510(k) Coalition - Short Comment Regarding a Proposed Exemption
Under 17 U.S.C. 1201; Docket No. 2014-07
Proposed Class 25: Software – Security Research

Item 1. Commenter Information

The 510(k) Coalition is a group of medical device companies dedicated to patient health and to the promotion of efficient, rational regulation of medical devices. The Coalition appreciates the opportunity to provide comments on the proposed exemption for software security research (the "Proposed Exemption"). The 510(k) Coalition; Ralph Hall, Partner, Leavitt Partners; 1050 K Street, NW, Suite 310; Washington, DC 20001-4448; Ralph.Hall@leavittpartners.com.

Item 2. Proposed Class Addressed

These comments concern Proposed Class 25: Software – Security Research.

Item 3. Statement Regarding Proposed Exemption

The Coalition supports the joint comments on this Proposed Exemption previously submitted by the Advanced Medical Technology Association ("AdvaMed") and the Medical Imaging and Technology Alliance ("MITA") (the "AdvaMed/MITA Comments"). A summary of the main points stated in the AdvaMed/MITA Comments is included below. For the following reasons and the reasons listed in the AdvaMed/MITA Comments, we respectfully request that the Copyright Office oppose the inclusion of medical devices in an exemption under Proposed Class 25.

- The Proposed Exemption would permit the unauthorized circumvention of technological protection measures ("TPMs") in medical devices, which can harm patients, compromise patient privacy, and place valuable intellectual property at risk. The risk of damage, malfunction, degradation, and/or data corruption and the associated potential harm to patient safety outweighs the benefit offered by unauthorized security research. The Proposed Exemption may also negatively impact innovation, health care costs, and supply chain integrity.
- Robust medical device cybersecurity research is already ongoing under a framework that includes the necessary protections for patient privacy, patient safety, and intellectual property.
- The Proposed Exemption, as applied to medical devices, will do more damage than good, because it eliminates the proper and controlled frameworks in place that afford appropriate research and testing of medical technologies without compromising patients and intellectual property.
- The Proposed Exemption would also place patients' personal health information at risk and would contravene federal and state privacy laws concerning the storage and transmission of protected health information ("PHI")—such as requirements for certain levels of encryption, as well as the development of policies and measures to ensure the safekeeping of PHI.
- The Proposed Exemption may directly conflict with FDA regulations and creates jurisdictional questions. As the FDA is the federal agency responsible for assuring the safety, efficacy and security of medical devices, we respectfully request that the Copyright Office oppose the Proposed Exemption and defer to FDA management of the framework to further research the safety, efficacy and security of medical devices.