JUN 18 1999

K991243

ATTACHMENT 1

510(k) Summary of Safety and Effectiveness

ODIN Technologies Ltd.
P.O. Box 248, Yokneam Elit 20698, Israel. Tel. 972-4-9591010, Fax. 972-4-9591011

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 – Regulatory Affairs / Quality Assurance Director
Address:	P.O. Box 248, Yokneam Elit 20698, Israel
Phone:	+972-4-959-1010
Fax:	+972-4-959-1011
E-mail:	adi@odin.co.il
Contact Person:	Adi Ickowicz – Regulatory Affairs / Quality Assurance Director
Date:	March 15, 1999

807.92(a)(2) - Device Details:

Trade Name and Common Name:	NORMA 10 - Magnetic Resonance Diagnostic Device
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:

Medical Device Name	Applicant Name	510(k) Number	Classification
Ortho 8000	Inner Vision	K963186	Class II device
MRP-5000	Hitachi	K911642	Class II device

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

807.92(a)(4) – Device Description:

Device Functions:

The NORMA 10 utilizes a permanent magnet to acquire 2D single-slice, multi slice, and 3d volume images. A wide variety of pulse sequences are provided to the operator, including spin echo, gradient echo, fast spin echo, and steady state free precession acquisitions. The NORMA 10 is a fixed system.

Scientific Concepts:

Magnetic Resonance (MR) is based on the fact that certain anatomic nuclei have electromagnetic properties, which cause them to act as small spinning bar magnets. The most ubiquitous of these nuclei is hydrogen, which makes it the primary nucleus used in current imaging experiments in magnetic resonance. When placed in a magnetic field, there is a slight net orientation or alignment of these atomic nuclei with the magnetic field. The introduction of a short burst of Radiofrequency (RF) excitation of wavelength specific to the magnetic field strength and to the atomic nuclei under consideration can cause a reorientation of the proton's magnetization vector. When the RF excitation is removed, the proton relaxes and returns to its original orientation. The rate of relaxation is exponential, and varies with the character of the proton and its adjacent molecular environment. This reorientation process is characterized by two exponential relaxation times called TI and T2, which can be measured.

These relaxation events are accompanied by an RF emission or echo which can be measured and used to develop a representation of these emissions on a three dimensional matrix. Spatial localization is encoded into the echo by varying the RF excitation and by appropriately applying magnetic field gradients in x, y, and z directions, and changing the direction and strength of these gradients. Images depicting the spatial distribution of NMR characteristics of the nuclei under

consideration can he constructed by using image processing techniques similar to those used in CT.

For magnetic fields up to 1.5T, the RF frequencies commonly used range up to 65MHz. The RF fields have pulsed power from several watts to greater than 2 kilowatts, and repeat at rates from once every few seconds to greater than fifty per second. The time-varying magnetic gradient fields have a typical duration of sub-millisecond to several milliseconds.

Physical and Performance Characteristics:

ODIN Technologies Ltd., has developed an open MRI system based on an innovatively designed permanent magnet of 0.12 Tesla. The system is compact, displaceable, inexpensive and widely open.

The magnetic probe consists of two lateral permanent-magnet poles that can be adjusted laterally and longitudinally, mounted on a C-arm gantry. The anatomic region to be scanned is positioned between the poles. Except for the anatomic region been scanned, the patient is positioned outside of the gantry, thus enhancing patient comfort and reducing the possibility of a claustrophobic reaction.

807.92(a)(5) – Device Intended Use:

The NORMA 10 is a Magnetic Resonance Diagnostic Device intended to produce transverse, sagittal, coronal, and oblique 2D and 3D images of the extremities and selected sections of the head. The images produced by the NORMA 10 reflect the special distribution of protons (Hydrogen Nuclei) exhibiting magnetic resonance. The NMR properties that determine the image appearance are proton density, spin-lattice relaxation time (T1), spin-spin relaxation time (T2) and T2*.

When interpreted by trained physicians, these images provide information that can be useful in determining a diagnosis.

- Anatomical regions: extremities and selected sections of the head.
- Nuclei excited: H-1
- Diagnostic uses: T1, T2, T2* and density weighted imaging.

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

Model / parameter	Odin NORMA 10	Hitachi MRP-5000	Innervision Ortho 8000
Clinical application	Extremities and selected sections of the head	Whole body	Extremities
Magnet type	Permanent	Permanent	Permanent
Field strength	0.12T	0.2T	0.17T
5 gauss fringe field (radial/axial, m)	1.5	<2.1	0.3
Shimming	Passive, active	Passive	Passive, active
Gradient subsystem			
- Strength mT/m	25	8	15
- Rise time to 10mT/m msec	<1	<1	<1

