accessory of Odin's PoleStar Intraoperative Magnetic Resonance system. It is intended to create an area of substantially reduced Electromagnetic Interference (EMI) in the area enclosed by the RF Tent, required during MRI acquisition.The RF Tent is a portable modular structure that consist of four principal components:

- The foldable frame
- The cover
- The control unit
- The floor

The RF Tent is not connected to the PoleStar gantry or the OR table.

807.92(a)(5) – Device Intended Use:

The general purpose of the device as defined in 21 CFR 892.1000:

The PoleStar system is a magnetic resonance diagnostic device intended for general diagnostic use to present images, which reflect the spatial distribution and/or magnetic resonance spectra, which reflect frequency and distribution of nuclei exhibiting nuclear magnetic resonance.

The StarShield V3 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 system.

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

Model / parameter	Odin RF Tent (K022157)	Odin StarShield V3
Application	To create an area of substantially reduced Electromagnetic Interference (EMI) in the area enclosed by the RF Tent during image acquisition by the PoleStar system	Same
Materials		
Frame	Aluminum alloy AlMg Si 0.5	Same
Cover	(Polyethylene Terephthalate) PET incorporating Cu+Ni, laminated with flame-retardant PVC.	Same
Dimensions		
Length (Folded)	950 mm	Same
Length (Extended)	3500	Same
Width/Base	1250 mm	Same
Maximum height	1650 mm	Same
Clearance between the RF tent and the operating table		
Foot side (height)	200 mm	Same
Width (easch side)	100 mm	Same
Head side (distance from scanner)	70 mm	Same
Average Attenuation	>40dB at 100 MHz	Same
Floor	Matte aluminum alloy sheet measuring 3.8 x 1.5 m	Same
Energy used	Pneumatic	Electric
Where Used	Operating Room	Same
Biocompatibility	Does not contact patient	Same

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 8 2005

Mr. Adi Ickowicz
Director of Regulatory Affairs
Odin Medical Technologies Ltd.
Kochav Yokneam Building
P.O. Box 548
Yokneam Elite, 20698 (2)
ISRAEL

Re: K050237
Trade/Device Name: StarShield V3
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance imaging system
Regulatory Class: II
Product Code: LNH
Dated: January 31, 2005
Received: February 23, 2005

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 (Premarket Approval), it may be subject to such 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 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 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:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.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): K050237

Device Name: **StarShield V3**

Indication For Use:

The PoleStar system is a magnetic resonance diagnostic device intended for general diagnostic use to present images, which reflect the spatial distribution and/or magnetic resonance spectra, which reflect frequency and distribution of nuclei exhibiting nuclear magnetic resonance.

The StarShield V3 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 system.

(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 K050237