Making the Invisible Visible

Analyzing the 510(k) Device Dependencies

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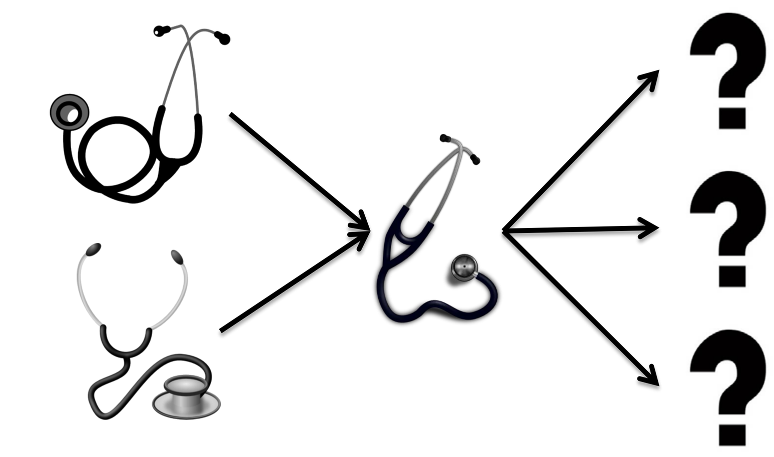
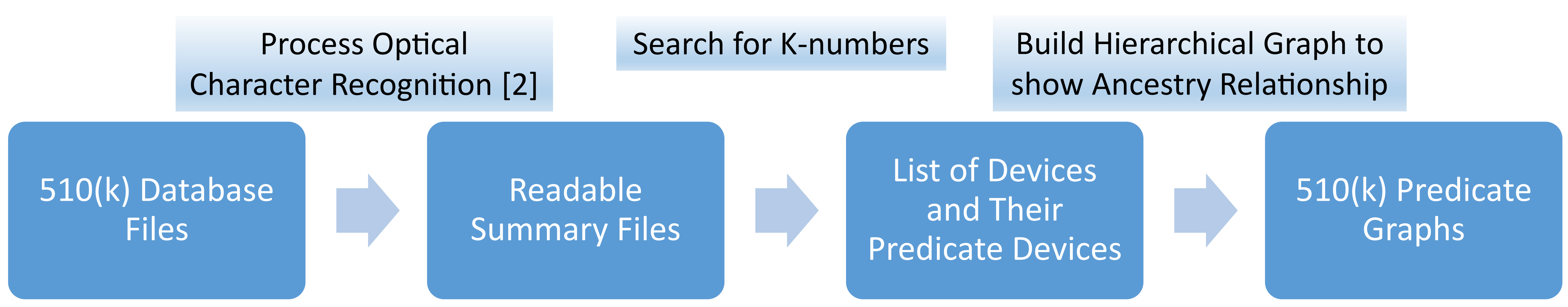
Problem: How do we find dependents?

The FDA's 510(K) premarket notification [1] allows manufacturers to demonstrate the safety and efficacy of a medical device by comparing them to previous "predicate" devices. Each submission for a particular device contains a predicate list. However, given a predicate device it is harder to get a list of all the devices that depend on it. The lack of a global dependency graph may hide critical information about the inheritance relationship between devices.



