



MAY 31 2000

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In Re: Patent Term Extension
Application for
U.S. Patent No. 4,343,049

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,343,049, which claims the medical device Monostrut™ Cardiac Valve Prosthesis, is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be two years.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Commissioner will issue a certificate of extension, under seal, for a period of two years.

The period of extension has been calculated using the FDA determination of the length of the regulatory review period published in the Federal Register of May 19, 1999 (64 Fed. Reg. 27273). Under 35 U.S.C. § 156(c):

$$\begin{aligned} \text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (1,729 - 88) + 3,891 \\ &= 4,712 \text{ days} \end{aligned}$$

Since the regulatory review period began May 14, 1982, before the patent issued (August 10, 1982), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From May 14, 1982 to August 10, 1982 is 88 days; this period is subtracted from the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period.) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

The two year limitation of 35 U.S.C. § 156(g)(6)(C) applies in the present situation because the patent was issued and an action described in 35 U.S.C. § 156(g)(6)(B) was taken before the date of enactment of 35 U.S.C. § 156. Since the period of extension calculated under 35 U.S.C. § 156(c) for the patent cannot exceed two years under 35 U.S.C. § 156(g)(6)(C), the period of extension will be for two years.

The 14 year limitation of 35 U.S.C. § 156(c)(3) does not operate to further reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.	4,343,049
Granted	August 10, 1982

