**Head Armor Pro Group – 510K Mock Draft**

**Indications for Use Statement (FDA Form 3881)**

* **Device Name**: Head Armor Pro Internal Helmet Padding System
* **Regulation Number**: 890.3050
* **Regulatory Classification**: Class II
* **Indications for Use**: Head Armor Pro is intended for youth athletes in high-impact contact sports, specifically designed to reduce concussion and head injury risks by improving helmet interior padding and adding real-time impact sensors to alert athletic staff of high-impact forces. This device is to be worn alongside other protective sports equipment such as helmets. It is non-invasive, non-sterile, and requires professional installation by sports organizations or healthcare providers.

**2. 510(k) Summary or 510(k) Statement**

* **Predicate Device**: Q-Collar (DEN200017)
* **Device Comparison**:
  + Both Head Armor Pro and the Q-Collar aim to protect against head injuries in athletes participating in contact sports. Head Armor Pro leverages auxetic foam padding technology within helmets to reduce impact forces, whereas the Q-Collar uses jugular compression to increase intracranial blood volume and reduce brain movement during head impacts.
  + Head Armor Pro incorporates an additional impact sensor feature that notifies coaches and trainers of high-impact events, offering an enhanced tool for proactive concussion management.
* **Substantial Equivalence Rationale**:
  + While Head Armor Pro utilizes a different mechanism than the Q-Collar, its intended use and safety profile are comparable. Both devices are non-invasive and provide enhanced head protection through unique mechanisms. The added sensor functionality in Head Armor Pro for real-time monitoring does not alter its primary intended use and serves as a supplementary feature to improve user safety.

**3. Device Description**

* **Overview**:
  + Head Armor Pro is an innovative internal padding system designed specifically for youth football helmets, featuring a unique auxetic foam structure that disperses impact forces to reduce concussion risk. The device includes a real-time impact sensor embedded in the padding, alerting coaches or trainers when forces exceed a preset threshold.
* **Components**:
  + **Auxetic Foam**: Constructed with a honeycomb-patterned hourglass design, the foam is made from 80A elastomer, offering superior impact dispersion properties. When compressed, the auxetic structure expands laterally, minimizing both linear and rotational forces.
  + **Impact Sensor**: The sensor detects forces and transmits alerts to connected mobile devices, providing real-time notifications to athletic staff for immediate concussion assessment.
  + **Material Composition**: Medical-grade, non-toxic elastomer foam, meeting ISO 10993 standards for biocompatibility, ensuring it is safe for contact with skin.
* **Dimensions and Compatibility**: The device is available in multiple sizes and is designed to fit universally within most standard youth football helmets, enhancing their internal padding without modifying the external structure.

**4. Predicate Device Comparison Table**

| **Attribute** | **Head Armor Pro** | **Q-Collar (Predicate Device)** | **Justification for Equivalence** |
| --- | --- | --- | --- |
| **Regulation Number** | 890.3050 | 890.3050 | Both are under the same regulation |
| **Classification** | Class II | Class II | Same classification requirement |
| **Intended Use** | Reduces head injury risk in youth athletes | Reduces brain injury risk in athletes | Both devices target reduction of head injury risks |
| **Mechanism of Action** | Auxetic foam padding for impact dispersion | Jugular compression to stabilize brain movement | Different mechanisms to achieve a similar protective aim |
| **Impact Monitoring** | Embedded sensor for real-time alerts | None | Provides additional monitoring for concussion risk |
| **Material Composition** | Medical-grade auxetic elastomer foam | Non-compressible, Biocompatible Material | Both meet biocompatibility requirements |
| **Special Controls Compliance** | Yes | Yes | Both meet all required special controls |

**5. Substantial Equivalence Discussion**

* **Functional Comparison**:
  + Head Armor Pro and the Q-Collar both function to reduce head injury risk during contact sports. Head Armor Pro provides this protection through an advanced auxetic foam design within the helmet, whereas the Q-Collar achieves similar effects through jugular compression.
* **Technological Differences**:
  + Head Armor Pro uses an impact sensor that triggers real-time alerts to inform coaches and trainers of high-impact events, a feature absent in the Q-Collar. This addition is intended to provide supplemental safety information and does not alter the fundamental function of injury risk reduction.
* **Safety and Biocompatibility**:
  + Both devices have passed ISO 10993 biocompatibility testing, ensuring materials are safe for skin contact. Additionally, both devices are compliant with special controls, including human factors testing, to confirm correct use, fit, and understanding of product limitations.
* **Conclusion**:
  + The Head Armor Pro is substantially equivalent to the Q-Collar, with added sensor functionality for real-time impact monitoring. The primary function remains comparable, and the device meets the same regulatory requirements and standards.

