Medical Device Reporting (MDR) Rate in 510(k) Cleared Devices Using Multiple Predicates

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Center for Devices and Radiological Health
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SUMMARY

According to data analysis from 18,332 510(k) submissions submitted between Jan. 1, 2005 and Dec. 31, 2009, the Center for Devices and Radiological Health (CDRH) determined that the use of five or more predicate devices in 510(k) submission does not appear to be an independent risk factor for poor device performance or a high number of MDRs.

In addition, this analysis found that CDRH data sources have significant limitations that preclude reliable assessment of MDR rate associated with 510(k) submissions and an earlier reported association of increased MDR rate to devices with more than five predicates cited appears due, at least in part, to three devices associated with a high number of MDRs.

CDRH conducted this more comprehensive data analysis after an earlier look suggested that 510(k) submissions that cite more than five predicate devices shows an apparent increased MDR rate. CDRH first identified an apparent association of an increased MDR rate with more than five predicates in its August 510(k) Working Group Preliminary Report and Recommendations.

FINDINGS

The August 2010 510(k) Working Group Preliminary Report and Recommendations cited results of a preliminary analysis of 18,332 510(k) submissions submitted between Jan. 1, 2005 and Dec. 31, 2009. The preliminary analysis (Table 1) showed an apparent association between citing more than five predicates and a greater mean MDR rate.

Table 1. Mean MDR Rate per 510(k) by Number of Predicates Cited

Number of Predicates Cited	All MDRs	Death	Injury	Malfunction
1	1.75	0.02	0.74	0.93
2-5	1.78	0.02	0.79	0.93
>5	5.35	0.05	1.73	3.38
Unknown	0.43	0.01	0.30	0.13
All	2.10	0.02	0.85	1.16

In an effort to explore this potential association further, CDRH performed the following additional analysis of the same data set:

- Review of the methodology used for assigning the number of predicates to a 510(k) submission;
- Detailed review of selected 510(k) submissions associated with a high number of predicates and MDRs to determine the actual number of cited predicates;
- Assessment of the MDR database to determine the ability to link MDRs to individual 510(k) submissions based on 510(k) number and brand name;
- Analysis of MDRs by predicate to identify product areas most affected by the use of more than five predicates.

From the more detailed analysis, we found that:

- Existing CDRH IT systems cannot reliably capture the number of predicates associated with individual 510(k) submissions;
- The overall mean MDR rate was greatly influenced by three devices that had high numbers of MDRs during the analysis timeframe;
- The majority of MDRs lack the information needed to definitively identify the associated 510(k) product.

BACKGROUND

There are several reasons for submitters to cite more than one predicate in a 510(k) submission, and submissions may list more than one "potential predicate."

One reason is that devices bundled into a single submission may have a unique predicate for each device. CDRH determines substantial equivalence for each individual device in the bundled submission but the submission itself will contain more than one predicate.

Another reason a submitter may cite more than one predicate is because the new device combines the functions of more than one predicate device. In this case, the submitter may seek to compare its device to more than one predicate and demonstrate that each functional component of the new device is substantially equivalent to its corresponding predicate. For example, a multi-parameter monitoring system could combine the functions of two devices, such as an electrocardiograph and a blood pressure monitor, into a single device that performs the intended functions of both devices. This practice is known as the use of "multiple predicates."

CONCLUSIONS

Further evaluation by CDRH of an apparent association of an increased MDR rate with more than five predicates showed that:

- The available data sources have significant limitations that preclude reliable assessment of MDR rate associated with 510(k) submissions.
- The reported association of increased MDR rate to devices with more than five predicates cited appears due, at least in part, to three devices with high MDR rates during the analysis timeframe.

Based on available data and analyses, we conclude that having five or more predicates does not appear to be an independent risk factor for poor device performance or a high number of MDRs.