SEP 13 1999

510(k) Summary K992308

Submitted on behalf of:

	Company Name:	**Lifetek Medical, Inc.**
	Address:	**732 Morningstar Drive**
		Portage, WI 53901
	Telephone:	**608-742-1188**
by:		Elaine Duncan, M.S.M.E., RAC
		President, Paladin Medical, Inc.
		PO Box 560
		Stillwater, MN 55082
Telephone:		715-549-6035
Fax:		715-549-5380

CONTACT PERSON: **Elaine Duncan**

DATE PREPARED: **July 8, 1999**

TRADE NAME: **Oocyte Retrieval Needle Set**
COMMON NAME: **Assisted Reproduction Needle**

SUBSTANTIALLY EQUIVALENT TO:

The **Oocyte Retrieval Needle Set** is Class II and substantially equivalent, due to conformance with descriptions from CFR 884.6100 Assisted Reproduction Catheters (Procode 85 MQE) as described in the Final Rule in the Federal Register, Vol. 63. No. 175, Thursday, September 10, 1998, page 48436.

DESCRIPTION of the DEVICE:

The **Oocyte Retrieval Needle Set** is used in In-Vitro Fertilization (IVF) procedures to obtain female gametes/oocytes from the body. It is a single-lumen needle of the proper length and diameter. Some physicians experienced in this procedure prefer a 17 ga x 35 cm needle which complies to the government specification GG-N-196. For convenience the needle is provided with PTFE connecting tubes and a silicone stopper.

INDICATIONS FOR USE:

The Lifetek Medical **Oocyte Retrieval Needle Set** is an assisted reproduction needle indicated for use and intended to be used for obtaining female gametes/oocytes from the body.

SUMMARY of TESTING:

Based upon conventional biocompatibility testing (per blue book memorandum #G95-1 entitled: Use of International Standard ISO 10993: "Biological Evaluation of Medical Devices, Part 1: Evaluation and Testing." the materials of which the **Oocyte Needle Set** is fabricated are biocompatible with their intended use. Tests included those recommended for an "external communicating device" for tissue contact which have limited (short-term): 1) cytotoxicity, 2) sensitization and 3) irritation. In addition, FDA has required the mouse embryo assay (MEA) for any device coming into contact with gametes and/or embryos. The **Oocyte Needle Set** passed the bacterial endotoxin assay at a limit sensitivity of 9.6 EU/device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Lifetek Medical, Inc.
c/o Ms. Elaine Duncan, M.S.M.E., RAC
President, Paladin Medical®, Inc.
and Regulatory Consultant to Lifetek Medical, Inc.
P.O. Box 560
Stillwater, MN 55082-0560

Re: K992308
Oocyte Retrieval Needle Set
Dated: July 8, 1999
Received: July 9, 1999
Regulatory Class: II
21 CFR §884.6110/Procode: 85 MQE

Dear Ms. Duncan:

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) K992308

Device Name: Oocyte Retrieval Set.

Indications for Use:

The Lifetek Medical Oocyte Retrieval Needle Set is an assisted reproduction needle indicated for use and intended to be used for obtaining female gametes/oocytes from the body.

(Please Do Not Write Below This Line-Continue On Another Page If Needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over -The-Counter Use _____

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K992308