



## STANDARD OF REVIEW

[3] The Appellants acknowledge that decisions on certification motions are generally owed deference on appeal but submit that the standard of review here is correctness, because they say the motion judge made “fundamental legal errors in principle such that any deference is displaced”.

[4] On appeals from decisions of a motion judge of the Superior Court, issues of pure law will be reviewed on a standard of correctness. However, deference is due to other types of decisions. The standard applicable to reviewing questions of fact was discussed by Barnes J. in *Alliance Door Products Canada Inc. v. 2341321 Ontario Inc.*, 2018 ONSC 6703 (CanLII), at para. 13:

An appeal court is bound to show great deference to findings of fact made by the lower court. The appeal court may allow an appeal based on a factual finding only where the lower court has made a “palpable and overriding error”. *Housen v. Nikolaisen*, 2002 SCC 33 (CanLII), [2002] 2 S.C.R. 235 at para. 10 (S.C.C.). Thus, an appeal court cannot interfere simply because it takes a different view of the evidence than the trial judge. Where a finding of fact by the trial judge is one, which from the evidence is open for the trial judge to make, the finding is entitled to deference unless it constitutes a palpable and overriding error.

[5] Questions of mixed fact and law are also reviewed on the deferential “palpable and overriding error” standard unless they present extricable questions of law that can be reviewed for correctness: *Housen* at paras. 27 and 28.

[6] Where a judge exercises his or her judgment to resolve a question for which the law provides him or her with discretion, the standard of review is also deferential. An appellate court will intervene in a trial judge's exercise of discretion only if the trial judge misdirects himself or herself or if the decision is so clearly wrong as to amount to an injustice: *Elsom v. Elsom*, 1989 CanLII 100 (SCC), [1989] 1 S.C.R. 1367, or gave no or insufficient weight to relevant considerations: *Friends of the Oldman River Society v. Canada (Minister of Transport)*, 1992 CanLII 110 (SCC), [1992] 1 S.C.R. 3, at pp. 76-77.

This standard of review exists in class actions proceedings because appellate courts recognize the special expertise of class action judges and have held that substantial deference is owed on certification decisions. This deference does not extend to “errors in principle which are directly relevant to the conclusion reached”: *AIC Limited v. Fischer*, 2013 SCC 69 (CanLII), [2013] 3 S.C.R. 949, at para. 65; and *Cassano*, at para. 23.

## FACTS

[7] The facts are set out in detail in the motion judge’s decision. I set out here only a brief synopsis.

[8] The Respondents are a group of related corporations that manufacture and distribute medical devices. At issue in this litigation is a line of filters which are implanted into the inferior vena cava (“IVC”), designed to trap blood clots formed in the legs (deep vein thromboses), and prevent them from travelling to the heart or lungs and causing life-threatening pulmonary embolisms. These filters are designed to be used in patients for whom blood thinners are ineffective or contraindicated. Some of Cook’s IVC filters are designed to be permanent and others retrievable. This case involves three models that are designed to be “optionally retrievable.” As of January 2018, approximately 23,000 Cook retrievable IVC filters had been sold in Canada.

## THE PROPOSED CLASS ACTION

[9] This proposed class action alleges (i) defective design and (ii) a breach of Cook's duty to warn learned intermediaries (in this case, the doctors who recommended or prescribed the IVC filter) of the dangers of using the IVC filters. As is often the case in class proceedings, through amendments to the statement of claim, the focus of the plaintiffs' claim has changed throughout the certification process.

### 1. Defective Design

[10] The original Statement of Claim claimed that IVC filters were not effective for their intended purpose of catching blood clots. The design features of the Cook IVC filters that allegedly made them retrievable also made them unable to withstand the constant movement and changes in pressure in the inferior vena cava. That caused the IVC filter to be increasingly prone to malfunctions and injuries as the amount of time the device is in place increases.

[11] On December 13, 2016, a Fresh as Amended Statement of Claim was delivered. With respect to negligent design and manufacture, it said, simply:

The failure of Defendants' IVC Filters is attributable, in part, to the fact that all of the Defendants' IVC Filters suffer from a common design defect resulting in the inability to withstand the normal anatomical and physiological loading cycles exerted *in vivo*.

