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Blue Print Of Regulation Of Extra Terrestrial Vision Aid As Medical Device In India

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ABSTRACT

As it is said the Eyes are gateway to one's soul. It is one of the most important parts of human body as it plays very unique role and functions. We recognise face after seeing through eyes and memory stored.

Through interactions with others, an individual develops a self-image which is mainly based on how others react to them and how they see themselves. Men (but mostly women) are judged by their appearance and their self-esteem is influenced by how others see them. The eye is an important and one of the most complex sensory organs that we humans are endowed with. The vision aid helps us in visualizing objects and also helps us in spectrum perception, colour and depth perception. Beneath all it has characteristicsthat mimics the sense organs and are pretty much similar to cameras and camcorders, and they help us see and visualise objects when light coming from outside enters them.

Keywords: *Extraterrestrial, vision abridges therapy, visible spectrum reading, retinonucleasis, and sight perceptible tangibility*

1. INTRODUCTION

The organ of sight of a human being is like a camera. Much like the automatic electronic device, the human eyelet also focuses and lets in light to produce images transferred through its aperture. So eventually, light rays that are reflected and deflected from or by distant objects capable of landing on the retina after they trespass through various mediums like the cornea, crystalline lens, aqueous humor, along with the lens, and vitreous humor. Below is the diagrammatical presentation of general anatomy of eye (Fig 1).

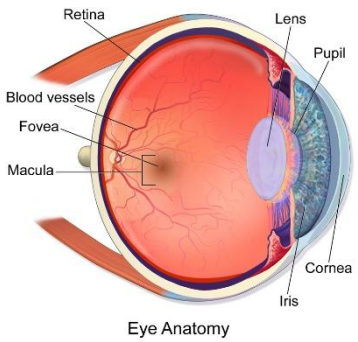

Fig 1: Diagrammatical presentation of general anatomy of eye

Average dimensions of Human eye: The size of a human adult eye is approximately 24.2 mm (transverse) × 23.7 mm (sagittal) × 22.0–24.8 mm (axial) with no difference between age and gender[2]. The eyeball size may vary from 21 mm to 27 mm. Humans have two vision aperture, instated on the left and the right premises of the homo sapien's face. The vision aid is placed in bony cavities namely the orbits, embarked in the skull. There are six extraocular muscles that govern eye movements. The surface of visible part of the eye is build up of the whitish sclera, a coloured iris, and the pupil, the conjunctiva blanketing the top surface as shown in the Fig 1. Having two eyeletpacify the brain to determine the profound symmetry and distance along with displacement of an object and its images, called statuary stereovision providing the 3-Ddepiction of shades and fonts of entities. Both benevolentvision aperture must point precisely enough on the retina otherwise there is possibility of double vision to occur. Some recipients with congenitally damaged vision tends to ignore one's pertinent visionary aid, thus they do not suffer double vision, and do not procure stereovision. Individuals with congenitally absent eyes, retinal diseases, visual impairment, accidents, and war injuries require external visual aid is suited forextra-terrestrial eyes visual aid. The Extraterrestrial eyes are technically electrical eye prosthesis that are surgically implanted into eyes to permitthe light and sends guided signals to the brain (i.e. the change of light from the environment into impulses the brain can process) in cases with severe damaged retina[3]. The role of human retina is inevitable in image perception and processing to the foremost visual cortex in the brain.

2. FUNCTIONING OF THE DEVICE:

The retina is a visible spectrum-sensitive tissue and abridge layer found within the encored eye that transcends images obtained into neural impulses, which archives the transduction along the optic nerve to the thalamus to further relay to the foremost visual cortex (the vision processing centre), instated in the occipital lobe of the brain[4].

In a meanwhile the retina is thwarted bydiseases such as macular degeneration, congenital condition. The constrained individuals moreover have been able to see at some pinpoint aspects in their lives in order to generate the nerve connections in the brain for the device to function at the apex of its possibility.