**6. Proposed Labeling**

* **Device Purpose**: Head Armor Pro is intended to reduce head injury risk for youth athletes in high-impact sports. It is designed to be worn inside helmets, complementing other protective sports equipment.
* **Usage Instructions**:
  + Step-by-step fitting instructions with diagrams for correct placement within the helmet. Guidelines for adjusting the padding to maximize coverage and comfort.
* **Sensor Setup**:
  + Instructions on pairing and activating the sensor with a mobile app, interpreting alerts, and responding to high-impact notifications.
* **Warnings and Precautions**:
  + Clear warnings that Head Armor Pro does not replace standard protective sports equipment.
  + Cautionary statements emphasizing that the device cannot eliminate head injury risks, and users should seek medical evaluation following any significant head impacts.
  + Specific warnings about avoiding excessive pressure on the neck, and to ensure correct fit to prevent discomfort or harm.

**7. Sterilization and Shelf Life**

* **Sterilization**: Head Armor Pro is a non-sterile device and should not undergo sterilization. Users are instructed to clean the device by wiping with a mild disinfectant to maintain hygiene.
* **Shelf Life**: Accelerated aging tests indicate that the device maintains optimal performance for up to five years under recommended storage conditions (dry and at room temperature). Users are provided with storage instructions to ensure the longevity of the auxetic foam and sensor components.

**8. Biocompatibility**

* **ISO 10993 Testing Compliance**: All skin-contacting materials have been tested under ISO 10993 standards, confirming that they do not cause cytotoxicity, irritation, or sensitization, ensuring the device’s safety for regular use in youth sports.
* **Detailed Test Results**:
  + **Cytotoxicity**: Confirmed non-toxic upon contact.
  + **Sensitization**: Passed sensitization testing with no allergic reactions noted.
  + **Irritation**: No irritation observed with prolonged contact, ensuring the device’s comfort and safety for users.

**9. Software**

* **Software Functionality**: The embedded sensor software continuously monitors impact forces and sends an alert to designated mobile devices when forces exceed a set threshold.
* **FDA Compliance with Device Software Standards**:
  + **Hazard Analysis**: Conducted to address any potential software inaccuracies or malfunctions.
  + **Traceability Matrix**: Ensures all design requirements are fulfilled, documenting verification of software functions.
  + **Validation and Verification**: Testing confirms reliable impact detection, accurate threshold alerts, and consistent connectivity.
  + **Level of Concern**: Rated as Moderate Level of Concern because it provides supplementary information for concussion risk management rather than a diagnostic output.

**10. Electromagnetic Compatibility and Electrical Safety**

* **EMC Compliance**: Verified to ensure that the sensor does not interfere with other electronic equipment, adhering to electromagnetic compatibility standards.
* **Electrical Safety**: Testing ensures that the sensor meets all necessary electrical safety requirements for safe usage and charging, reducing risks associated with accidental exposure or device malfunction.

**11. Performance Testing – Bench**

* **Linear Impact Absorption Tests**:
  + Conducted according to NOCSAE standards, simulating helmet impacts across multiple angles and intensities. Head Armor Pro demonstrated a 20% improvement in linear force absorption compared to traditional helmet padding.
* **Rotational Impact Tests**:
  + Using an instrumented headform, rotational impact testing verified Head Armor Pro’s capability to reduce rotational forces by approximately 25% relative to standard helmet padding materials.
* **Real-World Field Testing**:
  + Trials with youth athletes in simulated sports environments confirmed the device’s comfort, proper fit, and reliable performance of the impact sensor. Coaches reported that alerts allowed for rapid response in evaluating players after high-impact events.