Our Solution: Building the 510(k) Predicate Graphs

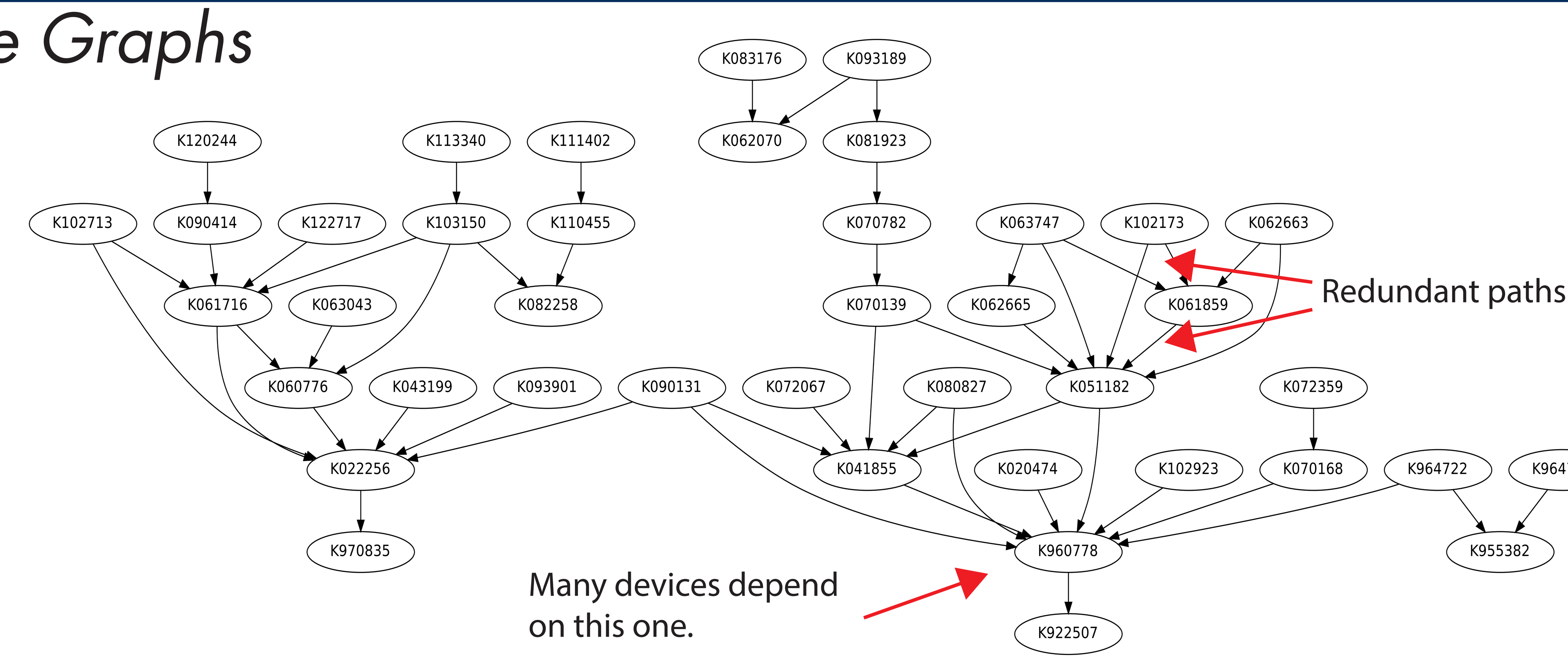


The K-number: The FDA tracks each medical device in the 510(k) process through a unique "K-number".

From the 510(k) submissions, we collected the list of predicates for each devices to build the relationship graphs. Most of the legacy forms are scanned copies, and the Optical Character Recognition step may introduce errors. Using a simple random sample of 100 devices from our corpus of over 50,000 devices and manually inspecting the dependencies, estimated the false negative error rate to 10% and the false positive rate to 3%.

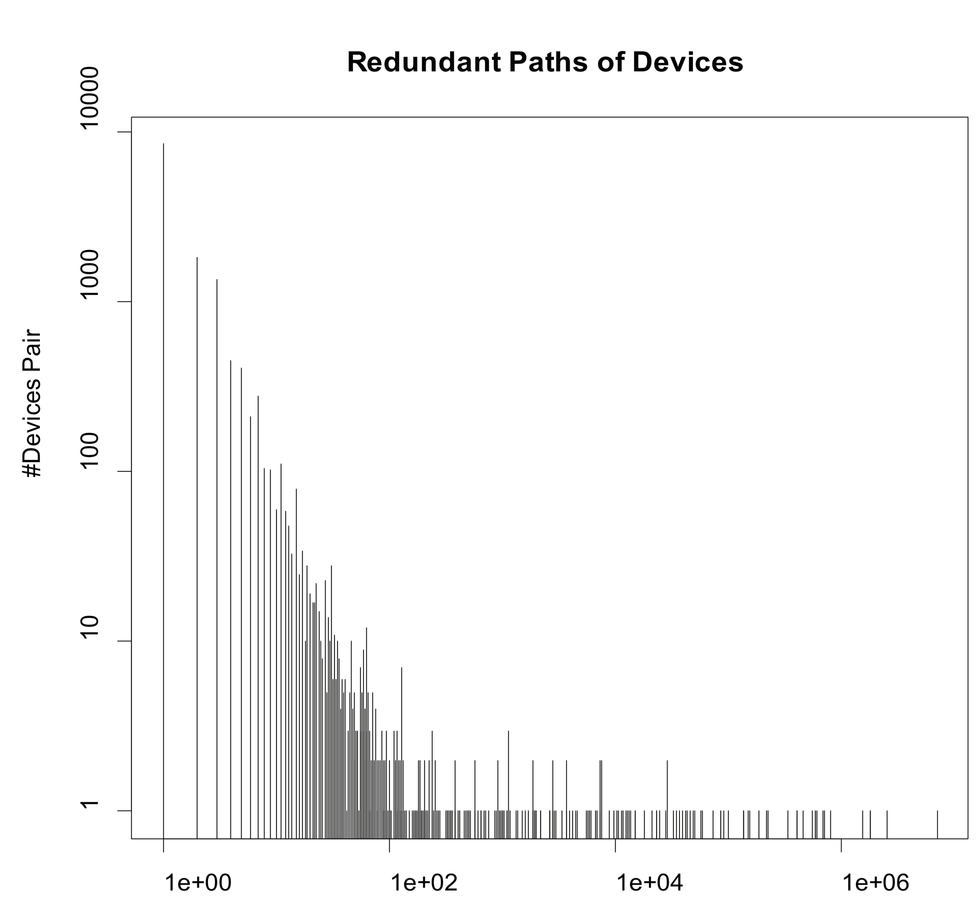
An Example of the 510(k) Predicate Graphs

This hierarchical graph shows the equivalence relationship of a kind of face masks. Each node represents a medical device through its K-number. The edges going out from a node point to its predicate device(s). Likewise, the edges pointing into the node trace the dependents of the device.