[12] At the hearing of the certification motion before the motion judge, the focus of the plaintiffs' claim changed again. Plaintiffs' counsel submitted that the defect that caused the IVC filters to fail was not one factor, but a 'matrix of factors' including the filter's conical shape, the choice of a cobalt-chromium alloy for the filter, and the anchoring mechanism.

[13] At the hearing before this Court, the Appellants provided a proposed draft Second Fresh as Amended Consolidated Statement of Claim, which for current purposes, included sub-paragraphs 39 a to d, which detailed certain defects. The amended paragraph 39 reads:

- 39 The failure of Defendant's IVC Filters is attributable, in part, to the fact that all of the Defendants' IVC Filters suffer from a common design defects, including the Conichrome material, conical shape, and primary anchoring struts, resulting in instability within the inferior vena cava and the inability to withstand the normal anatomical and physiological loading cycles exerted *in vivo*.
- 39a. The Conichrome material used by the Defendants was a defective design choice. The properties of the Conichrome (also known as Elgiloy) material were not properly considered, including the high elastic modulus (high stiffness). A more compliant material should have been used to, *inter alia*, reduce: the stiffness of the primary anchoring struts, the forces applied by the filter feet to the vena cava wall, the strain energy stored in the filter, and the alternating stresses experienced by the filters. As a result of this defect, Cook IVC Filters are prone to tilt, perforate the inferior vena cava, and fatigue fracture.
- 39b. Further, the conical shape used by the Defendants was a defective design choice. The conical shape design was not properly considered, including the primary anchoring struts spreading apart and the strain energy being reduced, as well as the interaction of the filter with the wall of the inferior vena cava. As a result of this defect, Cook IVC Filters are more likely to tilt, fracture, and perforate the inferior vena cava.

- 39c. Further, the primary anchoring struts used by the Defendants were a defective design choice. The design of the primary anchoring struts was not properly considered, including reducing the diameter to reduce the stiffness to, *inter alia*, lower the forces applied to the inferior vena cava wall and reduce the likelihood of tilt, perforation and fracture.
- 39d. These design defects (“the Defects”) are common to each of the Cook IVC Filters at issue. The Defects make Cook IVC Filter products more dangerous to use than they would have been had other and safer design choices been made for the Conichrome material, conical shape, and/or primary anchoring struts. The Plaintiffs allege that Cook made particular design choices that were careless when other safer choices, including for material, shape, and primary anchoring strut design, could have been made, and other alternatives, including permanent filters and/or other retrievable filters with different material, shape, and/or primary strut design, were safer and available for us, such as *inter alia*, the Cook Bird’s Nest filter.

## **2. The Failure to Warn**

[14] The issue of Cook’s alleged breach of its duty to warn intermediaries of the dangers of using the IVC filters also changed during the course of the litigation.

[15] The Appellants argue that the warning in the products’ Information for Use documents (IFU) did not adequately warn of the risks of use, including:

- device migration (where the filter moves within the inferior vena cava);
- perforation (where the struts that hold the filter in place perforate the wall of the inferior vena cava);
- fracture (where pieces of the filter break off, travel through the blood stream and cause damage elsewhere in the body);
- embolization (where the whole filter or parts of it travel to the heart or lungs); and
- inability to retrieve the filter.

[16] These various risks may cause hemorrhage, severe and persistent pain and cardiac issues, which in turn, may (i) require further surgeries or long-term anticoagulation therapy with its attendant complications, or (ii) cause death.

### **THE DECISION UNDER APPEAL**

[17] The motion judge held that there was an identifiable class, that a class proceeding would be preferable had all other requirements been met, and that there were representative Plaintiffs. He held, however, that the pleading with respect to negligent design did not disclose a reasonable cause of action (although the pleading with respect to duty to warn did), and that the Appellants had not satisfied their onus of showing that there were common issues of either negligent design or duty to warn.

## ISSUES ON APPEAL

[18] The Appellants submit that the motion judge:

- a) erred in applying a two-part, rather than a one-part test with respect to commonality;
- b) applied the wrong standard in assessing the duty to warn claim;
- c) improperly weighed expert evidence;
- d) applied the wrong approach to the cause of action for design negligence;
- e) erred in finding that there was no claim against certain Defendants; and
- f) erred in not adjourning the certification motion to permit the Appellants to amend the Statement of Claim and/or produce additional evidence.

