University of California Los Angeles
10889 Wilshire Blvd, Suite 830
Los Angeles, CA 90095-1406

http://ora.research.ucla.edu/ohrpp
General Campus IRB: (310) 825-7122
Medical IRB: (310) 825-5344

APPROVAL NOTICE

DATE:	12/18/2018
TO:	KENNETH LU, MD OPHTHALMOLOGY
FROM:	DANIEL CLEMENS, MD, PhD Chair, MIRB1
RE:	IRB#17-001386-CR-00001 2018 Review for IRB#17-001386 Comparing the I-RIng to the Malyugin Ring used during cataract surgery.

The UCLA Institutional Review Board (UCLA IRB) has approved the submission listed below. UCLA's Federalwide Assurance (FWA) with Department of Health and Human Services is FWA00004642.

Submission and Review Information

Type of Submission	Continuing Review
Type of Review	Expedited Review
Approval Date for this Submission	12/18/2018
Expiration Date of the Study	12/17/2019
Funding Source(s)	1) BEAVER-VISITEC INTERNATIONAL INC. *Grant PI*: KENNETH LU *Grant Title*: N/A Gift fund
Initial IRB Approval Type & Date for this Study	IRB Review: Expedited or Full Board (insert initial approval date)

Specific Conditions for Approval

-- **Data Analysis Only** - the remaining research activities are limited to data analysis.

Regulatory Determinations

-- **Expedited Review Category(ies)** - The UCLA IRB determined that the research meets the requirements for expedited review per 45 CFR 46.110 and 21 CFR 56.110, categories 1b, 4 and 5.

Important Note: Approval by the Institutional Review Board does not, in and of itself, constitute approval for the implementation of this research. Other UCLA clearances and approvals or other external agency or collaborating institutional approvals may be required before study activities are initiated. Research undertaken in conjunction with outside entities, such as drug or device companies, are typically contractual in nature and require an agreement between the University and the entity.

General Conditions of Approval
As indicated in the PI Assurances as part of the IRB requirements for approval, the PI has ultimate responsibility for the conduct of the study, the ethical performance of the project, the protection of the rights and welfare of human subjects, and strict adherence to any stipulations imposed by the IRB.

The PI and study team will comply with all UCLA policies and procedures, as well as with all applicable Federal, State, and local laws regarding the protection of human subjects in research, including, but not limited to, the following:

- Ensuring that the personnel performing the project are qualified, appropriately trained, and will adhere to the provisions of the approved protocol,
- Implementing no changes in the approved protocol or consent process or documents without prior IRB approval (except in an emergency, if necessary to safeguard the well-being of human subjects and then notifying the IRB as soon as possible afterwards),
- Obtaining the legally effective informed consent from human subjects of their legally responsible representative, and using only the currently approved consent process and stamped consent documents, as appropriate, with human subjects,
- Reporting serious or unexpected adverse events as well as protocol violations or other incidents related to the protocol to the IRB according to the OHRPP reporting requirements.
- Assuring that adequate resources to protect research participants (i.e., personnel, funding, time, equipment and space) are in place before implementing the research project, and that the research will stop if adequate resources become unavailable.
- Arranging for a co-investigator to assume direct responsibility of the study if the PI will be unavailable to direct this research personally, for example, when on sabbatical leave or vacation or other absences. Either this person is named as co-investigator in this application, or advising IRB via webIRB in advance of such arrangements.

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APPROVAL NOTICE
New Study

DATE:	11/2/2017
TO:	KENNETH LU, MD OPHTHALMOLOGY
FROM:	DANIEL CLEMENS, MD, PhD Chair, MIRB1
RE:	IRB#17-001386 Comparing the I-RIng to the Malyugin Ring used during cataract surgery.

The UCLA Institutional Review Board (UCLA IRB) has approved the above-referenced study. UCLA's Federalwide Assurance (FWA) with Department of Health and Human Services is FWA00004642.

Submission and Review Information

Type of Review	Expedited Review
Approval Date	10/31/2017
Expiration Date of the Study	11/1/2018
Funding Source(s)	1) BEAVER-VISITEC INTERNATIONAL INC. *Grant PI*: KENNETH LU *Grant Title*: N/A Gift fund

Specific Conditions for Approval

-- **Translations Needed** - Please submit translated copies of your consent documents as an amendment(s) before recruiting or consenting any subjects for whom these translations are required.

-- **Research Participants Bill of Rights** - By California law, a copy of the Research Participants Bill of Rights in a language in which the participant is fluent must be given to all research participants in this study as there is a real or foreseeable risk of biomedical harm. Numerous translations are available for download on the HRPP website at http://www.ohrpp.research.ucla.edu/pages/bill-of-rights.

Regulatory Determinations

-- **Expedited Review Category(ies)** - The UCLA IRB determined that the research meets the requirements for expedited review per 45 CFR 46.110 and 21 CFR 56.110, categories 1b, 4 and 5.

-- **HIPAA General Waiver** - The UCLA IRB waived the requirement for HIPAA Research Authorization retrospective medical record review portion of the study.

-- **Waiver of Informed Consent** - The UCLA IRB waived the requirement for informed consent under 45 CFR 46.116(d) retrospective medical record review portion of the study.

Documents Reviewed included, but were not limited to:

Document Name	Document Version #
17-001386_LU_clean.pdf.pdf	0.01

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