Redundant Paths

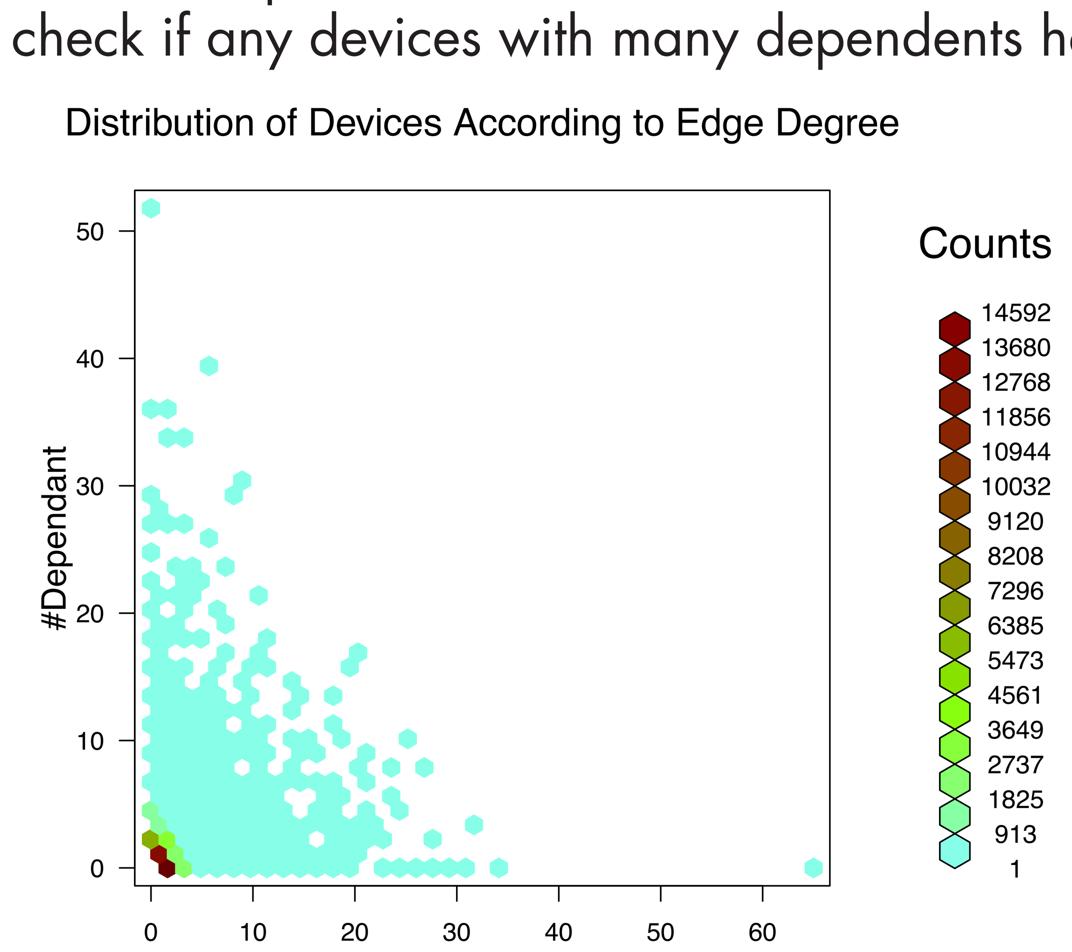
We expected a tree structure, but we observed that the 510(k) graphs contain many redundant paths where both of the device and its predicate share the same ancestor.



The distribution of redundant paths between pairs of devices in the 510(k) predicate graph.

Number of Ancestors and Dependants

In the 510(k) predicate graphs, edges from and to a node connect its predicates and dependents. By counting the edges, we can get the number of predicates of each device and of its dependents. We can also check if any devices with many dependents have adverse event records.



The distribution of 510(k) devices according to the number of ancestors and dependents.

References

[1] U.S. Food and Drug Administration. Premarket notification (510k). http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/default.htm, Visited June 2013.

[2] Smith, Ray. Tesseract-ocr (Version 3.02). Available at http://code.google.com/p/tesseract-ocr/.

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