## RESULT

[19] For the reasons that follow, I would allow the appeal with respect to the common issue of the alleged deficiencies in the duty to warn and certify the class with respect to common questions 5, 6, and 9 to 12 of the proposed common issues set out at paragraph 167 of the motion judge's decision. I would dismiss the balance of the appeal.

## ANALYSIS

### 1. No Properly Pled Cause of Action re Defective Design - Section 5(1)a:

[20] I agree with the motion judge's analysis and conclusion that in the Amended Statement of Claim in the record before him, along with their oral position as revised in argument that the defect was a "matrix" of things, the Appellants did not properly plead the cause of action of defective design. From the case law on this issue, the law is clear that in order to properly plead a claim of defective design, the Plaintiff must set out the particulars of the design defect and of the specific design alternative that would have been safer.<sup>1</sup>

[21] In my view, paragraphs 39a to 39d of the proposed Second Amended Consolidated Statement of Claim do not meet this pleading requirement. The revised paragraphs are an improvement over the previous pleading insofar as they identify design defects. They fail, however, to meet the pleading requirements since the revisions do not contain any reference to the specific alternative design that would have been safer. Rather, the amendments remain generic, leaving the Defendants to guess at what the Plaintiffs say was the better or safer design.

### Adjournment of the Motion – Section 5(4)

[22] The Appellants argue that the motion judge ought to have adjourned the motion to permit the Appellants to amend the Claim further and/or file further evidence. The Appellants did not request an adjournment, but they argue that the motion judge ought to have adjourned the certification

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<sup>1</sup> See: *Martin v. Astrazenica Pharmaceuticals Plc*, 2012 ONSC 2744, at paras. 136-137, aff'd 2-13 ONSC 1169 (Div. Ct.); *Richardson v. Samsung*, 2018 ONSC 6130, at paras. 43-45; *Kreutner v. Waterloo-Oxford Cooperative Inc.* (2000), O.R. (3d) 140 (C.A.); *Vester v. Boston Scientific Ltd.*, 2015 ONSC 7930, at paras. 11-12.

motion on his own motion. The Respondents submit that the Appellants, having made the strategic, tactical decision to not request an adjournment, should not be allowed to claim that it was an error on the learned motion judge's part not to grant one on his own motion.

[23] I note that while the plaintiffs requested no adjournment to amend their pleadings, the motion judge, in effect, allowed them to elaborate on their claim of defective design when he said at para. 133 of his reasons that he would proceed on the motion as if the 'matrix' of design defect the plaintiffs argued was part of their pleading.

[24] Granting an adjournment is a matter of discretion.

[25] As discussed above, absent an error of law, or being "clearly wrong," the motion judge's decision is entitled to deference. I see no error of law in the motion judge's reasons or in his consideration of the question of an adjournment.

## **2. Two-Step or One-Step Test for Commonality, Section 5(1)c.**

### **a. Some Basis in Fact - Generally**

[26] At paragraphs 98 to 101, the motion judge instructed himself on the law with respect to the test under s. 5(1)c, namely, that in the context of the common issues criterion, the Appellants must show "some basis in fact" for the common issue. The Appellants must show (1) that the proposed common issue actually exists, and (2) that the proposed issue can be answered in common across the entire class. He said as follows:

[99] The some-basis-in-fact standard sets a low evidentiary standard for plaintiffs, and a court should not resolve conflicting facts and evidence at the certification stage or opine on the strengths of the plaintiff's case.[14] In particular, there must be a basis in the evidence to establish the existence of common issues.[15] To establish commonality, evidence that the alleged misconduct actually occurred is not required; rather, the necessary evidence goes only to establishing whether the questions are common to all the class members.[16]

[100] On a certification motion, evidence directed at the merits may be admissible if it also bears on the requirements for certification but, in such cases, the issues are not decided on the basis of a balance of probabilities, but rather on the much less stringent test of some basis in fact.[17] The evidence on a motion for certification must meet the usual standards for admissibility.[18] While evidence on a certification motion must meet the usual standards for admissibility, the weighing and testing of the evidence is not meant to be extensive, and if the expert evidence is admissible, the scrutiny of it is modest.[19] In a class proceeding, the close scrutiny of the evidence of experts should be reserved for the trial judge.[20]