**12. Risk Analysis and Mitigation Measures**

* **Identified Risks**:
  + **Incorrect Fit**: Mitigated by comprehensive instructions for sizing

**HeadSafe Impact Sensor – 510k Mock Draft**

**Indications for Use Statement (FDA Form 3881)**

* Device Name: Nurocheck Impact Sensor for Concussions
* Regulation Number: 882.1450
* Regulatory Classification: Class II
* Indications for Use: The Nurocheck Impact Sensor is intended for use in sports settings to monitor impact forces experienced by athletes wearing football helmets. This device provides real-time impact data, assisting athletic staff in managing concussion risks by identifying potentially injurious impacts that may require further medical evaluation. The device is designed for non-invasive integration within football helmets.

**2. 510(k) Summary or 510(k) Statement**

* Predicate Device: Nurochek-II System (K231914)
* Device Comparison:
  + Both the Nurocheck Impact Sensor and the Nurochek-II System serve as monitoring tools to assist in concussion risk management.
  + The Nurocheck Impact Sensor is used in a sports setting to alert staff of significant head impacts, while the Nurochek-II System aids healthcare professionals in diagnosing mild traumatic brain injuries through EEG data analysis.
* Substantial Equivalence Rationale:
  + The primary function of both devices is to detect and monitor head-related trauma, helping to manage concussion risks. Although the Nurocheck Impact Sensor is embedded in sports helmets, whereas the Nurochek-II System is for clinical EEG monitoring, both share similar goals of providing objective data related to head impacts.

**3. Device Description**

* Overview: The Nurocheck Impact Sensor is an embedded impact sensor designed for installation within football helmets. It detects high-impact events, sending real-time alerts to athletic staff when forces exceed a specific threshold, thereby aiding in concussion risk assessment.
* Components:
  + Impact Sensor: Monitors linear and rotational forces.
  + Mobile Connectivity Module: Communicates impact data to a mobile app for remote monitoring.
  + Power Source: Rechargeable battery with an 8-hour life span per charge.
  + Material Composition: Encased in a biocompatible, shock-resistant casing compliant with ISO 10993 standards for safety.

**4. Predicate Device Comparison Table**

|  |  |  |  |
| --- | --- | --- | --- |
| **Attribute** | **Nurocheck Impact Sensor** | **Nurochek-II System (Predicate Device)** | **Justification for Equivalence** |
| Regulation Number | 882.1450 | 882.1450 | Both devices regulated under the same classification |
| Classification | Class II | Class II | Identical regulatory classification |
| Intended Use | Monitoring impacts for athletes | Brain injury adjunctive assessment | Both monitor head impacts for potential brain injury |
| Application Environment | Sports (football helmet) | Clinical (healthcare facility) | Different setting, but both monitor head trauma risks |
| Data Collection | Real-time impact detection | EEG data collection and analysis | Both collect and analyze data for brain injury management |
| Battery Life | 8 hours | Rechargeable 3.7V lithium-ion battery | Comparable battery setup |
| Data Transmission | Bluetooth-enabled to mobile app | Mobile app communication | Both utilize mobile devices for data monitoring |

**5. Substantial Equivalence Discussion**

* **Functional Comparison: Both the Nurocheck Impact Sensor and the Nurochek-II System are designed to monitor head-related trauma and provide data to assist in assessing concussion risk. While Nurocheck Impact Sensor functions specifically in sports environments, the purpose of providing real-time data related to potential head injury is aligned with the clinical goals of the Nurochek-II System.**
* **Technological Differences:** The Nurocheck Impact Sensor is embedded in sports helmets for impact monitoring, while the Nurochek-II System is a wearable EEG monitor. Despite these differences, both aim to support concussion risk management, whether in clinical or sports settings.
* **Safety and Biocompatibility:** Both devices comply with ISO 10993 for biocompatibility, ensuring safe use in contact with the skin. The Nurocheck Impact Sensor’s material selection is consistent with the Nurochek-II System’s standards for safety.

**6. Proposed Labeling**

* Device Purpose: The Nurocheck Impact Sensor is a monitoring device intended to detect high-impact events within football helmets, supporting concussion risk assessment for athletes.
* Usage Instructions Step-by-step installation instructions for embedding the sensor in helmets, and pairing instructions with the mobile app for real-time monitoring.
* Warnings and Precautions: Advises that the Nurocheck Impact Sensor is supplementary and does not replace standard concussion protocols. Recommends seeking medical evaluation following any alert or high-impact notification.

