PrediGen: A Tool for Tracing the Genealogy of Medical Devices

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In the United States, medical devices are regulated and subject to review by the Food and Drug Administration (“FDA”) before they can be marketed. Novel medical devices have to undergo a premarket authorization (PMA) process before they can proceed to market, and this process can be fairly cumbersome, expensive, and time-consuming. An alternate faster and economic pathway to going to market is the 510(k) pathway. In this approach, if the medical device manufacturer can show that their device is substantially equivalent in safety and effectiveness to a pre-existing FDA-approved marketed device (or “predicates”), they can go to market with their device. However, medical devices cleared through the less rigorous 510(k) pathway comprise more than two-thirds of the products that are recalled by the FDA because they could seriously harm patients or result in death. Since 510(k) approved devices are approved through this predicate approach, it can very quickly be difficult to unravel the logic and justification of how a particular medical device’s equivalence was established. From a patient’s perspective, this minimizes transparency in the process. There is a pressing need for tracing predicate genealogy and its temporal evolution, in order to benefit consumers. Analysis of recalls as predicate lines evolve is crucial to ensuring consumer safety; understanding the recalls landscape can help protect device manufacturers when they are taking their medical devices through the regulatory approval process for marketing in the US. The goal of this project is to provide a more comprehensive view of the evolution of the U.S. FDA 510 (k) predicate system, focusing on approvals in recent years.

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