[101] The representative plaintiff must come forward with sufficient evidence to support certification, and the opposing party may respond with evidence of its own to challenge certification.[21] Certification will be denied if there is an insufficient evidentiary basis for the facts on which the claims of the class members depend.[22] The certification motion is not a merits-based screening of the action but it is a meaningful screening device. In *Pro-Sys Consultants Ltd. v. Microsoft Corporation* [citation omitted] the Supreme Court of Canada stated:

103. [I]t is worth reaffirming the importance of certification as a meaningful screening device. The standard for assessing evidence at certification does not give rise to "a determination of the merits of the proceeding" (CPA, s. 5(7)); nor

does it involve such a superficial level of analysis into the sufficiency of the evidence that it would amount to nothing more than symbolic scrutiny.

[Footnotes omitted]

[27] As the motion judge stated, the “some basis in fact” standard requires the Plaintiff to adduce some evidence demonstrating that there is a “colourable claim,” or a rational connection between the class members as defined, and the proposed common issues. While the standard is low, it is not “subterranean”.

[28] The Appellants rely on three cases in support of the proposition that the two-part test for “some basis in fact” from *Hollick*<sup>2</sup> no longer applies, and that the Appellants are not required to lead evidence that the alleged acts actually occurred.<sup>3</sup>

[29] In my view, except for Belobaba J.’s comments in *Kalra*, the weight of judicial and appellate authority is that the two-part test still exists, and representative Plaintiffs have a low evidentiary burden to show that there is a common issue that affects the class of Plaintiffs.<sup>4</sup>

[30] The Appellants rely on paragraph 110 from *Pro-Sys* in which the Supreme Court said:

“The multitude of variables involved in indirect purchaser actions may well present a significant challenge at the merits stage. However, there would appear to be a number of common issues that are identifiable. In order to establish commonality, evidence that the acts alleged actually occurred is not required. Rather, the factual evidence required at this stage goes only to establishing whether these questions are common to all the class members.”

[31] The Appellants submit that *Pro-Sys* eliminated the two-step test, created a one-step test, and eliminated any “air of reality,” “arguable case,” or other merits-based approach because it said in paragraph 110 “*In order to establish commonality, evidence that the acts alleged actually occurred is not required.*”

[32] *Pro-Sys* confirmed the low standard of “some basis in fact” insofar as it applied to the class Plaintiffs’ damage or injury. That the whole class suffered class wide damage, injury, or loss must still be demonstrated by some evidence meeting the “some basis in fact” standard.<sup>5</sup> To put it another way, the Supreme Court in *Hollick* and *Pro-Sys* did not use the term “common” to mean that the common issue was invariable between the class members. Rather, they used the word “common” in the sense that all class members had to have some basis in fact to say that they all suffered the loss and therefore have a genuine interest in the litigation’s resolution.

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<sup>2</sup> *Hollick v. Toronto (Municipality)*, 2001 SCC 68.

<sup>3</sup> *Pro-Sys Consultants Ltd. V. Microsoft Corporation*, 2013 SCC 57 at para. 110; *Fehr v. Sunlife Ass. Co.*, 2018 ONCA 718, at paras. 85-87; and *Kalra v. Mercedes Benz*, 2017 ONSC 3795, at paras. 45-46.

<sup>4</sup> See, for example, *Batten v. Boehringer Ingelheim (Canada) Ltd.* 2017 ONSC 6098 (Div. Ct.), at paras. 14 to 15; and re the evidentiary requirement, see: *Williams v. Cannon Canada Inc.*, 2012 ONSC 3692 (Div. Ct.), at para. 23, *Pro-Sys*, at para. 102 to 104, and *Fulawka v. Bank of Nova Scotia*, 2012 ONCA 443, at para. 53. re the evidentiary requirement.

<sup>5</sup> *Pro-Sys*, at paragraphs 99-103.

