APR 2 4 2002

K020601

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
Address:	P.O. Box 548, Yokneam Elit 20692, Israel
Phone:	+972-4-959-1010
Fax:	+972-4-959-1011
E-mail:	adi@odin.co.il
Contact Person:	Adi Ickowicz - Corporate Director of Regulatory Affairs, IP and Quality
Date:	February 11, 2002

807.92(a)(2) - Device Details:

Trade Name and Common Name:	Flex*i*Coil - malleable receive-only surface coil
Classification:	21 CFR 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:	MOS - Magnetic Resonance Specialty Coil
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 Flex*i*Coil - malleable receive-only surface coil is substantially equivalent to the following legally marketed medical devices:

Medical Device Name	Applicant Name	510(k) Number	Product Code
NORMA 10 surface coil	Odin Medical Technologies Ltd.	K991243	LNH
Phased Array Musculo - Skeletal Flex Coil Package	IGC-Medical Advances, Inc.	K003366	MOS

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

807.92(a)(4) – Device Description:

The Flexi*Coil* is a malleable receive-only surface coil intended to facilitate intraoperative MR imaging of selected sections of the head and extremities. This component is a malleable circular enclosed coil that consists of copper straps covered with Medical Foam Tape and an electronic tuning box, which can be placed around the anatomy of interest for MR imaging. The malleable structure of the coil allows adjustment of size and shape by pulling/releasing the plastic holders on both sides of the coil, providing the highest possible contact between the coil and the area to be imaged.

Due to its malleability the Flexi*Coil* can cover a wider area than the presently used coils (K991243) resulting in better image uniformity and a better overall SNR when imaging structures near the surface of the patient's head or extremity. The improved SNR is a result of the coil being closer to the signal-emitting anatomy, and being fully tuned and matched to the signal and receive channel. In addition the coil can be easily placed near the anatomy to be imaged with little or no patient post procedure discomfort. The Flexi*Coil* is for single use only and is supplied non-sterile.

807.92(a)(5) – Device Intended Use:

The Flexi*Coil* - malleable receive-only surface coil expands the capability of the PoleStar N-10 MR Imaging System (K002242). It improves imaging of selected sections of the head and extremities.

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

Parameter	Candidate Device	Predicate Devices	
	Flex*i*Coil	**NORMA 10 surface coil**	**Phased Array Musculo -Skeletal Flex Coil Package**
Coil enclosure material	Closed-cell polyethylene	Polyolefin	Cotton fabric
Coil design	Receive-Only Surface Coil	Receive-Only Surface Coil	Receive-Only or Transmit and Receive Coil
Decoupling	Active PIN diode decoupling	Active PIN diode decoupling	Active PIN diode decoupling
Formation of Resonant Loops	Surface Coil	Surface Coil	Phased Array Coil
Potential for RF burns	SAR substantially below the permissible limit	SAR substantially below the permissible limit	Not Available
RF absorption	Does not transmit RF power	Does not transmit RF power	Not Available
Intended use	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	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	2D, 3D imaging, proton density, Ti and T2 weighted imaging. 2D, 3D time of flight, phase contrast imaging
Indications for use	Selected sections of the head and extremities	Selected sections of the head and extremities	Cranial structures, musculoskeletal structures, peripheral nerves and pediatric applications

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

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Performance Data:

Substantial equivalence was based on performance data. Sample images were provided in attachment 4 of the 510(k) submission.

Conclusions:

The PoleStar N-10 operated with the Flex*i*Coil - malleable receive-only surface coil adressed in this premarket notification, has the same intended use and technological characteristics as the same system operated with the legally marketed coil cleared in K991243 and does not affect the PoleStar N-10 system safety parameter specification. The Flex*i*Coil also has the the same intended use and technological characteristics as the other OEM predicate coil.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 4 2002

Mr. Adi Ickowicz
Corporate Director of Regulatory
Affairs, IP and Quality
Odin Medical Technologies Ltd.
P.O. Box 248
Yokneam Elit
20692 ISRAEL

Re: K020601
Trade/Device Name: FlexiCoil-Malleable receive-only surface coil
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: 90 MOS
Dated: February 20, 2002
Received: February 22, 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): K020601

Device Name: **FlexiCoil - malleable receive-only surface coil**

Indication For Use:

A magnetic resonance diagnostic device is 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 FlexiCoil - malleable receive-only surface coil expands the capability of the PoleStar N-10 MR Imaging System. It improves imaging of selected sections of the head and extremities.

(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 K020601