**7. Sterilization and Shelf Life**

* Sterilization: The Nurocheck Impact Sensor is a non-sterile device and does not require sterilization before use. To maintain hygiene, users are advised to clean the outer surface of the sensor with a mild disinfectant wipe between uses. The sensor casing is sealed to prevent contamination or damage to internal components.
* Shelf Life: Based on accelerated aging tests, the estimated shelf life of the Nurocheck Impact Sensor is 3 years under recommended storage conditions (ambient room temperature and low humidity). Packaging includes expiration labeling to inform users of the sensor's usable lifespan.

**8. Biocompatibility**

The materials used in the Nurocheck Impact Sensor have been tested and verified under ISO 10993 standards for biocompatibility. These tests ensure that the device is safe for skin contact and that it poses no risk of irritation, toxicity, or sensitization for the wearer.

* Cytotoxicity: The device casing was tested for cytotoxicity and confirmed as non-toxic.
* Sensitization: The materials used in contact with the skin showed no allergic or sensitizing reactions.
* Irritation: The sensor passed prolonged contact tests without causing any irritation, making it safe for continuous skin contact over extended periods.

**9. Software**

Software Functionality: The Nurocheck Impact Sensor software continuously monitors and analyzes impact data, transmitting this data to a paired mobile device through a secure Bluetooth connection. The app processes data to detect impact events that exceed the preset thresholds and sends real-time notifications to designated staff, such as coaches or athletic trainers.

Compliance with FDA Software Standards:

* Hazard Analysis: A comprehensive hazard analysis was conducted to identify potential risks associated with software operation and connectivity. Mitigations were implemented for high-risk items.
* Traceability Matrix: A traceability matrix has been developed to confirm all software requirements align with intended use specifications.
* Validation and Verification: Extensive validation and verification testing confirm that the software reliably detects and transmits impact data, with an accuracy of ±5% for impacts over 50g.

Level of Concern: The Nurocheck Impact Sensor software is classified as Moderate Level of Concern since it serves as an impact-monitoring tool that informs concussion management but is not diagnostic.

**10. Electromagnetic Compatibility (EMC) and Electrical Safety**

* Electromagnetic Compatibility (EMC): The Nurocheck Impact Sensor meets all relevant EMC standards to ensure that it does not interfere with other electronic equipment. Testing was conducted to confirm compliance with FCC Part 15 standards, ensuring reliable Bluetooth transmission without causing interference.
* Electrical Safety: The device has been tested for electrical safety according to **IEC 60601-1** standards. The rechargeable lithium-ion battery and power management system meet safety requirements to prevent overheating or electrical hazards during athletic use.

**11. Performance Testing – Bench and Field**

* Bench Testing: A series of bench tests were conducted to validate the impact sensor's durability, accuracy, and response time under controlled conditions.
  + Impact Attenuation: The helmet with the embedded sensor was tested according to ASTM F1447 to confirm its ability to absorb impact energy effectively.
  + Rotational Force Resistance: Rotational impact tests were performed under ISO 20623 standards to evaluate the sensor’s performance under twisting and rotational forces.
  + Padding Durability: ASTM D3574 testing confirmed that the embedded sensor and padding maintain integrity and performance under repeated high-impact conditions.
* Field Testing: Field tests were conducted with high school football athletes during practice to simulate real-world conditions. Key outcomes of field testing included:
  + Real-Time Responsiveness: The sensor accurately detected and transmitted data within 1 second of impact.
  + Comfort and Fit: Feedback from athletes confirmed that the embedded sensor did not disrupt the fit or comfort of the helmet.
  + Durability in Varied Conditions: Performance was consistent across varying weather conditions, with no drop in accuracy.

**12. Risk Analysis and Mitigation Measures**

* Identified Risks and Mitigations:
  + Incorrect Fit or Installation: To address the potential for improper installation, the sensor kit includes detailed step-by-step installation instructions with visuals. Additionally, instructional videos are accessible via the mobile app.
  + Device Malfunction: Thorough software and hardware testing minimize the likelihood of device malfunction. All components undergo stress testing to ensure durability.
  + Data Transmission Issues: To mitigate connectivity loss, the sensor’s Bluetooth module includes error-detection algorithms, and the app provides alerts if connection strength is weak.
* Battery Safety: The sensor uses a rechargeable lithium-ion battery with built-in overheating protection. It passed IEC 62133 testing to ensure safe operation under high-impact and temperature-variable conditions.