The Extra-Terrestrial eye (electrical prosthetic eye) comprises of an external mechanic vision observer and capturing instrument namely (camera) and transmitter and transponder and an internal microchip. The cameras and camcorders are mounted on a pair of eyeglasses, where it serves to organize the visual stimuli of the environment before emitting high-frequency radio waves generating transient epiphany of all wavelength perception abilities encored around the exploratory symmetry of depiction and reading of visual signals sent to the brain. The ardent stimulator microchip consists of an electroplated electrode array that is surgically implanted into the subjugate retina. That functions as an electrical relay in place of degenerated retinal cells and replenish it time and again. The radio waves that are emitted by the extruded camera and transmitted signals are received by the stimulator, which then fires electrical impulses.

3. RESULTS AND DISCUSSIONS/ NOVELTY:

The medical devices in terms of eye prosthesis is classified under 136 categories under section 40. In India the medical devices are classified based on safety and performance.

Under the 2017 Rules, medical devices are said to be Specific devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals which are notified by the government from the time and again under the Drugs and Cosmetics Act,1940 ("D&C Act")[5]. The MDR outlines procedures for registration, manufacturing, import, labeling, and post-market surveillance. However, there is no current provision explicitly covering devices designed for extraterrestrial use. Any medical device is classified /based on purpose intended, target patients and risk involved in the usage (invasive/non-invasive). According to the method of placement the extra-terrestrial eyes aresurgicallyimplanted into retina to establish connection with brain making it to be Class 2B and class 3 medical devices in India. However, it is not yet classified and the guidelines for the classification are under process. There are following regulatory Challenges for these devices in India

Absence of Defined Categories: Devices designed for extraterrestrial use do not fit into any existing classification under MDR 2017.

Ambiguity in Risk Classification: It is unclear how risk assessment will be conducted for devices.

Validation and Testing Constraints: India lacks testing environments for devices designed for extraterrestrial use.

Dual-use Nature: Many devices designed for extraterrestrial use may have both civilian and defense applications, requiring cross-sectoral regulatory coordination.

Lack of Precedent and Guidelines: No formal guidance exists for assessing the safety and efficacy of such devices in India.

When we look on global practices and comparative Analysis we found that there is no specific global standard for such devices, organizations such as NASA and the European Space Agency (ESA) are investing in space medicine and human spaceflight health solutions. The U.S. FDA has begun exploratory discussions around space-related biomedical technologies. India can leverage these international developments to create a harmonized regulatory path.

There are following recommendations for Policy Development in India for devices designed for extraterrestrial use.

Introduce a New Regulatory Category: Propose amendments to MDR 2017 to introduce a category for "extraterrestrial devices."

Develop Specialized Testing Protocols: Establish simulation labs and space analog facilities in collaboration with ISRO and academic institutions.

Facilitate Public-Private Partnerships: Encourage joint R&D ventures among government, academia, and industry.

Align with International Standards: Engage with global regulatory bodies to ensure consistency in safety benchmarks.

Ethical Oversight Mechanism: Create dedicated bioethics boards for evaluating long-term impact and ethical implications.

4. SUMMARY AND CONCLUSION:

Today, the idea has become less the subject of scientific theories or hypothetical situation and more the pursuit of intense scientific research[6]. Advances within the realms of micro and macrofabrication, microelectronics, material science, wireless and spectral analytics technology and high-speed computer processing power hasempowered us for the development of electro neuroprosthetic device i.e Extraterrestrial eyes designed to assist individuals living with sensory loss and/or motor impairment. The basic premise underlying all electro neuroprosthetic approaches is that targeted and controlled delivery of electrical stimulation to nerves or muscles can potentially restore (to a certain degree) the physiological function of a damaged organ or limb (Marbach et al., 1982)[7]. It becomes mandatory for regulatory bodies to check quality; risk associated and eases of usage with the neuroprosthetic devices.

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