

# MEDICAL DEVICE & DIAGNOSTIC INDUSTRY

## Third-Party 510(k) Reviews Gaining Popularity

According to FDA statistics, 510(k) submissions are receiving market clearance faster when third parties review them. It appears that device companies are taking notice, as the practice has spiked in popularity recently.

The FY 2002 annual report of CDRH's Office of Device Evaluation (ODE) notes that the agency made decisions on 132 510(k) submissions received by third parties during the year, up from 99 in FY 2001. That number should be easily surpassed in FY 2003, as the ODE had made 120 decisions on third-party-reviewed submissions as of July 31, 2003.

The report attributes the increase to an expanded pilot program that went into effect in 2001. Originally, third parties could review submissions for Class II devices only if the agency had written a specific guidance for that device. The expanded pilot program al-

lows third-party review of about 460 Class II devices without a specific guidance.

Those who are using the program are seeing significant reductions in review time: 510(k) submissions reviewed by third parties in FY 2002 received marketing clearance about 30% faster than comparable 510(k)s reviewed entirely by FDA, the report states. The average time between a third-party reviewer receiving a submission and ODE making a substantial equivalence decision was 70 days for non-pilot-program devices and 105 days for pilot-program devices. The comparable figures are 105 days for nonpilot devices and 147 days for pilot devices that FDA reviewed itself.

Interest in third-party use is growing stronger, and there may be reasons beyond the pilot-program expansion. Most months between July 2002 and April 2003, 3–4% of the 510(k) submissions FDA decided on were reviewed by third parties. But those numbers are jumping significantly. In May 2003, third-party-reviewed applications accounted for 6.0% of the total; in June 2003, 6.4%; and in July 2003, 7.0%.

One theory for the spike: user fees. "Before the Medical Device User Fee and Modernization Act of 2002 (MDUFMA), third-party reviewers were charging for doing 510(k)s, and FDA couldn't," said Harvey Rudolph, PhD. Rudolph is global program manager for medical devices at Underwriters Laboratories Inc. (UL; Northbrook, IL), one of 14 bodies (accredited persons) authorized to be a third-party reviewer. "Then FDA started charging about \$2200, which is considerably less than what we would charge, but it narrowed the gap. Now, FDA is raising the fee to

\$3400, and our prices are not going up that much, so the differential is even smaller. I expect to see a big jump after October in addition to what we're seeing now." Third-party review submissions are exempt from the FDA user fees.

The third-party reviewers are positioning themselves for this expected surge in interest. Two firms, Medtech Review LLC (Minnetonka, MN) and Regulatory Technology Services LLC (Buffalo, MN), entered into the accredited persons program this year, the first new arrivals in several years.

For its part, UL, which says it is the most used of the 14 reviewers with 25% market share, is hoping to spur more interest in the program with a two-week money-back service delivery guarantee for devices that have a specific guidance document. UL says that if it does not complete the review in 10 business days after receiving all the required information, the manufacturer will pay nothing.

"We found that historically we had been able to turn these around in 10 days or less, and were saying so informally to prospective customers," said Rudolph. "We hope that it spurs interest in the third-party program and brings manufacturers' attention to it. A lot of them still do not know that third

MONTH OF DECISION DATE	% REVIEWED BY THIRD PARTIES
July 2002	3.4%
Aug. 2002	3.0%
Sept. 2002	4.6%
Oct. 2002	2.1%
Nov. 2002	3.5%
Dec. 2002	2.8%
Jan. 2003	3.7%
Feb. 2003	3.5%
March 2003	3.0%
Apr. 2003	3.9%
May 2003	6.0%
June 2003	6.4%
July 2003	7.0%

Source: 510(k) database at [www.fda.gov](http://www.fda.gov)

Table I. Percentage of 510(k) submissions reviewed by third parties.

FISCAL YEAR	SUBMISSION DECISIONS
FY 2003*	120
FY 2002	132
FY 2001	99

\* through July 31, 2003

Sources: 510(k) database at [www.fda.gov](http://www.fda.gov), FY 2002 ODE Annual Report

Table II. Third-party submissions decided by FDA, between FY 2001 and FY 2003.

parties can review some 510(k)s.”

He said the 10-day commitment can be honored because UL reviewers are not overwhelmed with too many projects, and can start reviewing a submission as soon as it is received.

For devices in the extended pilot program, the 10-day guarantee will not apply, but UL will negotiate specific timetables by which completion will

be guaranteed.

Whether because of faster review times, user fees, or UL's guarantee, even greater use of the third-party program is expected in the near future. UL, in fact, is training new reviewers in anticipation of a boost in interest.

If that happens, it means industry has come to realize the benefits of the program that Rudolph, a former FDA

official who helped establish the accredited persons program, has always known.

“FDA saves its own resources to deal with more difficult reviews. Manufacturers get their products on the market quicker. And users get the products they need quicker,” he said. “It's the American way.”

—Erik Swain

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## Working for a safer world

As global program manager for medical devices for Underwriters Laboratories, Dr. Harvey Rudolph is involved with developing a global regulatory conformity assessment program as well as a new regulatory services portfolio. Prior to joining UL, he was with the US Food and Drug Administration for 25 years, serving in a wide variety of regulatory roles, including the establishment of the accredited persons program for 510(k) review, the recognition of consensus standards for satisfying regulatory requirements, and the evolution of the FDA's software policy.

He has served on the Joint Working Group of the International Organization for Standardization (ISO) and International Electrotechnical Commission (IEC) for Risk Management of

Medical Devices since its inception and co-chairs the US Technical Advisory Group. Dr. Rudolph has published numerous technical reports and articles in various journals and has delivered more than 100 presentations at professional and technical meetings, as well as seminars at various academic and nonacademic institutions.

He is a recipient of a number of Public Health Service Medals for exemplary career service in the Medical Device and Radiological Health programs, outstanding leadership in managing a program to address high priority medical device issues, and for outstanding contributions in education, product approval and enforcement. Dr. Rudolph earned his doctorate in nuclear physics at the State University of New York.



Harvey Rudolph of UL cites FDA user fees as contributing to increased interest in thirdparty review.