[33] This court also has rejected the argument that *Pro-Sys* altered the two-step test or altered the “some evidence in fact” standard. In *Batten v. Boehringer Ingelheim (Canada) Ltd.*, above, it said:

I see no conflict between the common issues test as applied by the motions judge in the present case and the existing jurisprudence. For example, the Ontario Court of Appeal stated in *Fulawka v. Bank of Nova Scotia*, 2012 ONCA 443 (CanLII) at para. 79 that there must be some evidentiary basis to show that a common issue exists beyond a bare assertion in the pleadings. There is no conflict between this approach and that in *Pro-Sys Consultants Ltd. v. Microsoft Corporation*, 2013 SCC 57 (CanLII), [2013] 3 S.C.R. 477. That case does not directly address a one stage versus a two-stage inquiry. Rather, it emphasizes that “the factual evidence required at this stage goes only to establishing whether these questions are common to all the class members” (at para. 110). In my view, the motions judge applied the governing legal principles.

[34] In *Fehr v. Sun Life Assurance Company of Canada*,<sup>6</sup> the Court of Appeal approved of the motion judge’s formulation of the “some basis in fact” standard, which is the same formulation that he used in this case. However, it found that by requiring additional evidence on whether Sun Life had actually breached the contract, the motion judge went beyond the “some basis in fact” standard and entered into a merits-based inquiry.<sup>7</sup>

[35] In its most recent statement, in *Pioneer Corp. v. Godfrey*, 2019 SCC 42, the majority in the Supreme Court of Canada upheld the B.C. Court of Appeal’s and the motion judge’s holding that the two-step test applied and that the “some basis in fact” standard applied.

[36] I agree with the motion judge that the two-part test still governs the commonality inquiry.

#### **b. Some Basis in Fact – Deficient Design**

[37] The Appellants argue that, even if the two step test applies to the determination of whether there are common issues, the motion judge erred in finding that they have not met the “some basis in fact” requirement. They argue that a) their expert, Dr. Crowther, gave evidence that there was a design defect, and b) his evidence was “some basis in fact” to support design defect. In addition, the Appellants argue that the Respondent’s expert, Dr. Robertson referred to design “compromises,” which conflicted with each other in that honouring one design criteria compromised another. Dr. Robertson’s opinion, the Appellants argue, also provided some basis in fact for a design defect.

[38] I concur with the motion judge that there was no qualified evidence about design defect on the record before him. Questions such as defective design are proven through expert opinion evidence. Dr. Crowther was clear on his cross-examination that he had no expertise in the design or manufacture of IVC filters.<sup>8</sup>

[39] These are findings of fact made by the motion judge to which deference is owed. There was no palpable and overriding error.

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<sup>6</sup> 2018 ONCA 718, at para. 42 (leave to appeal denied, May 2, 2019).

<sup>7</sup> *Ibid.*, at paras. 86 to 87.

<sup>8</sup> See Crowther Cross-Examination, questions 137 to 149, 167, 168, 188, 189, 196, and 208.



**c. Some Basis in Fact – Deficient Duty to Warn**

[40] Most of the argument before this Court, and before the motion judge, concerned the issue of Cook’s duty to warn learned intermediaries of the risks of using the IVC filter, and the need to remove it as soon as possible after its insertion, as contained in the filter’s IFU documents.

[41] The motion judge held that that Dr. Crowther’s evidence did not constitute some basis in fact for the common issue of design defect. In doing so, the Appellant argues that the motion judge conducted a merits-based assessment of Dr. Crowther’s evidence on the duty to warn, improperly weighing and dismissing it. The Appellants correctly submit that this is not permitted at the certification stage.

[42] In addition, the Appellant argues that the motion judge, in dismissing Dr. Crowther’s opinion, also dismissed that portion of his opinion in which he indicated that the Respondents did not incorporate into their IFU several Advisories issued by regulatory authorities in the U.K., U.S., and Health Canada<sup>9</sup> advising doctors to remove the IVC filters as early as possible, some proposing removal within defined windows of time after insertion. Dr. Crowther opined that the Cook Respondents did not include in their IFU the risks and recommendations set out in these Advisories, although all were issued before the representative Plaintiffs received their IVC filters.