Model / parameter	Odin NORMA 10	Hitachi MRP-5000	Innervision Ortho 8000
Computer system			
- CPU:	Pentium 586	Motorola 32 bit	IBM PC
- Memory size [MB]	64	4	32
array processor	4xDSP C44 TI	Hitachi	TI
- Memory size [MB]	4000	68	Not specified
storage media	magnetic disk, floppy disk	magnetic disk, optical disk	optical disk, tape, CD-R, floppy disk
number of images stored	5000	2000 magnetic disk 4300 optical disk	5000
Imaging modes:			
- single	Yes	Yes	Yes
- multislice	Yes	Yes	Yes
- volume study	Yes	Yes	Optional
- other	FSE, Multislice	Multislab, multiangle, FS, dual slice, MRA, cardiac gated, multislice/multiple angle	Dynamic scan
Reconstruction time:			
- single slice, sec	<3/slice	<4/slice	<3/slice
- multislice, sec	<3/slice	<4/slice	<3/slice
- volume sec	<20/slice, ave.	<4/slice	<20/slice, ave.

model / parameter	Odin NORMA 10	Hitachi MRP-5000	Innervision Ortho 8000
Cardiac gating (ECG/peripheral)	No	Yes/yes	NA
Respiratory gating	No	No	NA
Angiography	Optional	Optional	NA
Spectroscopy	No	No	NA
Imaging;			
- pulse sequence	Spin Echo, Fast Spin Echo, Gradient Echo, 2D 3D	SE, multiple SE, GE, IR, STIR, FSE,dual slice, MRA	SE, FE, IR, multiecho, dynamic
- repetition time, msec	50-5000 increments of 1	50-4000	50-5000 increments of 1
- echo time, msec	5-150	10-150	7-100 increments of 1
- inversion time, msec	N/A	100-800	15-5000 incr. of 1
- slice thickness, mm	4-10	3,4,5,6,7,8,10,12.5, 15,17.5,20,30,50 (2D) 1-5 (3D)	3-10 incr. of 1
- FOV, cm	5-18	12-40	8-16 increments of 0.1

model / parameter	Odin NORMA 10	Hitachi MRP-5000	Innervision Ortho 8000
- scan orientation	Transverse, coronal, sagittal, oblique	Transverse, coronal, sagittal, dual axis, oblique	Orthogonal, oblique
- measuring matrix	64x64 to 256x256 steps of 1 in phase encoding	128x256, 160x256 192x256, 256x256, half scan, rectang.	64x256 to 256x256 steps of 1 in phase encoding
- display matrix	1024x768	512x512	Up to 512x512
- pixel intensity	0-4095	-2000 to +4000	0-255
Surface coils:			
- spine	No	Yes	NA
- knee	Yes	Yes	Yes
- neck	No	Yes	NA
- TMJ	No	Bilateral	NA
- extremity	Yes	Oval Solenoid	Yes
- head	Yes	Solenoid quad.	NA
- breast	No	Optional bilateral	NA
- shoulder	No	Yes	NA
- others	No	Flexible	Small dynamic (12cm) large dynamic (18cm)
Bore diameter or WxH, cm	24.5x39	100x48 rectangle	20x75

model / parameter	Odin NORMA 10	Hitachi MRP-5000	Innervision Ortho 8000
Bore features	Open access to patient	Wide bore short depth, intercom, soft sound gradients	Open access to patient, quiet gradient system built in CD sound sys.
Cooling system type	Water cooling (Gradients only)	None, room air-conditioning	Thermal insulation
Cryogen use	NA	NA	NA
Magnet weight, kg	380	12200	500
HxWxD, cm	135x86x80	175x228x157	118x51x52
Dicom 3.0 interface	No	Optional	From 3rd party
Power requirements:			
- line voltage, V	3x208 (3 phase)	200-240 single phase	110/240
- Kva	16	6	<3
- A/C, BTU/hr	<10000	<10000	10000

Clinical Data:

Testing of the system was performed at the Odin premises, during the period of October 1998 through February 1999. The scans were performed on normal anatomy including extremities and selected sections of the head.

Conclusions from Testing:

Safety and magnetic resonance performance tests were performed on the NORMA 10 in accordance with the NEMA standards.
The results obtained from the safety tests including acoustic noise, Specific Absorption Rate (SAR) and Time-Varying Gradient Fields (dB/dt) were found to be below the levels of significant risk as described in the FDA Guidance for the Submission Of Premarket Notification for Magnetic Resonance Diagnostic Device, dated November 14, 1998. The performance results obtained including Signal-to-Noise Ratio (SNR), Geometric Distortion, Image Uniformity, Slice Thickness, Characterization of Special Purpose Coils and spatial resolution meets the performance specifications claimed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 18 1999

Adi Ickowicz
Odin Technologies, Ltd.
P.O. Box 248
Yokneam, Elet 20698
ISRAEL

RE: K991243
Norma 10 MR Diagnostic Device
Dated: April 10, 1999
Received: April 12, 1999
Regulatory Class: II
21 CFR 892.1000/Procode: 90 LNH

Dear Mr. Ickowicz:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K991243

Device Name: **NORMA 10**

Indication For Use:

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- **Anatomical regions: extremities and selected sections of the head.**
- **Nuclei excited: H-1**
- **Diagnostic uses: T1, T2, T2* and density weighted imaging.**

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K991243

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

(Optional Format 1-2-96)