[43] The Respondents argued that the IFU is adequate. They argued that Dr. Crowther was not an expert on the duty to warn, having not previously reviewed the IFU’s, other than in preparing his evidence on the certification motion. Further, the Respondents pointed out that the IFU is not a document that can be altered as the manufacturer sees fit. The IFU wording is submitted with all the documents at the time the manufacturer applies for its licence. The IFU’s wording is approved by the regulator and cannot be changed without a change order from the regulator. The Respondents conceded, however, that there is no prohibition with respect to it issuing supplementary information bulletins based on information it acquires after a licence is granted.

[44] In my view, there was evidence to form some basis in fact for the common issue of defect in the duty to warn with respect to the IVC filters; namely, that there were four regulatory Advisories issued by various regulatory bodies in the U.S., U.K., and Canada, and the fact that in November 2014, Cook issued “Field Safety Notice - Updated Product Information” to the medical profession in Europe, which included the information from the 2010 FDA Advisory, in November 2014.<sup>10</sup>

[45] From the motion judge’s reasons, it appears that the Appellants did not argue that the four Advisories, themselves, formed some basis in fact for the alleged breach of the duty to warn. Rather, the Appellants relied on Dr. Crowther’s opinion as some basis in fact of the breach of the duty to warn. The Advisories were offered as evidence supporting the reasonableness of Dr.

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<sup>9</sup> Appeal Book and Compendium, Vol. 2, at page 717 – August 9, 2010 FDA Advisory entitled “Removing Retrievable Inferior Vena Cava Filters: Initial Communication; at ABC, Vol. 2, page 711 – May 2, 2013 U.K. Advisory entitled “Retrievable Inferior Vena Cava Filters- serious complications associated with attempted IVC filter retrieval.”; at ABC, Vol. 2, page 719, May 6, 2014 FDA Advisor entitled “Removing Retrievable Inferior Vena Cava Filters: FDA Safety Communication; and July 25, 2016 Health Canada advisory entitled “Inferior Vena Cava (IVC) Filters – Risk of Serious Complications.

<sup>10</sup> Appeal Book and Compendium, Vol. 2, page 716.

Crowther's opinion. As with other aspects of this motion, the Appellants' argument changed at the appeal to stress the Advisories themselves as evidence in fact of a deficiency in the IFU. With this change in emphasis, it is evident that the Appellants' evidence meets the low bar for finding that the duty to warn is a common issue.

[46] My finding with respect to the Advisories as a basis in fact makes unnecessary any discussion of whether the motion judge engaged in a merits-based analysis or weighing of Dr. Crowther's evidence.

### 3. Proper Defendants

[47] I concur with the motion judge's findings that the only Defendants against which the class action should be certified are Cook (Canada) Inc., Cook Incorporated, and William Cook Europe APS. There was no evidentiary basis in fact to indicate that the other proposed Defendants were proper parties.

### CONCLUSION

[48] For the reasons above, I would allow the appeal with respect to the common issue of the alleged deficiencies in the duty to warn and certify the class with respect to common questions 5, 6, and 9 to 12 of the proposed common issues set out at paragraph 167 of the motion judge's decision. I would dismiss the balance of the appeal.

[49] At the conclusion of the hearing, the parties advised that they had reached an agreement on costs and did not require the Court to address the issue of costs.

  
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TRIMBLE J.

I agree

  
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M.G.J. QUIGLEY J.

I agree

  
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FAVREAU J.

**CITATION:** Kuiper v. Cook (Canada) Inc., 2019 ONSC 128  
**DIVISIONAL COURT FILE NO.:** 766/18  
**DATE:** 20200108

**ONTARIO  
SUPERIOR COURT OF JUSTICE  
DIVISIONAL COURT**

**Quigley, Trimble and Favreau JJ.**

**BETWEEN:**

ARIE KUIPER, WENDY KOPECK and GARRY  
KOPECK

Appellants (Plaintiffs)

**– and –**

COOK (CANADA) INC., COOK MEDICAL LLC,  
COOK MEDICAL INCORPORATED A/K/A/ COOK  
MEDICAL, INC., COOK INCORPORATED, COOK  
GROUP, INC. and WILLIAM COOK EUROPE APS

Respondents (Defendants)

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**REASONS FOR DECISION**

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**Trimble J.**

**Released:** January 8, 2019